REFORMING SGR: PRIORITIZING QUALITY IN A MODERNIZED PHYSICIAN PAYMENT SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JUNE 5, 2013

Serial No. 113–50

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

85–440 WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
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WITNESSES

SUBMITTED MATERIAL

REFORMING SGR: PRIORITIZING QUALITY IN A MODERNIZED PHYSICIAN PAYMENT SYSTEM

WEDNESDAY, JUNE 5, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Burgess, Shimkus, Rogers, Murphy, Blackburn, Gingrey, Lance, Cassidy, Guthrie, Griffith, Bilirakis, Ellmers, Barton, Upton (ex officio), Dingell, Capps, Schakowsky, Green, Barrow, Christensen, Castor, Sarbanes, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Mike Bloomquist, General Counsel; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Steve Ferrara, Health Fellow; Julie Goon, Health Policy Advisor; Sydne Harwick, Legislative Clerk; Sean Hayes, Counsel, O&I; Robert Horne, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Krista Rosenthall, Counsel to Chairman Emeritus; Chris Sarley, Policy Coordinator, Environment & Economy; Heidi Stirrup, Health Policy Coordinator; Lyn Walker, Coordinator, Admin/Human Resources; Alli Corr, Minority Policy Analyst; Amy Hall, Minority Senior Professional Staff Member; Elizabeth Letter, Minority Assistant Press Secretary; and Karen Lightfoot, Minority Communications Director and Senior Policy Advisor.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for an opening statement.

On February 7th and April 3rd, 2013, the Energy and Commerce and Ways and Means Committee Republicans released a three-phased outline for permanently repealing the Sustainable Growth Rate, the SGR, and moving toward a Medicare reimbursement system that rewards quality over volume. Stakeholder feedback followed each release and has been integral to the development of this

policy, culminating in the draft legislative framework released on May 28th.

[The discussion draft follows:]

[DISCUSSION DRAFT]

SEC. ___. REFORM OF SUSTAINABLE GROWTH RATE (SGR) AND MEDICARE PAYMENT FOR PHYSICIANS' SERVICES.

(a) STABILIZING FEE UPDATES (PHASE I).—

(1) REPEAL OF SGR PAYMENT METHODOLOGY.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended—

(A) in subsection (d)—

(i) in paragraph (1)(A), by inserting "or a subsequent paragraph or section 1848A" after "paragraph (4)"; and

(ii) in paragraph (4)—

(I) in the heading, by striking "YEARS BEGINNING WITH 2001" and inserting "2001, 2002, AND 2003"; and

(II) in subparagraph (A), by striking "a year beginning with 2001" and inserting "2001, 2002, and 2003"; and

(B) in subsection (f)—

(i) in paragraph (1)(B), by inserting "through 2013" after "of such succeeding year"; and

(ii) in paragraph (2), by inserting "and ending with 2013" after "beginning with 2000".

(2) UPDATE OF RATES FOR [PERIOD OF STABILITY].—Subsection (d) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new paragraph:

"(15) UPDATE FOR [PERIOD OF STABILITY].—The update to the single conversion factor established in paragraph (1)(C) for [the period of stability (as defined in ____)] shall be [_____].".

(b) UPDATE INCENTIVE PROGRAM (PHASE II).—

(1) IN GENERAL.—Section 1848 of such Act (42 U.S.C. 1395w–4), as amended by subsection (a), is further amended in subsection (d), by adding at the end the following new paragraph:

"(16) CONVERSION FACTOR BEGINNING WITH [FIRST YEAR AFTER PERIOD OF STABILITY].—The single conversion factor established in paragraph (1)(C) for each year beginning with [the first year after the period of stability] shall be [determined in accordance with section 1848A(e)].".

(2) ESTABLISHMENT OF PROGRAM.—Part B of title XVIII of the Social Security Act (42 U.S.C. 1395w–4 et seq.) is amended by adding at the end the following new section:

"SEC. 1848A. FEE SCHEDULE PROVIDER COMPETENCY UPDATE INCENTIVE PROGRAM.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary shall establish a fee schedule provider competency update incentive program (in this section referred to as the 'update incentive program') under which—

"(A) the Secretary shall, in accordance with subsection (b), approve and publish a final quality measure set for each peer cohort identified under paragraph (1) of such subsection;

"(B) each fee schedule provider—

"(i) self-identifies, in accordance with subsection (b)(1), within such a peer cohort; and

"(ii) provides information on each quality measure within such a final quality measure set applicable to such peer cohort with respect to which such provider shall be assessed for purposes of determining for [years beginning with the first year after

the period of stability] the [quality-based update adjustment under subsection (e)] applicable to such provider;

"(C) the Secretary shall develop and apply, in accordance with subsection (d), appropriate—

["(i) methodologies for assessing the performance of fee schedule providers with respect to such measures included within the measure sets applicable to the peer cohorts of such providers; and]

"(ii) methods for collecting information needed for such assessments (which shall involve the minimum amount of administrative burden needed to ensure reliable results); and

"(D) based on such assessments, the Secretary shall determine the applicable [quality-based update adjustments under subsection (e)].

"(2) FEE SCHEDULE PROVIDER DEFINED.—In this section, the term 'fee schedule provider' means a [physician, practitioner, or other] supplier that furnishes items and services that are paid under the fee schedule established under section 1848.

"(3) CONSULTATION WITH MEDICAL SPECIALTY ORGANIZATIONS AND OTHER RELEVANT STAKEHOLDERS.—The Secretary shall consult with medical specialty organizations and other relevant stakeholders, including State medical societies, in carrying out this section.

"(4) MODIFICATION FOR NON-PHYSICIAN FEE SCHEDULE PROVIDERS WHO ARE AUTHORIZED TO BILL MEDICARE DIRECTLY FOR REIMBURSEMENT.—Not later than [____], the Secretary shall determine how to apply the update incentive program to fee schedule providers who are not physicians described in section 1861(r)(1). [*Duplicative with paragraph (3)?:* In making such determination, the Secretary shall consult with relevant stakeholders.] In applying this paragraph, the Secretary shall at a minimum determine if there are applicable quality measures [selected] under subsection (b) that can be utilized for determining applicable update adjustments to the fee schedule under [subsection (e)] for such fee schedule providers. If adequate measures are not available, the Secretary shall apply a similar [performance]/[competency]-based program to determine the [quality-based update adjustment under subsection (e)] for such fee schedule providers.

[“(5) ELECTION FOR APPLICATION AT GROUP PRACTICE OR INDIVIDUAL PHYSICIAN LEVEL.—[*Policy question if wish to specifically provide for an election opportunity, or remain silent (in which case the Secretary may decide to apply assessments at a group level, but the element specifically allowing the providers and groups to make an election would not be implied):*] For purposes of this section, in the case of a fee schedule provider who participates in a [group practice] [*Definition? As defined by the Secretary, following the section 1848(o) or 1848(m) model? As such term is defined in section 1877(h)(4)?*], a fee schedule provider may elect, in a form and manner specified by the Secretary, to apply at either the group practice level or individual provider level the [applicable final quality measure set] approved under subsection (b), performance on quality, composite scores, and the update adjustments under this section. Such election made by a fee schedule provider shall apply with respect to all measures within such set, performance scores, and update adjustments for such provider. The feedback and performance data required to be provided by the Secretary under subsections (b)(5) and (g) shall be provided to a fee schedule provider regardless of the

election made by the provider under this paragraph. [*Review: How would this apply in the case of a provider participating in multiple practices? Would the election be on an individual provider level or would all providers within a group have to collectively make this election? If the assessment is based on the group level, how is feedback to be provided for the individual?*]]

"(b) QUALITY MEASURES FOR COMPETENCY ASSESSMENTS.—

"(1) ESTABLISHMENT OF LIST OF PEER COHORTS.—[Not later than ____,] the Secretary shall identify ([and publish?] a list [*Is this list to be updated?*]) of peer cohorts (each in this section referred to as a 'peer cohort') with respect to which fee schedule providers will self-identify [through a process and at such time as specified by the Secretary *Review: How is the self identification to be 'approved by the Secretary'?*] for purposes of this section and with respect to a performance period described in subsection (d)(3) for a year beginning with [the first year after the period of stability]. Such list shall include as a peer cohort the [each provider specialty [in which the American Board of Medical Specialties offers certification]/[defined by

the American Board of Medical Specialties as of ____]] and any other cohort established by the Secretary to capture classifications of providers across such provider specialties.

"(2) ESTABLISHMENT OF CORE COMPETENCY CATEGORIES AND IDENTIFICATION OF AREAS OF NEED FOR QUALITY MEASURES.—The Secretary shall convene multi-stakeholder groups to—

"(A) establish core competency categories [for all peer cohorts], which shall identify areas that are to be assessed by the quality measures selected under this subsection for inclusion in final quality measure sets by which fee schedule providers [in such cohorts] are to be assessed under subsection (d); and

"(B) identify areas and peer cohorts for which there are insufficient quality measures to address the categories established under subparagraph (A).

"(3) QUALITY MEASURES DEVELOPMENT.—The Secretary shall establish a process for the development of quality measures under this paragraph for purposes of potential inclusion of such measures [in measure sets under paragraph (4)]. Under such process, the Secretary shall—

"(A) provide for the coordination of development of such measures across fee schedule providers and other relevant stakeholders;

"(B) request from [medical specialty organizations and other relevant stakeholders]/[consensus-based entities] [representing the peer cohorts] best practices and clinical practice guidelines for the development of quality measures [within the core competency categories established under paragraph (2)?] for potential inclusion of such measures in final quality measure sets under paragraph (4)(F);

"(C) ensure the core competency categories and peer cohorts are addressed; and

"(D) ensure that all quality measures developed under this paragraph are developed with consideration of best clinical practices.

"(4) [QUALITY MEASURES SELECTION]/[SELECTION AND APPROVAL OF QUALITY MEASURE SETS].—

"(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph, provide for a quality measures process to approve final quality measure sets for peer cohorts. Each such final measure set shall be composed of the

quality measures with respect to which fee schedule providers within such peer cohort shall be assessed under subsection (d). Under such process the Secretary shall establish, and prior to making the request under subparagraph (C) make publicly available, criteria for selecting such measures [for potential inclusion in such final quality measure sets].

"(B) SOURCES OF MEASURES.—A quality measure selected [for inclusion in a [provisional] core quality measure set] under the process under this paragraph may be—

"(i) an [existing] [*What if a measure is endorsed in the future?*] quality measure that has been endorsed by [a consensus-based entity];

"(ii) a quality measure developed under paragraph (3); or

"(iii) a quality measure that is developed by a [medical specialty organization or other relevant stakeholder] [and submitted under subparagraph (C)?].

"(C) SOLICITATION OF PUBLIC QUALITY MEASURE INPUT.—Not later than [____], the Secretary shall request [medical specialty orga-

nizations and other] relevant stakeholders to identify and submit to the Secretary quality measures for selection under this paragraph.

"(D) PROVISIONAL CORE MEASURE SETS.—

"(i) IN GENERAL.—Under the process established under subparagraph (A), [not later than ____,] the Secretary shall select quality measures described in subparagraph (B) [applicable to a peer cohort] to be included in a provisional core measure set [for such cohort]. Any [applicable] quality measure developed under the process established under paragraph (3) may be included in a provisional core measure set.

"(ii) TRANSPARENCY.—[*Any deadline for public availability?*] The Secretary shall make publicly available, including by publishing in specialty-appropriate peer-reviewed journals, [each applicable] provisional core measure set under clause (i) and the method for developing [and selecting] measures included within such set. [*Specs: 'Create exception that in event soci-*

ety declines, Secretary can still go forward in process.' What does that exception mean? Is this in the case a specialty society does not want to publish the core set?]

"(E) PUBLIC COMMENT.—Under the process established under subparagraph (A), before a provisional core measure set under subparagraph (D) may be approved as a final quality measure set under subparagraph (F) the Secretary shall provide for a reasonable public comment period on the provisional core measure set.

"(F) FINAL MEASURE SETS.—At least [____] days before the first day of a performance period described in subsection (d)(3) [and taking into account public comment received pursuant to subparagraph (E)], the Secretary shall approve and publish a final quality measure set for each peer cohort.

"(5) FEEDBACK.—

"(A) INITIAL FEEDBACK PERIOD.—Each fee schedule provider self-identified with respect to a peer cohort shall, before any assessment of the fee schedule provider under subsection (d) for determining the applicable update adjust-

ment under subsection (e) for such provider and the year involved, have a [____] period during which the provider shall report on the applicable quality measures and receive feedback on the performance of such provider with respect to such measures.

"(B) FEEDBACK.—The Secretary shall provide each fee schedule provider with feedback on the performance of such provider with respect to quality measures within the final measure set approved under paragraph (4)(F) for the applicable performance period and the peer cohort of such provider.

"(e) GENERAL PROVISIONS APPLICABLE TO ADOPTION OF ALL MEASURES.—

"(1) RANGE OF MEASURES.—In carrying out subsection (b), the Secretary shall, to the greatest extent practicable and for each peer cohort, [select] a sufficient number of quality measures for potential inclusion of such measures [in measure sets under paragraph (4)].

"(2) ANNUAL REVIEW AND UPDATES.—

"(A) IN GENERAL.—The Secretary shall review—

"(i) the quality measures selected under subsection (b)(4) for inclusion in final quality measure sets under subparagraph (F) of such subsection for each year such measures are to be applied under subsection (e) to ensure that such measures continue to meet the conditions applicable to such measures for such selection; and

"(ii) the final quality measures sets approved under subsection (b)(4)(F) for each year such set is to be applied to peer cohorts of fee schedule providers to ensure that each applicable set continues to meet the conditions applicable to such sets for such approval.

"(B) INPUT FROM STAKEHOLDERS.—For purposes of conducting the review under subparagraph (A), the Secretary shall request medical specialty organizations and other relevant stakeholders to, as needed, identify and submit to the Secretary updates to quality measures selected under subsection (b)(4) as well as any additional quality measures. The Secretary shall [____] review submissions under this subparagraph.

"(C) UPDATES.—Based on the review conducted under [this paragraph] for a year, the Secretary shall as needed—

"(i) select additional, and updates to, quality measures under subsection (b) for potential inclusion in [final quality measure sets under paragraph (4)(F) of such subsection] in the same manner as the Secretary selects such quality measures under such subsection; and

"(ii) modify final quality measure sets approved under subsection (b)(4)(F) [in the same manner as the Secretary approves such sets under such subsection].

In the case of a modification under clause (ii) that removes a quality measure from a final quality measure set, such modification shall not apply under this subsection unless notification of such modification is made available to all applicable fee schedule providers.

"(3) COORDINATION WITH EXISTING PROGRAMS.—The Secretary shall, as appropriate, coordinate [the selection of] quality measures under subsection (b) with existing measures and requirements, such as the development of the Physician Compare

Website under section 1848(m)(5)(G). To the extent feasible, such measures should align with measures used under similar incentive programs of other payers and with measures in use under other provisions of section 1848. The Secretary shall explore options for combining performance data from incentive programs with similar commercial payer data to develop a more comprehensive picture of fee schedule provider performance that can be shared with consumers and providers to improve performance.

[“(4) ADOPTION OF ADDITIONAL MEASURES.—[*Is this needed? If so, why?*] The Secretary shall—]

[“(A) determine whether or not to select additional or updates to quality measures under [paragraph (2)(C)(i)]; and]

[“(B) make determinations as to the need to approve modifications under paragraph (2)(C)(ii).]

“(d) ASSESSING PERFORMANCE WITH RESPECT TO FINAL QUALITY MEASURE SETS FOR APPLICABLE PEER COHORTS.—

“(1) ESTABLISHMENT OF METHODS FOR ASSESSMENT.—

"(A) IN GENERAL.—The Secretary shall establish one or more methods, applicable to each year beginning with [the first year after the period of stability], to assess the performance of a fee schedule provider with respect to each quality measure included within the [final quality measure set approved under subsection (b)(4)(F) applicable for the performance period established under paragraph (3) for such year to the peer cohort in which the provider self-identified under subsection (b)(1)] for such performance period and compute a composite quality score for such provider for such performance period. Such methods shall include methods for collecting fee schedule provider information in order to make such assessments.

"(B) METHODS.—Such methods shall, with respect to a fee schedule provider—

"(i) [*Review:*] provide that the performance of such provider shall be assessed for a performance period established under paragraph (3) with respect to the [quality measures within the final quality measure set for such period for the peer cohort of

such provider and on which information is collected from such provider]; and

"(ii) allow for the collection and utilization of data from registries or electronic health records.

"(C) WEIGHTING OF MEASURES.—Such a method may provide for the assignment of different scoring weights based on type or category of quality measure.

"(D) INTEGRATION OF PHYSICIAN QUALITY PROGRAMS.—In establishing such methods, the Secretary shall, as appropriate, incorporate comparable physician quality incentive programs, such as under subsections (k), (n), and (p) of section 1848.

["(2) USE OF SPECIALTY REGISTRIES.—For purposes of this subsection, the Secretary [may]/[shall] use data from qualified clinical data registries that meet the requirements established under section 1848(m)(3)(E).]

"(3) PERFORMANCE PERIOD.—Not later than [____], the Secretary shall establish a period, with respect to a year, to assess under this subsection performance of fee schedule providers with respect to quality measures.

"(e) UPDATE ADJUSTMENT TAKING INTO ACCOUNT ASSESSMENTS WITH RESPECT TO QUALITY MEASURES.—[_____]

"(f) TRANSITION FOR NEW FEE SCHEDULE PROVIDERS.—

"(1) IN GENERAL.—In the case of a new fee schedule provider [there shall be____].

"(2) NEW FEE SCHEDULE PROVIDER DEFINED.—For purposes of this subsection, the term 'new fee schedule provider' means a physician, practitioner, or other supplier that first becomes a fee schedule provider (and had not previously submitted claims under this title as a person, as an entity, or as part of a physician group or under a different billing number or tax identifier).

"(g) FEEDBACK; EDUCATION; RECONSIDERATION.—[*Review relationship with feedback provision under subsection (b)(5).*] The Secretary shall give fee schedule providers feedback to assess their progress.

"(h) OPT OUT FOR PROVIDERS PAID UNDER ALTERNATIVE PAYMENT MODELS.—

"(1) IN GENERAL.—Payment for services that are provided by a fee schedule provider under an approved Alternative Payment Model shall be made in accordance with the payment arrangement under

such model [instead of in accordance with the update incentive program]. [Beginning with [20____], the Secretary shall identify [and publish in the Federal Register?] such models applicable under this subsection for such year.]

"(2) APPROVED ALTERNATIVE PAYMENT MODEL; ALTERNATIVE PAYMENT MODEL.—For purposes of this subsection:

"(A) APPROVED ALTERNATIVE PAYMENT MODEL.—The term 'approved Alternative Payment Model' means an Alternative Payment Model that is developed by the Secretary under paragraph (3) or proposed by an entity and approved by the Secretary under paragraph (4).

"(B) ALTERNATIVE PAYMENT MODEL.—The term 'Alternative Payment Model' or 'APM' means a mechanism by which payment under this title is made to a [fee schedule provider?] for most or all of the items and services furnished by such provider. Such a mechanism shall have appropriate protections to assure that changes in care associated with the application of the APM will not reduce the quality or access to care for individuals enrolled under

this part. Such a mechanism may include, but not be limited to, any of the following:

"(i) Accountable Care Organizations.

"(ii) Medical Homes.

"(iii) Bundled payments.

"(3) DEVELOPMENT BY SECRETARY OF ALTERNATIVE PAYMENT MODELS.—The Secretary shall develop [and annually review and update?] Alternative Payment Models to be applied under this subsection.

"(4) APPROVAL OF PROPOSED ALTERNATIVE PAYMENT MODELS.—The Secretary shall develop a process by which physicians, medical societies, health care provider organizations, and other entities may propose Alternative Payment Models for consideration [for approval by the Secretary to apply under this subsection?].".

(c) REPORTS ON MODIFIED PFS SYSTEM AND PAYMENT SYSTEM ALTERNATIVES.—

(1) BIANNUAL PROGRESS REPORTS BY SECRETARY.—Not later than [____], and every 6 months thereafter, the Secretary of Health and Human Services shall submit to Congress and post on the public Internet website of the Centers for Medicare & Medicaid Services a biannual progress report on the implementation of the update incentive

program under section 1848A of the Social Security Act, as added by subsection (b)(2). Each such report shall include an evaluation of such update incentive program and recommendations with respect to such program and appropriate update mechanisms.

(2) GAO AND MEDPAC REPORTS.—

(A) GAO REPORT ON INITIAL STAGES OF PROGRAM.—Not later than [____], the Comptroller General of the United States shall submit to Congress a report analyzing the extent to which such update incentive program under section 1848A of the Social Security Act, as added by subsection (b)(2), as of such date, is successfully satisfying [performance objectives], including with respect to—

(i) the process for developing and selecting quality measures and approving quality measure sets [, including updates and modifications,] under subsection[s] (b) [and (c)] of such section 1848A;

(ii) the process for assessing performance against such measures and sets under subsection (d) of such section; and

(iii) the adequacy of the measures and sets so selected and approved.

(B) EVALUATION BY GAO AND MEDPAC ON IMPLEMENTATION OF PHASE II.—The Comptroller General and the Medicare Payment Advisory Commission shall each evaluate the initial phase of the update incentive program under such section 1848A and shall submit to Congress, not later than [____], a report with recommendations for improving such update incentive program.

(3) SECRETARIAL REPORT ON PAYMENT SYSTEM ALTERNATIVES.—

(A) IN GENERAL.—Not later than [____], the Secretary of Health and Human Services shall submit to Congress a report that analyzes multiple options for alternative payment models [under]/[to]/[in lieu of] section 1848 of the Social Security Act (42 U.S.C. 1395w–4). In analyzing such models, the Secretary shall examine at least the following models:

(i) Accountable care organization payment models.

(ii) Primary care medical home payment models.

(iii) Bundled or episodic payments for certain conditions and services.

(iv) Gainsharing arrangements.

(B) ITEMS TO BE INCLUDED.—Such report shall include information on how each recommended new payment model will achieve maximum flexibility to reward high quality, efficient care.

(4) TRACKING EXPENDITURE GROWTH AND ACCESS.—Beginning in [____], the Secretary shall track expenditure growth and beneficiary access to physicians' services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and shall post on the public Internet website of the Centers for Medicare & Medicaid Services annual reports on such topics.

Mr. PITTS. This discussion draft took into account the conversations and work of the Energy and Commerce majority and minority staffs, as well as the long collaborative relationship we have had with the Ways and Means Committee.

It was also not a complete reform proposal. Rather, it was designed to be a partial release that allows for input from stakeholders and members of this committee. Again, we are seeking substantive feedback on ways to complete this draft, and I would encourage all interested parties to submit their comments to the committee by June 10th.

The committee has sought to accomplish SGR reform through an open and transparent process with consideration given to all relevant stakeholders. To briefly summarize the draft legislation, Phase I repeals the SGR formula and provides a period of payment stability. During this time, providers will work with the Secretary to identify quality goals and methods of measurement. Phase II will build upon the work of Phase I, tying quality measurement to fee-for-service payment. Provider input will be essential to defining quality medicine during Phases I and II. Any time throughout Phase I and II providers may voluntarily opt out of fee for service by participating in an alternate payment model.

These models will be flexible. Some exist today, such as medical homes, while new and innovative models may also be created and adopted. Some specifics, such as the duration of payment stability, or the methods of assessing providers on quality measures, have intentionally been left open in our discussion draft. We look forward to input on these and other topics from today's witnesses and the stakeholder community at large with the goal of achieving meaningful Medicare payment reform and designing the best possible system for patients and providers alike.

From the beginning of this process, there has been one clear goal: to remove the annual threat of looming provider cuts by permanently repealing the flawed SGR and replacing it with a system that incentivizes quality care, not simply volume of services. If we are to succeed in getting reform to the President's desk during this Congress, reform must be bipartisan and bicameral. It must also be fully offset and fiscally responsible. However, we are not making the mistake that has sidelined SGR in years past by having the pay-for discussion before we know what we are paying for.

The commitment to exploring bipartisan reform from Mr. Pallone, Mr. Waxman, leaves me hopeful that bipartisan reform is indeed possible. In addition, our longstanding and continuing relationship with Chairmen Camp and Brady from the Ways and Means Committee underscores the commitment that the House has to reforming SGR this Congress. I look forward to working with all parties in the coming weeks and months with the goal of getting SGR reform to the President's desk. And I look forward to hearing the views and opinions of our witnesses today, and I would like to thank each of them for appearing before this subcommittee.

Thank you. And I yield the balance of my time to the vice chair, Dr. Burgess.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

On February 7 and April 3, 2013, the Energy and Commerce and Ways and Means Committee Republicans released three-phase outlines for permanently repealing the Sustainable Growth Rate (SGR) and moving toward a Medicare reimbursement system that rewards quality over volume. Stakeholder feedback followed each release and has been integral to the development of this policy, culminating in the draft legislative framework released on May 28th.

This discussion draft took into account the conversations and work of the Energy and Commerce majority and minority staffs, as well as the long collaborative relationship we have had with the Ways and Means Committee.

It is also not a complete reform proposal. Rather, it was designed to be a partial release that allows for input from stakeholders and members of this committee.

Again, we are seeking substantive feedback on ways to complete this draft, and I would encourage all interested parties to submit their comments to the Committee by June 10th.

The Committee has sought to accomplish SGR reform through an open and transparent process, with consideration given to all relevant stakeholders.

To briefly summarize the draft legislation, Phase 1 repeals the SGR formula and provides a period of payment stability.

During this time, providers will work with the Secretary to identify quality goals and methods of measurement.

Phase 2 will build upon the work of Phase 1, tying quality measurement to fee for service payment. Provider input will be essential to defining quality medicine during Phases 1 and 2.

Any time throughout Phases 1 and 2, providers may voluntarily opt-out of fee-for-service by participating in an alternate payment model. These models will be flexible. Some exist today, such as medical homes; while new and innovative models may also be created and adopted.

Some specifics, such as the duration of payment stability or the methods of assessing providers on quality measures have intentionally been left open in our discussion draft. We look forward to input on these and other topics from today's witnesses and the stakeholder community at large, with the goal of achieving meaningful Medicare payment reform and designing the best possible system for patients and providers alike .

From the beginning of this process, there has been one clear goal: to remove the annual threat of looming provider cuts by permanently repealing the flawed SGR and replacing it with a system that incentivizes quality care, not simply volume of services. If we are to succeed in getting reform to the President's desk during this Congress, reform must be bipartisan and bicameral. It must also be fully offset and fiscally responsible. However, we are not making the mistake that has sidelined SGR in years past by having the pay-for discussion before we know what we are paying for.

The commitment to exploring bipartisan reform from Mr. Pallone and Mr. Waxman leaves me hopeful that bipartisan reform is indeed possible. In addition, our long standing and continuing relationship with Chairmen Camp and Brady from the Ways and Means committee underscores the commitment that the House has to reforming SGR this Congress. I look forward to working with all parties in the coming weeks and months with a goal of getting SGR reform to the President's desk.

I look forward to hearing the views and opinions of our witnesses today, and I would like to thank each of them for appearing before the Subcommittee.

Thank you, and I yield the balance of my time to Rep. _____.

Mr. BURGESS. Thank you, Mr. Chairman.

This hearing is all about momentum. For 10 years I have been here in this committee. On both sides of the dais we have all agreed that the SGR needs to go, and then we get to hear from some really smart people from Washington think tanks to tell us what the brave new world should look like, and then nothing happens. And we all pat ourselves on the back because we agree that the Sustainable Growth Rate makes some unrealistic assumptions about spending inefficiency, but really doesn't move the needle.

Now, this morning, in spite of what you read in the newspapers, today is different. It is different in two respects. First, last week the committee released the first draft of legislative language to eliminate the SGR and move Medicare to a program that more aligns with the private sector in both model development and linking payment to quality. The draft continued the trend of soliciting more provider feedback than at any point in history, and I pledge to all Medicare providers that your feedback, if provided to the committee, accompanied by helpful guidance, will be given the full attention of the committee, and we will work with you.

Yes, this is a first draft, a very rough first draft. Nothing is sacrosanct except the original paragraph which repeals the Sustainable Growth Rate formula. We have got to catch Medicare up with what is happening in the real world. We have to allow every practice modality that is out there to flourish. Yes, that includes fee for service. But we have got to catch up with what is happening in the real world, and that is what this morning's hearing is all about.

I thank the chairman for calling the hearing, and I will yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman.

And now turns to the gentlelady from the Virgin Islands, Dr. Christensen, who is filling in for the ranking member today. Recognized for 5 minutes.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and I want to thank you and Ranking Member Pallone, who had to return home for the funeral of our beloved Senator Lautenberg, for holding this hearing today. We have come together many times to discuss this issue, and I hope that today's discussion finally puts us on a path to real and broadly implementable solutions that focus on quality, improved patient outcomes, fairer provider reimbursement, efficiency, and lower cost.

Replacement of Medicare's SGR payment system is something that we all agree needs to happen. And I think we also all agree that the healthcare delivery system itself is dysfunctional. It, too, needs to be fixed, and several provisions in the Affordable Care Act—to pilot new payment models and models of care, to innovate and to help guide the best treatments—can both improve care, help us to reform and replace the current payment system, and lower costs.

As a family physician, the concept of medical home is not a foreign one to me. And as a community health doctor in the public sphere in a small community I know the value of teamwork to patient outcome, as well as satisfaction. But because the system was not set up to support a team approach, it added time and efforts that could have better been spent caring for more patients, enhancing our knowledge, or quality time with our family.

We are fortunate that some healthcare providers and systems have begun to do the reforms we are attempting to create nationally through the Affordable Care Act and that they can share their journeys' successes and recommendations, based on experience

with us today, and I want to thank the panelists for being here, and I look forward to their testimonies.

As we highlighted in our last hearing on this issue, innovation is key to improving healthcare delivery and payment system. However, moving forward it is important for us to encourage innovation while also ensuring that the benefits of innovation reach all communities. Historically, innovation in health care has improved outcomes for those who are insured or are more affluent much faster than for those who are low income or uninsured, exacerbating existing health disparities.

It is also important that the efforts to reform and replace the SGR take into account those providers who currently work in communities and treat patients who have long been underserved by the health system. These patients are adversely affected by many social determinants of health, have less reliable access to quality care, and ultimately suffer poorer health outcomes as a result. I look forward to hearing how pay for performance and value or outcome-based reimbursement can address this particular concern.

Today, we have a lot to focus on, as the background memo for this hearing indicates. My colleagues on the other side of the aisle have released two sets of draft frameworks, together with their colleagues on Ways and Means. They have also released draft legislative language, and this hearing is intended to get feedback on the legislative language released and, more importantly, to help inform our Members on the committee process moving forward. And there are some gaps that this hearing I think can probably help to fill.

I also look forward to working with my colleagues on this and the Ways and Means Committee, and other colleagues, as well as the provider and patient advocacy organizations, to continue the efforts of our panelists and others and those of the Affordable Care Act for reform. Our Medicare patients need and deserve it.

Is there anyone who would like the balance of my time? And if not, Mr. Chairman, I will yield back.

Mr. PITTS. The chair thanks the gentlelady.

Now recognize the chair of the full committee, Mr. Upton, 5 minutes for opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Thank you, Mr. Chairman.

You know, today we are building upon the significant progress that the committee has made during the past couple years and take a very important step in permanently repealing the flawed Sustainable Growth Rate, otherwise known as SGR or the doc fix. The legislative framework that we released last week, the review of which is the purpose of our hearing today, includes invaluable feedback from so many stakeholders.

However, this legislative framework is not etched in stone. And rather, it is an opportunity for the committee to continue working closely with Members and stakeholders towards a permanent repeal of SGR. It also doesn't contain a pay-for, as we intend to avoid the error made in years past of discussing how to pay for reform before the policy is actually developed. But make no mistake, SGR

reform will be offset with a real and responsibly paid-for item when it comes to the floor of the House for a vote.

When Chairman Camp and I began the push towards reform earlier this year and in the last Congress, it was with common purpose and mutual support. Our friendship and working relationship have never been stronger. Both committees, working closely together and with careful attention to public input, have been able to transform the initial February outline that we jointly released into a solid policy framework. There remains much more work to be done for sure, including the hope for bipartisanship, but we would not be where we are today without our good friends on the Ways and Means Committee, and that collaborative effort will continue.

Over the past several weeks Energy and Commerce Republicans and Democrats have labored hand-in-hand to explore whether bipartisan reform might be possible. And while the release last week was done without their names attached, the language it contained did reflect our talks and collaborative efforts with committee Democrats. I want to particularly thank Mr. Waxman and Pallone for their leadership and continued interest in exploring SGR reform.

And while we stand today at a point far beyond any reform efforts of the past, much work still remains. SGR is one of the most complex issues confronting the Congress and, not surprisingly, difficult policy questions remain to be answered. Today's testimony will help answer some of those questions.

The committee has been dedicated to making reform a transparent process. Such transparency has already given this committee insightful recommendations from multiple stakeholders that culminated in the legislative release last week. We look forward to continuing that process in the weeks to come.

So SGR reform is vital to ensuring economic stability for physicians, access to care for seniors, securing the future of the Medicare system. I want to conclude by sharing my sincere optimism that, in fact, we will achieve a bipartisan bill, one that represents the work of both sides of the aisle, and in the end the best chance for SGR reform to work its way to the President's desk is through that bipartisanship.

So let's not be satisfied with the unprecedented progress that we have already made. Let's continue working until we have solved the problem for not only our physicians, but certainly for our seniors.

And I yield the balance of my time to Dr. Cassidy.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

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Thank you, and I yield the balance of my time to Rep. _____.

Mr. CASSIDY. Thank you Mr. Chairman.

The recent CBO projection reducing the cost of repealing the SGR to $138 billion gives us an opportunity to reform this flawed payment formula. We should see this and provide reform that puts us on a financially sustainable path, incentivizing quality health care to individuals and certainly to physicians. I think we all agree on that.

In this process we must be careful to not sacrifice the independence and autonomy of the independent physician practice, and as a doc I am very sensitive to that. Mr. Chairman, I have working on a proposal that would ensure the independent physician and the small group is protected. I will be discussing it during my questions, and hope we can work together as we move forward with reform.

In addition, I would like to commend the chairman for including a process for alternative payment models in the committee discussion draft. I understand that this is an issue the chairman wishes to further develop. I fully support this approach, and, again, I look forward to working with the committee to develop it further.

I yield back to Mr. Upton or to Dr. Gingrey.

Mr. GINGREY. Dr. Cassidy, thank you for yielding.

Mr. Chairman, as a physician, I am pleased and excited that we are at this moment today. We are addressing the flawed SGR system, seeking to give doctors more certainty over reimbursement. By using specialty societies and other professional groups to create quality measures that will be used to promote best practices, we

will see better patient outcomes and a more efficient—a much more efficient payment system.

I do have a concern that the quality measures associated with payment reform may lead to unwarranted court claims. Government payment reform should not have any effect on a doctor's liability. During debate, then Chairman Waxman submitted comments for the record which stated that it was not the intent of the President's healthcare bill to, quote, "create any new actions or claims based on the issuance or implementation of any guideline or other standard of care," end quote. Nor is it to supercede, modify, or impair any State medical liability law governing legal standards or procedures used in their medical malpractice cases.

Mr. Chairman, there is bipartisan agreement that the intent of our Federal healthcare laws is to promote quality, not to create new avenues for medical malpractice claims. I look forward to working with the subcommittee to address this potential loophole as we work toward physician payment reform.

Thank you for your indulgence, and I yield back.

Mr. PITTS. The chair thanks the gentleman.

That concludes the opening statements. We have one panel today. I will introduce our panel at this time.

First of all, Dr. Cheryl Damberg, senior policy researcher and professor of the Pardee RAND Graduate School. Secondly, Mr. William Kramer, executive director for national health policy, Pacific Business Group on Health. Thirdly, Dr. Jeffrey Rich, immediate past president of the Society of Thoracic Surgeons, director at large, Virginia Cardiac Surgery Quality Initiative. And finally, Dr. Thomas Foels, executive vice president and chief medical officer, Independent Health.

Thank you all for coming. You will each have 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Dr. Damberg, you are recognized for 5 minutes for your opening statement.

STATEMENTS OF DR. CHERYL L. DAMBERG, PH.D., SENIOR POLICY RESEARCHER, PROFESSOR, PARDEE RAND GRADUATE SCHOOL; WILLIAM KRAMER, EXECUTIVE DIRECTOR FOR NATIONAL HEALTH POLICY, PACIFIC BUSINESS GROUP ON HEALTH; JEFFREY B. RICH, M.D., IMMEDIATE PAST PRESIDENT OF THE SOCIETY OF THORACIC SURGEONS, DIRECTOR AT LARGE, VIRGINIA CARDIAC SURGERY QUALITY INITIATIVE; AND THOMAS J. FOELS, M.D., M.M.M., EXECUTIVE VICE PRESIDENT, CHIEF MEDICAL OFFICER, INDEPENDENT HEALTH

STATEMENT OF CHERYL L. DAMBERG

Ms. DAMBERG. Thank you for inviting me here today. As the committee considers ways to revise the physician fee schedule so that payment policy supports the delivery of high quality, resource-conscious health care, there are important design features related to structuring performance-based incentive programs that I want to call to your attention. Thoughtful incentive design can ease the transition process for both physicians in the Medicare program and

enhance the likelihood of program success. Due to limited time I will touch on only a few of the important design issues. More details can be found in my written testimony.

First, encourage improvement among all physicians by using a continuous payment incentive approach. A continuous incentive approach pays physicians additional incentive payments for each increment of improvement they achieve. A continuous approach avoids the cliff effects that are common in incentive structures that tie payments to a single all-or-nothing cut point, setting up a large number of providers who will receive nothing despite making actual improvements and investments to improve. Paying more per increment of improvement at the beginning and the middle part of the continuum than toward the top strengthens incentives to physicians at the lower end who are making investments to improve.

Second, use fixed performance thresholds to make it clear in advance to physicians what level of performance is required to achieve an incentive. Over the last decade many performance-based incentive programs used tournament-style relative thresholds that create a competition among providers. Relative thresholds create a great deal of uncertainty and can lessen the response to the incentive, particularly for those physician who are a distance from the anticipated threshold. Instead, physicians should compete against a fixed national benchmark where all who improve and hit the designated targets win. Avoiding competition between physicians for a limited number of winning positions will help to foster sharing of best practices among physicians.

Third, make payments meaningful to generate the desired response. The experiments of the last decade in pay for performance generally found weak results in part because incentive payments were relatively small, on the order of 1 percent. Physician leaders indicate that incentives of 5 to 10 percent are required to be meaningful. In the beginning, while physicians are learning how to participate, incentives could be relatively modest. However, over time, and in the near term, rather than the long term, the size of the incentives should be increased.

Begin the transition now for primary care by leveraging measures used in Medicare Advantage and other private payer programs. Much work has gone on over the past decade to advance the development of performance measures, particularly for care delivered by primary care physicians. These measures have been widely deployed by private payers, Medicaid agencies, and Medicare in the context of performance measurement, accountability, and incentives, both in managed care and fee for service. The committee and Congress need to understand that a majority of primary care physicians in the United States have already been exposed to these programs. And they could start by working with the Medicare Advantage star rating program and in the process align measurement activities already targeting ambulatory providers.

Fifth, for many clinical subspecialties measures are completely lacking or few are available that could be readily deployed. As such, concerted effort and Federal investment is needed to develop and bring measures to market. CMS should identify and focus development efforts on 10 to 12 clinical subspecialty areas that contribute to a significant portion of Medicare spending and utiliza-

tion, and they should work with measure development experts and clinical specialties to identify performance gaps and develop those measures.

Sixth, allow physicians to opt out if they can demonstrate that they have moved to other value-based purchasing models that incentivize cost and quality. Some providers have already started to migrate toward alternative payment models such as ACOs, bundled payments, and medical homes. To the extent that these models contain performance-based incentives for cost and quality they should be considered acceptable opt-out arrangements. For physicians who do not participate in new payment models, they should minimally demonstrate that they are able to perform parallel functions to deliver high-quality, efficient care.

Seventh, rather than simply imposing this change on physicians, Medicare should work in partnership with physicians to support their improvement. Creating an environment where physicians can succeed should include such things as building support structures with local community partners to work on improvement and redesign, facilitating sharing of best practices and learning networks, providing meaningful, timely data feedback, and continuing to advance the health IT infrastructure.

In summary, the ability to move successfully forward with new performance-based payment models is predicated on having a robust set of measures, a good incentive design, and a support structure that can help physicians participate and succeed in the program. Thank you for the opportunity to appear here today, and I would be happy to take your questions.

Mr. PITTS. The chair thanks the gentlelady.

[The prepared statement of Ms. Damberg follows:]

Physician Payment Reform

Designing a Performance-based Incentive Program

Cheryl L. Damberg

RAND Office of External Affairs

CT-389

June 2013

Testimony presented before the House Energy and Commerce Committee, Subcommittee on Health on June 5, 2013

Published 2013 by the RAND Corporation
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Cheryl L. Damberg[1]
The RAND Corporation

Physician Payment Reform:
Designing a Performance-based Incentive Program[2]

Before the Committee on Energy and Commerce
Subcommittee on Health
House of Representatives

June 5, 2013

Chairman Pitts, Ranking Member Pallone, and distinguished Members of the Subcommittee, thank you for inviting me here today. My name is Cheryl Damberg and I am a senior health policy researcher at the RAND Corporation. I appreciate the opportunity to appear before you to discuss physician payment reform. As you work to shift physician payment policy from one that currently incentivizes the delivery of more services without regard to quality or outcomes to a payment policy that incentivizes the delivery of high quality, resource conscious (i.e., high value) health care, there are a number of important design elements that I ask you to consider. The lessons draw from the experiences of both public and private sector payers who over the last decade have implemented performance measurement and performance-based incentive systems. Thoughtful incentive design can ease the transition process for both physicians and the Medicare program, provide a robust, credible system of measurement that will serve as the basis for determining who receives incentive payments and how they receive them, and enhance the likelihood of program success—all of which serves the ultimate goal of improving care for Medicare beneficiaries. My comments derive from research I have conducted examining the use of financial incentives tied to performance and my experience working with provider organizations over the past decade to measure health care quality and costs.

As highlighted in testimony that I gave to this committee in February (Damberg, Cheryl L., "Efforts to Reform Physician Payment: Tying Payment to Performance," testimony presented before the House Energy and Commerce Committee, Subcommittee on Health, February 14, 2013. As of May 28, 2013: http://www.rand.org/pubs/testimonies/CT381), performance-based incentive models (also referred to as pay for performance or value-based payment (VBP))—which tie payments to performance on a set of defined quality and cost measures—are relatively new to the health system and represent a work in progress. It is vitally important to

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[2] This testimony is available for free download at http://www.rand.org/pubs/testimonies/CT389.html.

signal to providers what patients and payers expect them to be working towards in terms of delivery of appropriate care and care that helps achieve the best outcomes for patients. Explicit measures—when tied to payment—help focus and redirect physicians and the organizations in which they work towards redesigning care processes and how they coordinate actions with other care providers in order to deliver better value. Value is defined as the outcomes (outputs) achieved divided by the cost or resources used (inputs) to generate those outcomes.

By linking payment to performance, value-based payment programs seek to incentivize providers to innovate and redesign care delivery to drive improvements in quality and how resources are used (i.e., costs). Including costs as part of what is measured and how providers are paid is critical to ensure that services are efficiently delivered. Physicians who make decisions about treatments have a central role to play in helping to ensure that health care remains affordable for patients and other entities (employers, government agencies) that pay for care. The current fee-for-service (FFS) system used in Medicare to pay physicians contains incentives to the opposite effect. I will return to this issue at the close of my testimony.

Designing a performance-based incentive program is a complex undertaking and how it is designed will determine the likelihood of its success. I will touch on several of the central design features that are important for you to consider.

(1) Structure of Payment Incentives: There are several elements that comprise an "incentive payment structure," including whether providers are paid for attainment or improvement or both, the performance thresholds used to determine who gets paid, the form of the incentive (e.g., bonuses, shared savings, or penalties[3]), and the size of the incentive. Each of these, depending on how structured, can lead to different responses by providers. Below I comment on several of these elements and the approaches that will likely yield the desired result.

a. ***Pay for improvement along the gradient:*** Medicare should pay providers using a continuous payment incentive approach so as to incentivize improvement along the continuum of performance. A continuous payment approach is used by Blue Cross Blue Shield of Massachusetts in its Alternative Quality Contract.[4] In the case of the Alternative Quality Contract (AQC), providers receive a bonus ranging from 2% to 10% of per member per month payments depending on where they are on the performance distribution. Providers receive additional payouts for each increment of improvement---they are paid along the continuum once they hit a

[3] Penalties (i.e., downside risk) are not favored by providers. They tend to be used to discourage actions/outcomes that should not occur such as hospital acquired infections which can be prevented.
[4] Song et al., Health Care Spending and Quality in Year 1 of the Alternative Quality Contract. NEJM. 365:10. September 8, 2011.

minimum threshold of performance. This approach avoids the "cliff" effects that are common in payment structures that tie payments to a single all or nothing cut point (such as having to hit the 75th percentile of performance among providers); all or nothing payment structures set up a large number of providers who will receive nothing despite the fact that they are making improvements and making investments to improve. In the AQC model, the formula that translates each increment of improvement into payment incentivizes improvement at the beginning and middle of the continuum more than toward the top part of the distribution. This approach acknowledges that providers at the lower end of the performance distribution likely need to make more substantial investments to achieve quality improvement than providers who move from 95% to 98% performance.

b. ***Use fixed thresholds:*** Over the last decade, many performance-based incentive programs used relative thresholds that were only known to providers after the close of the performance measurement period.[5] While this "tournament style" approach incentivizes continued improvement because the target moves as the entire group of providers improve, it creates a great deal of uncertainty for providers and can lessen the response to the incentive, particularly for those providers who are a distance from the anticipated threshold. The incentive structure should establish fixed performance targets that remain stable over some time period. This will help providers understand what level of performance they need to achieve to secure incentive payments and it will send a clear signal about performance expectations. Providers should compete against a national benchmark rather than a moving target based on relative comparisons of performance. This will establish an environment where all providers who improve and hit the designated targets win; because there isn't a competition between providers for a limited number of winning positions, this will help to foster the sharing of best practices among providers. One approach to setting targets that is used in the Alternative Quality Contract is to use empirically derived cut points based on the data.[6] Another approach is to use national benchmarks—such as the National Committee for Quality Assurance's (NCQA) Health Employer Data Information Set (HEDIS) measure benchmarks. The highest level benchmark can be set for what is best in class and is achievable, based on the actual performance of peer specialty physicians.

c.. ***Make payments meaningful:*** In the beginning, while physicians are learning how to participate in the incentive program (learning how to collect/capture the data and submit the

[5] For example, physicians who might receive a bonus payment in 2013 based on their 2012 calendar year performance would not know the threshold for winning (say the 75th percentile cutpoint) until May of 2013 once scores are in for all physicians.

[6] Safran, DG et al. *Evaluating the Potential for an Empirically-derived Standard of Performance Excellence in Ambulatory Patient Care Experience Measures: Analysis in Support of NCQA's Efforts to Develop a Physician Recognition Program in Patient-Centered Care.* October 2007.

information and redesigning care processes to improve), incentives could be relatively modest; however, over time (and in the nearer rather than longer term), bonuses should be increased. Incentives on the order of 5% to 10% of pay are required to change the behavior of physicians. The experiments of the last decade in the area of pay for performance generally found weak results, in part, because incentives were relatively small (on the order of 1%). I have conducted interviews with physician leaders who have indicated that incentives of 5% to 10% are required to be meaningful.

(2) Quality Measurement Infrastructure: Measures are the foundational element for determining payments under incentive-based payment models. While there are some measures ready to use, significant investments will need to be made over the next five years to develop and bring measures to market. A concerted effort will need to be undertaken, by specialty area, to advance measure development; in the near term, CMS should identify and focus development efforts on 10-12 clinical subspecialty areas that contribute to a significant portion of Medicare spending and utilization (e.g., cardiology, gastroenterology, endocrinology, orthopedics, oncology).

a. ***Leverage the measurement precedent in primary care:*** It is important to recognize that much work has gone on over the past decade to advance the development of performance measures—particularly for care delivered by primary care physicians (PCPs). These measures address preventive, acute, and chronic care areas and have been widely deployed by private sector payers and Medicaid agencies over the last decade in the context of performance measurement, accountability, and incentive programs—both on the managed care side and the PPO/FFS side. The Committee and Congress need to understand that a majority of PCPs in the United States have already been exposed to these performance measures and are familiar with the concept of pay for performance. Because these existing measures represent evidence-based practice and have been well tested, there is no reason that these should not be immediately deployed in the context of an incentive-based fee schedule within Medicare. For example, Medicare could start (and thereby align the measurement activities targeting ambulatory care providers) with existing measures used in the Medicare Advantage Star rating program. These measures are also the focus of the Physician Quality Reporting Initiative (PQRI), which will be the basis of the physician value-based payment modifier that will go into effect in 2015 as called for in the Affordable Care Act. Therefore, PCPs could begin immediately reporting on a set of measures during the payment stability period, to gain experience with data capture and reporting and to receive benchmarking reports from Medicare to identify areas for improvement well in advance of transitioning to incentive payments.

b. **Invest in measure development, particularly for clinical subspecialists.** Efforts to develop measures for clinical subspecialists have lagged those addressing primary care. Some clinical specialties have taken steps—such as through the American Medical Association's Physician Consortium on Performance Improvement (PCPI)—to develop measures; however, for many clinical subspecialties measures are completely lacking or there are few available measures that could be readily deployed. Recent efforts by the American Board of Internal Medicine Foundation (ABIMF), in partnership with clinical specialty societies, have generated a list of more than 90 recommended areas to reduce the overuse of services.[7] While not performance measures, these types of recommendations and clinical guidelines produced by specialty societies represent a starting place for identifying measure concepts that could be advanced for measure development. Substantial investment of resources is required to advance the development of measures for clinical subspecialties, and it will take several years (2.5 to 3 years) from measure concept identification to having measures ready for deployment.

c. **Use a rigorous measure development process.** Development of measures needs to occur using a scientifically rigorous process that is transparent, inclusive of physicians and other stakeholders, and ensures the reliability and validity of measures that become the basis of payment. Measure development is a science. It requires careful review of the scientific evidence to identify areas that define high quality care (which form the measure concept), vetting the evidence and concepts with clinical expert panels, specification of the concept using various data sources (e.g., claims data, electronic health records (EHRs)), field testing the measures across an array of providers with different data systems, assessing the measurement properties (reliability, validity of the measure), and finalizing the specification for uniform application across physicians in different settings. A model for development is the work that was conducted at RAND to develop the RAND Quality Assessment Tools (QA-Tools) and the ACOVE measures for the vulnerable elderly. (McGlynn et al., 1995; Wenger et al., 2003). Measures used in the incentive program should meet the scientific soundness criteria identified by the National Quality Measures Clearinghouse (NQMC).[8] These include the clinical logic (evidence supporting the measure is explicitly stated and strongly supported) and measure properties (i.e., reliability, validity, case-mix adjustment if appropriate).

To expedite measure development in a cost-effective manner, measure developers should have a consortium of EHR data partners that will be test beds for rapid testing of electronic health record (i.e., e-Measure) concepts and alternative specifications at an early stage to identify the strongest

[7] Choosing Wisely: an initiative of the ABIM Foundation. 2012 [updated 2012; cited 2012 October 29th, 2012]; Available from: http://choosingwisely.org/.
[8] Agency for Healthcare Research and Quality. National Quality Measures Clearinghouse. http://www.qualitymeasures.ahrq.gov/tutorial/attributes.aspx

candidates for full development.

Because of the high stakes application of measures for payment and for driving provider performance, the measure development work should undergo a peer review process—meaning that the work of the measure developers and clinical panels should be published in clinical journals. Transparency of the process and underlying science will enhance the face validity of the process and the acceptability by the clinical community.

d. **CMS should establish a process where measure development experts work with clinical specialties to identify performance gap areas and work to develop those as measures.** To engage providers to achieve the three aims of the National Quality Strategy, we must enlist them as true partners in defining the measures for which they will be held accountable as individuals, and more broadly, as care teams and systems of care. Physicians have a vitally important role to play in the selection of measure concepts, weighing the scientific evidence related to specific actions providers can take to influence the process or outcome, specifying measures (including how to adjust for differences in the patient populations they treat and which patients to exclude), assessing the feasibility of a measure in practice, and ultimately endorsing the measures once developed. Some physician specialty organizations have taken steps to identify measures and create registries containing process and outcome measures. These measures and data sources could provide a starting point. For example, the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®) generates validated, risk-adjusted, outcome measures to help surgeons improve the quality of surgical care. Prior to considering use of measures from specialty societies, the measures would need to meet the requirements of any measures—meaning that they are valid, reliable and evidence-based.

e. **Alignment and coordination is critical to reduce provider confusion and burden.** Medicare has a number of existing measurement and payment incentive programs that target ambulatory care providers. These include Medicare Advantage, the Physician Quality Reporting System (PQRS), which will support the emerging physician value-based payment modifier program, and the meaningful use (MU) of EHRs incentive program. The requirements that are introduced within the reformed SGR incentive program for physicians need to coordinate and align with these efforts to avoid creating a more complex environment for physicians to navigate. For example, MU standards for EHRs could require that vendors support the capture of data elements needed to construct measures that will be used in the SGR and physician value-based payment modifier programs.

f. ***Build out the measure set to address other priority areas:*** The measures being used in the Medicare Advantage Star rating system that determine Quality Bonus Payments to plans, as well as those used by private payers, represent a starting place for the early phases of the incentive program implementation. However, Medicare will need to work collaboratively with clinical specialists and measure developers to address other important performance areas where performance measures are currently lacking—including access to care, care coordination, overuse of services/resource use, and patient outcomes (e.g., functioning, health status)). The areas for future measure development should consider the work of the National Quality Forum's National Priorities Partnership (NPP) and the Department of Health and Human Service's National Quality Strategy (Table 1), which have outlined key domains or areas where performance should be measured. Measure development for use in the context of the Medicare FFS incentive program should align with these areas.

g. ***Promoting the delivery of high quality care means providing appropriate care and reducing the overuse of services.*** Development of efficiency measures is a national priority and these measures currently lag in development. While the concept of efficiency raises red flags of cost cutting in the minds of physicians, physicians will focus on reducing the overuse of services when they understand that the desired action (whether it is shifting from a name brand drug to a generic or watchful waiting before advancing to imaging) is equivalent to the alternative, more costly approach to managing the patient or that the alternative, less desired action could lead to unnecessary harm. When measures of clinical overuse/misuse of services are supported by evidence, this will facilitate physician buy-in.

Table 1

National Quality Strategy's three aims: *1.* ***Better Care:*** *Improve the overall quality of care, by making health care more patient-centered, reliable, accessible, and safe.* *2.* ***Healthy People/Healthy Communities:*** *Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.* *3.* ***Affordable Care:*** *Reduce the cost of quality health care for individuals, families, employers, and government.*
National Quality Strategy's six priorities: *1. Making care safer by reducing harm caused in the delivery of care.* *2. Ensuring that each person and family are engaged as partners in their care.* *3. Promoting effective communication and coordination of care.* *4. Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.* *5. Working with communities to promote wide use of best practices to enable healthy living.* ***6.*** *Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.*

(3) Shifting to New Payment Models

Some providers have already started to migrate towards alternative payment models such as accountable care organizations (ACOs), bundled payments that pay for pre-defined episodes of care, and medical homes. These payment models generally embed performance-based incentives into their structures and have pre-defined performance measures that must be met to receive shared savings or other types of incentive payments. ACOs require a certain size to enable providers to manage risk, and not all physicians will join ACOs. Primary care physicians, regardless of the size of their practice, can participate in medical homes, where they can earn extra dollars for managing patients at a high level of quality that can reduce the utilization of care in high cost settings such as emergency departments and hospitals. For some areas of care—such as an annual episode of diabetes or hip replacement surgery—specialists may be able to participate in bundled payment arrangements that provide a fixed fee with incentive payments tied to performance on quality measures (both process and outcome). All of these constitute value-based payment arrangements and should be considered acceptable opt-out arrangements to the extent that they address the Medicare population. The subset of physicians who do not participate in new payment models should minimally demonstrate they are able to perform parallel functions to deliver high quality, efficient care—such as connectivity to other providers (e.g., specialists, PCPs, hospitals) through health information exchange to better coordinate care, use of clinical decision support tools, and performance monitoring.

(4) Uniqueness of Providers

While there is diversity among physicians in where they practice (urban versus rural), their mix of patients (i.e., demographic and socioeconomic status (SES)), practice type, and specialty, it is important to remember that performance measures are "patient-driven." By that I mean that the measure defines what the patient needs, regardless of the type of physician practice where the patient is treated. Receipt of a flu shot should not be dependent on whether a patient is managed by a physician in a rural versus urban setting or solo practice versus large integrated system. Physicians who manage more complex patients (higher level of severity of illness) or who have lower SES patient populations often are concerned that they will be disadvantaged under performance-based accountability and payment systems. For outcome measures, it is important to adjust for differences in the patient mix to level the playing field and to ensure that the measures are valid. There is debate about whether to adjust for SES factors related to process measures; some practices have been successful in raising performance for minority patients and those who are disadvantaged economically when held accountable for these populations. Incentive structures can be designed to help mitigate these concerns related to redistribution of

resources away from practices that may need resources to help care for more challenging populations and to reduce the likelihood that providers will avoid more challenging populations. For example, my RAND team was involved in modeling an incentive design that sorted physician practices into "leagues" (based on the education level of patients and capitation rates of practices), and held the mean incentive payment equivalent across leagues to avoid large redistributions of money, while preserving incentives for improvement (meaning you earned more the better you performed within your league).

(5) Help create an environment where physicians can succeed.

The goal of incentive programs is to improve care delivery. Medicare can best work to change physician culture by helping physicians understand that Medicare is working to do this *in partnership* with physicians, rather than simply imposing change on them. Again, the design of a program can set the players up for cooperation to achieve desired goals, which will help promote successful implementation. Successful programs work to provide physicians with data and reporting to support problem identification and quality improvement, best practices sharing, coaching and training, and consultative advice.

a. Provide on-the-ground quality improvement support. The Centers for Medicare and Medicaid (CMS) could support, through cooperative agreements, funding of local community collaboratives and organizations that already have established relationships with physicians and that have experience helping providers make the changes to drive improvements. An example is the California Quality Collaborative, which for the past seven years has been working with physicians on practice redesign so they can succeed in improving performance on clinical, efficiency, and patient experience measures—all in the context of performance-based payment models. Additionally, because private plans are working with the same physicians to drive improvements and frequently investing quality improvement resources, CMS could partner with private commercial plans in cost-sharing the quality improvement support locally. Many commercial plans have the same "stake" in the game because they are financially at risk for quality performance in the context of the Medicare Advantage program—and these bonuses are substantial in size. The efforts of the public and private payers could align to support physicians in improvement.

b. Continue to support the advancement of clinical decision support (CDS) tools embedded within EHRs. To deliver high quality care, physicians need access to information that can help them make clinical decisions that are evidence-based and that help them evaluate cost-effective alternatives at the point of care. Meaningful use requirements seek to expand the use of CDS tools for clinical subspecialties and these tools should be focused on areas where there are performance gaps. Development of these tools should help providers be more successful in

meeting quality requirements.

c. Allow physicians multiple ways to participate (i.e., submit their data). Various options exist for submitting data on individual physician performance, including direct submission by the physician (e.g., EHR), submission by the physician's practice or physician group on behalf of the physician, or by a physician's specialty society drawing from their registry data. All data, regardless of method of submission, should be submitted at the individual physician level, not at the practice or group level. Physician-level data are needed to establish benchmarks (performance thresholds) and physician level data are required to account for the variation at the physician level (note: variation tends to be less at the practice site or group level as it blends the results of high and low performers; therefore, using these data would not reflect the entire distribution of physician performance). Additionally, should the data be eventually used in the context of Physician Compare, the results would need to be physician specific. A number of clinical professional societies—such as the American College of Cardiology or the Society for Thoracic Surgeons—maintain patient registries that contain important information about the quality of care (e.g., appropriateness of procedures, clinical process measures, outcomes). These registries are an important potential source of data and may help reduce the burden on physicians to comply with program requirements. Several issues that would need to be addressed prior to allowing this type of data submission are the need for audit, a data integrity assurance process related to the comparability of coding across different providers (e.g., is there training of data coders so that they are consistently applying definitions), and permission by the specialty society to allow Medicare access and use of the data.

d. Provide meaningful, timely feedback on performance. To take action to improve, physicians will need timely feedback on their performance and how they vary compared to peers. Generally, the sponsors of incentive programs are not in the business of providing real-time information; instead, that has fallen to the organization within which the physician works because the organization is better equipped to provide real time information. Increasingly, in the context of ACOs, health plans are partnering with health systems (physicians and hospitals) to provide daily reports to alert physicians that a patient's situation is worsening (so at risk for hospitalization) or that the patient has been admitted to the hospital or emergency department. Such data are valuable to the physician practice so they can intervene quickly to manage the patient in the most appropriate setting. Similarly, some integrated health systems are providing real time feedback to physicians on their performance (e.g., monthly), flagging areas where performance is lagging or signals a problem. While ideally real time data monitoring and feedback would be universal in our health system, it is not a near term reality. However, as electronic data systems improve and CMS is able to leverage data submissions from physicians on a more frequent basis, there is

potential to develop systems where CMS could generate more timely feedback reports (relative to benchmarks)—such as on a quarterly basis.

e. Foster HIT capabilities to support measure construction. EHRs can be leveraged as a data collection and reporting tool. Substantial progress has been made over the past few years in working to move EHRs into ambulatory practices. Providers are already receiving technical assistance related to EHR implementation through the efforts of the Office of the National Coordinator for Health Information Technology (ONC). Within the next five years, the capabilities of EHRs will be enhanced and should be designed to support capture of the data elements needed to construct performance measures, and CMS working with ONC and EHR vendors need to create the appropriate tools to extract needed data and organize it in formats for submission to programs such as the SGR incentive program. The ability of physicians in all practice types and sizes to collect and report data on performance measures should be enabled by HIT. Already, providers across the country are making significant investments in HIT---to enable their participation in new care delivery models and payment structures that demand quality outcomes. These systems are at the heart of clinical redesign and can provide the front line physician with clinical decision support and feedback on performance. CMS should work collaboratively with ONC and Electronic Health Record (EHR) vendors to ensure that EHR platforms are able to capture required data elements in a structured format to construct performance measures that are contained within Medicare measurement, reporting, and incentive programs. Measure development moving forward should emphasize e-Measure (meaning constructed from data contained in EHRs) development and e-Measures should be tested in a wide array of EHR environments prior to being applied nationally to minimize implementation problems.

6. Period of Transition

A period of payment stability will allow time to develop and vet measures and build the quality infrastructure. The question is how much time is required to start the transition. At noted earlier, because measures for primary care already exist and are widely deployed, the Medicare program should quickly advance the use of these measures and start all PCPs on the path to data collection, reporting, feedback, and improvement. It will likely take the next three years to generate a measure portfolio for specialists and to build out other high priority measure areas, provided we begin investment today. A potentially faster path for subspecialists is leveraging data already captured by specialty societies in registries that could allow the transition to begin sooner for the subset of clinical subspecialists that are reporting data to registries.

Earlier in my testimony I had commented on the perverse incentives in FFS payment structures

to provide more services irrespective of quality or costs. While the focus of my comments has been on embedding performance-based incentives into the existing FFS payment model, I would underscore for the Committee that more wholesale payment reform is required to move us beyond a payment structure that incentivizes physicians to do more, often with little to no clinical benefit or that may even harm the patient. The incentive structures I've discussed today work at the margin rather than on the structure of the base payment. To that end, I would encourage Congress to enable CMS and local communities to conduct payment reform innovations across the United States, allowing payers, physicians, and other stakeholders in communities to innovate to advance the delivery of high value health care.

Conclusion

In summary, design does matter related to whether and how providers will respond and how successful the incentive program will be. The ability to move successfully forward with new performance-based payment models is predicated on having (1) a robust set of measures; (2) a good incentive design; and (3) a support structure that can help physicians participate and succeed in the program.

As Congress considers the design of an incentive program, there are several areas where federal leadership and investment can facilitate and support the transition to performance based payment.

For clinical subspecialists,

1. ***Provide federal investment in the development of measures, to address the care delivered by subspecialists and to fill important performance measure gap areas (such as efficiency/overuse of services, care coordination, and outcomes)***:

    - ***Use a rigorous, transparent and inclusive process to develop measures.*** Because performance measurement will affect the behavior of physicians and the organizations in which they work, it is important that what we ask them to focus on is based on scientific evidence related to actions they can take to influence the outcomes of interest. While CMS may fund or lead efforts to develop measures working with measure development experts, physicians should be actively involved in these efforts, could lead such efforts. Existing physician-led data registries that track processes and outcomes could be leveraged.

- ***Ensure measures are valid and reliable.*** The development process should ensure that the measures that will be applied in high stakes applications are valid and reliable. Results from testing of measures should be publicly available for physicians to review; such transparency will build confidence in the measurement system.
- ***Ensure that measures reflect the current evidence base:*** CMS should provide resources to update measures (or retire them) to incorporate changes in the scientific evidence.

2. ***Begin the transition now for Primary Care.*** CMS can leverage the ambulatory care measures (most of which address primary care) drawn from Medicare Advantage and private payer performance measurement programs. These are well-vetted measures that are in routine use nationally.

3. ***Structure the incentive to achieve the desired result.***

- ***Pay along the continuum:*** The incentive structure should provide incentive rewards along the continuum of performance (with some minimum threshold that must be met to get any incentive) so that providers are rewarded for each increment of improvement. Incentivize improvement more at the low and middle of the continuum more than at the top, as the lower performers are making critical investments to succeed.

- ***Use fixed thresholds***

- Make payments meaningful

4. ***Create an environment where providers can succeed:*** CMS can create a culture of working in partnership to achieve the desired goals by supporting providers in their efforts to improve. Recommended actions include:

- Work to build support structures with local community partners who can help physicians with quality improvement support and system redesign.

- Facilitate sharing of best practices and learning networks among peer subspecialties

- Provide meaningful, timely feedback on performance.

- Continue to support the advancement of clinical decision support to help providers meet quality requirements. Work with EHR vendors to ensure that EHR are able to capture in structured data fields (rather than free text) the data required to construct performance measures.

- Allow providers flexibility in how they can participate and submit data

RAND researchers have developed performance measures, (McGlynn et al., 1995; Wenger et al., 2003), evaluated the impact of pay-for-performance (Damberg et al., 2009), and more recently value-based purchasing programs, helped to define alternative measurement approaches that can support new payment models (Hussey et al., 2009), and assessed the implications of alternative incentive designs and scoring systems to reward performance (Schneider et al., 2012; Mehrotra et al., 2010; Damberg et al., 2009; Stecher et al., 2010; Friedberg and Damberg, 2012). We are happy to work with Committee members to share the work we have done in this area to inform policy making.

Again, let me thank you Mr. Chairman, Mr. Ranking Member, and members of the Subcommittee for allowing me to appear before you today to discuss this important issue. I would be happy to take your questions.

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Mr. PITTS. And now recognize Mr. Kramer for 5 minutes for an opening statement.

STATEMENT OF WILLIAM KRAMER

Mr. KRAMER. Thank you, and good morning. My name is Bill Kramer from the Pacific Business Group on Health. I would like to express our deep appreciation to Chairman Joe Pitts, Vice Chairman Dr. Michael Burgess, as well as to Ms. Donna Christensen on behalf of Ranking Member Minority Member Frank Pallone, for convening today's hearing. I want to applaud the committee for stepping up to the challenge of finding a solution to this very important issue.

PBGH represents large employers who want to improve the quality and affordability of health care. PBGH consists of 60 member companies with employees in all 50 States that provide healthcare coverage of up to 10 million Americans and their dependents. Our members include many large national employers, such as GE, Walmart, Boeing, Tesla, Disney, Intel, Chevron, Wells Fargo, and Safeway, as well as public sector employers.

The basis for my testimony today is our members' significant experience in designing and implementing innovations in provider payment and care delivery. We believe the lessons learned in private sector purchasing can be applied to Medicare.

There are three key points I want to make in today's testimony. First, businesses have a big stake in how Medicare works. Second, large employers want to see physician payment tied directly to the value of the services that are provided. And third, we need new and better performance measures to support a new physician payment system.

First, why should businesses care about how Medicare works? For decades, large employers have been frustrated by the rising cost and inconsistent quality of health care. They know we need to change the way we pay providers. Large employers have supported innovative approaches to physician payment, such as the intensive outpatient care program piloted by Boeing and adopted by many other large employers.

We know, however, that these innovations do not have the scale to drive system-wide change and improve health care across the Nation. We need America's largest healthcare purchaser, the Federal Government, to work in alignment with us and join our efforts and apply its purchasing strategies as purposefully as our businesses do.

Second, large employers want to see physician payment tied directly to the value of services that are provided. We need to replace Medicare's current fee-for-service system over time with payment based on performance with a goal of achieving measurable improvements in quality and affordability. The new physician payment system should encourage individual as well as group accountability.

Although team-based care is often very effective, in many situations patients are most concerned about the performance of individual physicians. I recently had surgery to repair a broken bone in my face, an injury resulting from an elbow to the eye during a pickup basketball game. While I was pleased to know that I would

receive care within a large, high-quality healthcare system, what I really wanted to know was the track record of that surgeon. What was his success rate? How many infections or surgical complications did the patient have. By far the most important thing to me was that surgeon's performance record.

Third, we need to develop more and better performance measures. Among the nearly 700 measures endorsed by the National Quality Forum, the large majority are clinical process or structural measures. While these can be valuable for quality improvement initiatives by physicians, they do not provide information about the things that patients and employers care most about. We strongly recommend that Congress provide support for the rapid development and use of better performance measures, including patient-reported outcomes, patient experience of care, care coordination, appropriateness of care, and total resource use. The selection of these measures should be based on input from physicians, but ultimately be determined by those who receive and pay for care.

In summary, first, businesses have a big stake in how Medicare works and Medicare should adopt successful purchasing practices from the private sector. Second, large employers want to see physician payment directly tied to the value of services that are provided. PBGH and its member companies strongly support the replacement of the SGR as long as the new payment system results in significant improvements in healthcare quality and affordability.

Third, Congress should invest in the development of new and better performance measures to undergird the new payment system. The selection of these measures must meet the needs of those who receive and pay for care—patients, employers, and taxpayers.

Our Nation desperately needs to improve its healthcare system, and the SGR replacement is a rare opportunity to give it a shot in the arm. PBGH applauds the committee's efforts to get it right, and we offer our real world experience and expertise to you in advancing this important initiative. Thank you, and I am happy to answer any questions from the committee members.

Mr. PITTS. Thank you.

[The statement of Mr. Kramer follows:]

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Statement for the Record

Pacific Business Group on Health

Hearing before the House Committee on Energy and Commerce
Subcommittee on Health

"Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System"

June 5, 2013

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House Energy & Commerce – Health Subcommittee Hearing
June 5, 2013
Testimony

Good morning. My name is Bill Kramer, and I serve as Executive Director for National Health Policy at the Pacific Business Group on Health. On behalf of PBGH, I would like to express our deep appreciation to Chairman Joe Pitts, Vice Chairman Dr. Michael Burgess, and Ranking Minority Member Frank Pallone for convening today's hearing on physician payment policy under Medicare. I want to applaud the Committee for stepping up to the challenge of finding a solution on this very important issue.

The Pacific Business Group on Health represents large employers who want to improve the quality of health care and moderate cost increases. PBGH consists of 60 member companies, with employees in all 50 states, that provide health care coverage to 10 million Americans and their dependents. Our members include many large national employers such as GE, Walmart, Boeing, Tesla, Target, Disney, Intel, Bechtel, Chevron, Wells Fargo and Safeway, as well as public sector employers such as CalPERS and the City and County of San Francisco.[i] The basis for my testimony today is our members' significant experience in designing and implementing innovations in provider payment and care delivery. We believe the lessons learned in private sector purchasing can be applied to Medicare.

There are three key points that I want to make in today's testimony:

1. Businesses have a big stake in how Medicare works.

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2. Large employers want to see physician payment directly tied to the value of the services that are provided.
3. We need new and better performance measures to support a new physician payment system.

First, why should businesses care about how Medicare works?

For decades, large employers have been frustrated by the rising costs and inconsistent quality of health care, and they know we need to change the way we pay providers. Large employers have supported innovative approaches to physician payment, such as the Intensive Outpatient Care Program piloted by Boeing[ii] and adopted by other large employers[iii]. **Another example is the** Hill Physicians Medical Group in California, in which a significant portion of physician payment is based on value, not just the volume of services.[iv] Large employers know, however, that these innovations do not have the scale to drive system-wide change and improve health care across the nation. We need America's largest health care purchaser, the federal government, to join our efforts and apply its purchasing strategies as purposefully as our businesses do.

Second, large employers want to see physician payment directly tied to the value of the services that are provided -- clinical quality, patient-reported outcomes, and total cost of care. We need to replace Medicare's current fee-for-service system with payment based on performance, with the goal of achieving measureable improvements in quality and affordability.

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The new physician payment system should encourage individual as well as group accountability. Although team-based care is often very effective, patients are most concerned about the performance of individual physicians. I recently had surgery to repair a broken bone in my face – an injury resulting from an elbow to the eye during a pick-up basketball game. While I was pleased to know that I would receive care within a large, high quality health care system, what I really wanted to know was the track record of the surgeon. What was his success rate? How many infections or post-surgical complications did his patients have? By far the most important thing to me was that surgeon's performance record.

Third, we need to develop more and better performance measures. Among the nearly 700 measures endorsed to-date by the National Quality Forum, the large majority are clinical process or structural measures.[v] While these can be valuable for quality improvement initiatives by physicians, they do not provide information about the things that patients and employers care about most. We strongly recommend that Congress provide support for the rapid development and use of better performance measures, including patient-reported outcomes, patient experience of care, care coordination, appropriateness of care, and total resource use. The selection of these measures should be based on input from physicians but ultimately be determined by those who receive and pay for care.

In summary,

1. Businesses have a big stake in how Medicare works, and Medicare should adopt successful purchasing practices from the private sector.

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2. Large employers want to see physician payment directly tied to the value of the services that are provided -- clinical quality, patient-reported outcomes, and total cost of care. PBGH and its member companies strongly support the replacement of the SGR, but only if the new payment system results in significant improvements in health care quality and affordability.
3. Congress should invest in the development of new and better performance measures to undergird the new payment system. The selection of these measures must meet the needs of those who receive and pay for health care – patients, employers and taxpayers.

In other words – *Put patients first, help them identify the best doctors, and reward those doctors*.

Our nation desperately needs to improve its health care system, and the SGR replacement is a rare opportunity to give it a shot in the arm. The Pacific Business Group on Health applauds the Committee's efforts to get it right, and we offer our real-world experience and expertise to you in advancing this important initiative.

[i] Full list of PBGH members can be found at http://www.pbgh.org/about/members.

[ii] Milstein, A and Kothari P, Health Affairs, October 20, 2009. Accessed at http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/.

[iii] Additional information about the IOCP program can be found at http://www.pbgh.org/iocp.

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[iv] T. Emswiler and L. Nichols, Hill Physicians Medical Group: Independent Physicians Working to Improve Quality and Reduce Costs, The Commonwealth Fund, March 2009. http://www.commonwealthfund.org/~/media/Files/Publications/Case%20Study/2009/March/Hill%20Physicians%20Medical%20Group/1247_Emswiler_Hill_case_study_rev.pdf

[v] "Developing a Viable Physician Payment Policy". Statement of: Frank G. Opelka, MD, FACS, National Quality Forum. House Ways & Means Committee, Health Subcommittee hearing, May 7, 2013. http://waysandmeans.house.gov/calendar/eventsingle.aspx?EventID=332173.

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Supplemental Materials

Pacific Business Group on Health

Hearing before the House Committee on Energy and Commerce
Subcommittee on Health

"Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System"

June 5, 2013

PBGH
House Energy & Commerce Subcommittee on Health
Reforming SGR: Supplemental Materials
June 5, 2013

Summary of key testimony messages:

1. Businesses have a big stake in how Medicare works, and Medicare should adopt successful purchasing practices from the private sector.
2. Large employers want to see physician payment directly tied to the value of the services that are provided -- clinical quality, patient-reported outcomes, and total cost of care. PBGH and its member companies strongly support the replacement of the SGR, but only if the new payment system results in significant improvements in health care quality and affordability.
3. Congress should invest in the development of new and better performance measures to undergird the new payment system. The selection of these measures must meet the needs of those who receive and pay for health care – patients, employers and taxpayers.

Supplemental Information for Key Message #1

Large employers have supported innovative approaches to physician payment, such as the Intensive Outpatient Care Program (IOCP) piloted by Boeing and adopted by other large employers[i]. The IOCP is a primary care-led, high intensity care management model for high risk populations. The California HealthCare Foundation (CHCF) provided the funding to develop this groundbreaking model of delivering care as a strategy for reducing costs while maintaining or improving quality. The designs and financial projections underwent a peer review panel of subject matter experts and leaders of traditional and more innovative practices. Key features of the model include:

- A focus on high risk patients, i.e., the 5-20% who incur the highest costs.
- Each site creating a new ambulatory intensivist practice.
- Shared care plans, increased access, and proactively managed care.
- Copays for the initial intake visit were waived; there were no other benefit changes.
- Sites were paid a case rate per member per month (pmpm) to cover non-traditional services; otherwise, the sites continued to be paid based on traditional fee-for-service contracts.

- The sites received a portion of the savings in total medical expenses.

The Boeing Company initially implemented a pilot of this model in Seattle. Over a two-year period, Boeing achieved improved health outcomes (28% reduction in hospital admissions, 16% increase in mental functioning on the SF-36), 20% reduction in costs, and increased patient access to care.[ii,iii]

Following the success of the Boeing pilot, PBGH worked with CalPERS and Pacific Gas & Electric Company (PG&E) to replicate the model in rural Northern California with the Humboldt del Norte Foundation Medical Group. This program targets the top 20 percent of patients in terms of relative health risk. PBGH is now expanding the IOCP to the Medicare population. Under a grant from the CMMI, PBGH is rolling out this model to 17 medical groups in California, covering 23,000 Medicare patients, demonstrating commitment to public and private sector alignment.[iv]

Other PBGH members are experimenting with models for accountable care organizations (ACO). For instance, CalPERS implemented an ACO-like pilot with Hill Physicians Medical Group, Dignity Health and Blue Shield of California that introduced a shared savings model for improving care coordination and quality for 42,000 HMO beneficiaries in the greater Sacramento area. Early results showed a $15.5 million cost reduction annually due to a 17% reduction in patient readmissions and shorter lengths of stay.[v] Five months later, those results were updated to reflect $20 million cost reduction over the two years of the program, largely due to a 22% reduction in hospital readmissions.[vi, vii]

Large employers know, however, that these innovations do not have the scale to drive system-wide change and improve health care across the nation. As the largest health care purchaser, it is important to have the collaboration of the federal government in transforming the way health care

is delivered. Working together is also important to large employers to avoid the shifting of costs from the public to the private sector. In some markets, cost-shifting from Medicare to private payers can be as high as 40%.[viii,ix,x] Instead we should pursue strategies to improve quality while lowering the overall cost of care.

Supplemental Information for Key Message #2

The new physician payment system should encourage individual as well as group accountability. Individual physician accountability reinforces professional motivation for quality improvement, identifies variation that is masked by higher levels of aggregation[xi,xii] and is more appropriate in some instances. Although team-based care is often very effective, patients are most concerned about the performance of individual physicians.

Shared accountability also has a role in driving improvements in health care. It supports team-based care, coordination across providers, and progress toward a genuine system of care. Shared accountability can be accomplished by reporting at an aggregate level, such as the practice site, or basing physician-specific results on both physician and team (e.g., medical group) performance.

The new payment system should also reward high performers at a level that drives behavior. Over time as the program becomes more sophisticated, it should make a significant contribution to total compensation. For example, Hill Physicians Medical Group in California physician compensation is comprised of over 15% value-based compensation, and in some instances at high as 30-40%.[xiii] Hill Physicians are consistently rated in the top tier of performance in California's IHA Pay-for-Performance program. In 2010, Hill Physicians distributed $38.6 million from IHA and their internal

value-based payment program.[xiv] Hill Physicians Medical Group is an Independent Practice Association in Northern California, established in 1984, with over 3,800 physicians that serves 300,000 consumers.[xv]

Supplemental Information for Key Message #3

Many parties have a stake in the development and use of better measures for physician payment. PBGH has worked collaboratively with providers, payers, consumers and other stakeholders to support efforts to improve health care quality and outcomes while at the same time getting better value for the health care dollar. We engage in, and sometimes lead, multi-stakeholder collaborative processes to develop, evaluate, endorse, and recommend performance measures for use in federal and California-based reporting and payment programs. Physician involvement is critical in this process, but the ultimate stakeholders are those who receive and pay for medical care. It is essential for the process to involve all stakeholders, including strong representation from consumers and purchasers.

Ultimately, though, the HHS Secretary will decide which measures are used in Federal physician payment programs. That said, multi-stakeholder input to HHS via pre-rulemaking of the Measure Applications Partnership is a key part of the consensus-based entity National Quality Forum measure review and endorsement process and both should continue to be supported.

An example of multi-stakeholder collaborative using measures that meet the needs of a variety of users is the California Joint Replacement Registry (CJRR). Joint replacements have become the highest volume—and highest cost—surgeries for both Medicare and private payers. From 2001 to 2009, the rate of primary hip replacements increased by 52%, while the rate of primary knee replacements almost doubled.[xvi] Working with the California Orthopedic Association and the California HealthCare Foundation, PBGH launched the CJRR, a Level 3 clinical registry. The registry is: (1) collecting and reporting scientifically valid data on the results of hip and knee replacements performed in California, including device safety and effectiveness, post-operative complication and revision rates, and patient-reported assessments; and (2) encouraging quality and cost improvements through marketplace mechanisms by using performance information to guide physician and patient decisions and supporting programs for provider recognition and reward. There are 12 sites, which include 61 surgeons, submitting data and represent 20% of the California hip and knee replacement cases each year. An additional 19 sites are in the process of joining the program.[xvii]

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[i] Additional information about the IOCP program can be found at http://www.pbgh.org/iocp.
[ii] Milstein, A and Kothari P, Health Affairs, October 20, 2009. Accessed at http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/
[iii] This model was also highlighted in Atul Gawande's "Hot Spotters" article in the New Yorker, and documented on the Agency for Healthcare Research and Quality (AHRQ) Health Care Innovations Exchange. http://www.innovations.ahrq.gov/content.aspx?id=2941. Additionally, Steve Jacobson, MD and Jennifer Wilson-Norton of The Everett Clinic presented on "Connecting Providers and Managing High Risk Beneficiaries" at the CMS ACO Accelerated Development Learning Session on September 16, 2011, https://acoregister.rti.org/docx/dsp_lnks.cfm?doc=Module 3B. Connecting Providers Managing High Risk.pdf.
[iv] http://www.pbgh.org/key-strategies/paying-for-value/28-aicu-personalized-care-for-complex-patients.

[v] CalPERS Press Release. (2011, April 12). *Press Release: April 12, 2011.* Retrieved February 21, 2012, from www.calpers.ca.gov: http://www.calpers.ca.gov/index.jsp?bc=/about/press/pr-2011/april/integrated-health.xml.

[vi] CalPERS Agenda Item 4. (2011, October 18). *Agenda Item 4 Memo to the Members of the Health Benefits Committee.* Retrieved February 21, 2012, from www.calpers.ca.gov: http://www.calpers.ca.gov/eip-docs/about/board-cal-agenda/agendas/hbc/201110/item-4.pdf.

[vii] Blue Shield of California Press Release. (2011, September 16). *HHS Secretary Kathleen Sebelius Reviews Key Pilot Progrom Tied to Health Care Reform Goals.* Retrieved June 3, 2013, from www.blueshieldca.com: https://www.blueshieldca.com/bsca/about-blue-shield/newsroom/sebelius-reviews-aco-pilot-programs.sp.

[viii] W Fox & J Pickering. Cost Efficiency at Hospital Facilities in California: A Report Based on Publicly Available Data. Millman. Oct 2007.

[ix] Analysis of Hospital Cost Shift in Arizona. The Lewin Group. March 2009.

[x] Health Care Trends in America. BlueCross BlueShield Association. 2009 Edition.

[xi] H.P Rodriguez et al. Attributing Sources of Variation in Patients' Experiences of Ambulatory Care. *Medical Care* 2009; 47: 835–841.

[xii] Massachusetts Health Quality Partners, Quality Insights: Patient Experiences in Primary Care, http://www.mhqp.org/quality/pes/pesTechApp.asp?nav=031638&view=print.

[xiii] T. Emswiler and L. Nichols, Hill Physicians Medical Group: Independent Physicians Working to Improve Quality and Reduce Costs, The Commonwealth Fund, March 2009. http://www.commonwealthfund.org/~/media/Files/Publications/Case%20Study/2009/March/Hill%20Physicians%20Medical%20Group/1247_Emswiler_Hill_case_study_rev.pdf.

[xiv] http://www.hillphysicians.com/ourdoctors/ProviderInfo/Pages/Pay-for-Performance.aspx.

[xv] http://www.hillphysicians.com/AboutUs/Pages/fact-sheet.aspx

[xvi] The Agency for Healthcare Research and Quality. National and regional estimates on hospital use for all patients from The HCUP Nationwide Inpatient Sample (NIS). http://hcupnet.ahrq.gov/. Accessed June 3, 2013.

[xvii] http://caljrr.org/about/CJRR-2013-progress-update.aspx.

Mr. PITTS. The chair thanks the gentleman, and now recognizes Dr. Rich 5 minutes for an opening statement.

STATEMENT OF JEFFREY B. RICH

Dr. RICH. Thank you, and good morning. Chairman Pitts, Representative Christensen, and distinguished members of the committee. Thank you for the opportunity to present my testimony today on the behalf of the Society of Thoracic Surgeons.

I come to you wearing many hats. As mentioned, I am the immediate past president of the Society of Thoracic Surgeons and an active participant in our national database, one of the longest running, most robust clinical outcome data registries in existence. More importantly, or as importantly, I am the former director for the Center for Medicare Management at CMS. In other words, I ran the Medicare fee-for-service system in the last years of the prior administration and was involved very much in value-based purchasing and also physician reform initiatives.

I am a founder and director of the Virginia Cardiac Surgery Quality Initiative. I am now a practicing cardiac surgeon at Sentara Heart Hospital and president of the Mid-Atlantic Cardiothoracic Surgeons, so I have an active clinical practice and understanding of payment and payment reform.

The Society of Thoracic Surgeons represents more than 6,000 surgeons, researchers, and allied healthcare professionals who are dedicated to providing patient-centered high-quality care to patients with chest and cardiovascular diseases, including heart, lung, esophagus, transplantation, and critical care. The STS National Database was established in 1989 as an initiative for quality assessment, improvement in patient safety among cardiothoracic surgeons. The fundamental principle underlying the STS database initiative has been that engagement in the process of collecting information on every case, robust risk adjustment based on pooled national data, and feedback of this risk-adjusted data to the individual practice and institution will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients and the public. And I might add that the database will serve as a platform in all phases of reform, I, II, and III.

The Virginia Cardiac Surgery Quality Initiative was founded in 1994 by myself and others with the expressed purpose of improving clinical quality across an entire State in cardiac surgical programs of all sizes through data sharing, outcomes analysis, and process improvements. All of the Virginia programs participate in the STS National Database and uniformly follow the definitions and measures in its landmark clinical registry.

The database in our State has been unique in that it matches the patient clinical outcome data with each patient's discharge financial data from CMS on an ongoing basis. Each record includes clinical outcomes tied to the cost of each episode of care. In Virginia we have demonstrated that improving quality reduces costs. For example, using evidence-based guidelines, the Virginia Cardiac Surgery Quality Initiative has generated more than $43 million in savings over the last 2 years by reducing blood transfusions in the State. In addition we have reduced atrial fibrillation, a common

heart arrhythmia after surgery, and saved another 20-plus million dollars over the last 5 to 7 years. So it has been an effective tool for us not only to improve quality, but to provide cost savings throughout the States.

Since survival and resource utilization information is such an important part of the outcomes for cardiothoracic surgery quality improvement efforts, we urge that steps be taken to ensure these registries have access to administrative or financial data from CMS, and hopefully other payers, both for episodes of care and longitudinal follow-up, as well as outcomes data from the Social Security Administration or another accessible source. It is imperative that SGR reform legislation addresses this foundational issue and gives us a clinical financial tool to create improvement.

STS wishes to commend the committee and your colleagues on the Ways and Means Committee for taking the first steps toward meaningful physician payment reform. STS has provided substantial comments on the concept document released by the committees on April 3rd that we submit here for the record. Today I would like to highlight a few of our conceptual comments for the committee related to that proposal in a discussion draft just released last week.

STS is particularly grateful to this committee for your recognition of the utility of clinical registries in pursuit of a pay-for-quality physician payment system. To that end, we recognize that Congress faces a challenge in that many specialties do not yet have the ability to collect clinical data, develop risk-adjustive quality measures, and implement physician feedback and quality improvement programs.

That said, we hope that implementation of a pay-for-quality program will not have to wait for all of medicine to be at the same place at the same time. We believe that early innovators who are able to enter into Phase II, or even Phase III, should be able to do so now, while others are trying to play a game of catchup, if you would. For that reason, we recommend that policymakers consider ways to reward providers for incremental steps towards these quality assessment and improvement goals, while allowing those medical professionals whose specialties that already have the requisite infrastructure in place to engage in this new system as soon as possible.

We do believe that it is important to use the STS database for other uses—medical liability reform, public reporting. We believe that empowerment of patients with data is important and advancing medical technology.

In conclusion, we wish to thank you for your time and understanding and listening to our plea for engaging with the rest of medicine in clinical data and outcomes assessment.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Dr. Rich follows:]

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House Committee on Energy and Commerce
Subcommittee on Health
Hearing: Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System
June 5, 2013

Jeffrey B. Rich, MD, Testimony on behalf of
The Society of Thoracic Surgeons

Chairman Pitts, Ranking Member Pallone, and distinguished members of the Committee, thank you for the opportunity to present my testimony today on behalf of The Society of Thoracic Surgeons. I come to you wearing many hats: Immediate Past President of The Society of Thoracic Surgeons and participant in the STS National Database – one of the longest running, most robust clinical outcomes data registries in existence; former Director of the Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS); Director at Large of the Virginia Cardiac Surgery Quality Initiative; and a practicing cardiothoracic surgeon at Sentara Heart Hospital and President of Mid-Atlantic Cardiothoracic Surgeons, Ltd. in Norfolk, VA.

The Society of Thoracic Surgeons (STS) is the largest organization representing cardiothoracic surgeons in the United States and the world. Founded in 1964, STS is an international, not-for-profit organization representing more than 6,600 surgeons, researchers, and allied health care professionals in 85 countries who are dedicated to providing patient-centered high quality care to patients with chest and cardiovascular diseases, including

heart, lung, esophagus, transplantation, and critical care. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. The fundamental principle underlying the STS database initiative has been that engagement in the process of collecting information on every case, robust risk-adjustment based on pooled national data, and feedback of this risk-adjusted data to the individual practice and institution will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients and the public. In fact, published studies indicate that the quality of care has already improved as a result of research and feedback from the STS National Database.

For example, ElBardissi and colleagues studied 1,497,254 patients who underwent isolated primary Coronary Artery Bypass Graft (CABG) surgery at STS National Database-participating institutions from 2000 to 2009. They found that:

- Patients received more indicated care processes in recent years, including a 7.8% increase in the use of angiotension-converting enzyme inhibitors preoperatively and a significant increase in the use of the internal thoracic artery (88% in 2000 vs. 95% in 2009).

- The observed mortality rate over this period declined from 2.4% in 2000 to 1.9% in 2009, representing a relative risk reduction of 24.4% despite the predicted mortality rates (2.3%) remaining consistent between 2000 and 2009.
- The incidence of postoperative stroke decreased significantly from 1.6% to 1.2%, representing a relative risk reduction of 26.4%.
- There was also a 9.2% relative reduction in the risk of reoperation for bleeding and a 32.9% relative risk reduction in the incidence of sternal wound infection.

The Virginia Cardiac Surgery Quality Initiative (VCSQI) was formed in 1994, with the express purpose of improving clinical quality across an entire state in cardiac surgical programs of all sizes through data sharing, outcomes analysis, and process improvements. It is founded on the principle that a focus on quality will contain costs by lowering complications, improving efficiency, and reducing resource utilization. All of the VCSQI programs participate in the STS National Database and uniformly follow the definitions and measures in this landmark clinical registry. This regional quality initiative has constructed a database of over 80,000 patients who have undergone cardiac surgical procedures. The database is unique in that it matches the patient's clinical outcome data with each patient's discharge financial data on an ongoing basis. Each record includes clinical outcomes tied to costs for each episode of care. VCSQI has served as a test bed for the STS's evidence-based guidelines to be implemented.

VCSQI has attempted to test a global pricing model and has implemented a pay-for-performance program whereby physicians and hospitals are aligned with common objectives. Although this collaborative approach is a work in progress, collaborators point out that a road map of short-

term next steps is needed to create an adaptive payment system tied to the national agenda for reforming the delivery system. VCSQI has demonstrated that improving quality reduces cost. For example, using evidence-based guidelines, VCSQI has generated more than $43 million in savings through blood product conservation efforts and more than $20 million by providing the best treatment to patients with atrial fibrillation at the right time.

Comments

On behalf of STS, I would like to thank you for your very thoughtful proposal. The Society is particularly grateful that our endorsement of specialty-specific processes for determining quality and efficiency that rely on risk-adjusted outcomes (using registry data and associated quality measures) has resonated with the committees of jurisdiction and has a prominent role in your discussion draft. STS wishes to commend this Committee and your colleagues on the Ways and Means Committee for taking the first steps toward meaningful physician payment reform. STS has provided substantial comments on the concept document released by the Committees on April 3 that we submit here for the record.

Access to Administrative and Outcomes Data

Since survival and resource utilization information is such an important part of the outcomes for cardiothoracic surgery quality improvement efforts, we urge that steps be taken to insure these registries have access to administrative data from CMS (and, hopefully, other payors) both for episode of care and longitudinal follow-up, as well as outcomes (death) data from the Social Security Administration or another, accessible source. It is imperative that SGR reform legislation address this foundational issue.

The ability to link clinical data with administrative data has opened up important new ways to assess the effectiveness of treatment options, and has offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs. In addition, linking clinical registries to the Social Security Death Master File (SSDMF) once allowed for the verification of "life status" of patients who otherwise would be lost for follow up after their treatment.

The outcomes information derived from these data sources helps physicians educate today's patients and families so that they can play an active and informed role in the shared decision-making process. Valid and reliable outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term risks and benefits of medical procedures based on real-life, quantified experience rather than abstract concepts.

Unfortunately, CMS MEDPAR data have only been available for use in conjunction with the STS National Database on a project-by-project basis. Further, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the SSDMF. There are continuing efforts to further restrict access to the SSDMF so as to protect those listed in the file from identity theft.

Balanced against these legitimate privacy concerns are the many advantages of linked administrative and outcomes data when placed in the right hands, with adequate protections in place. It is important to note that STS, through its contracts with the Duke Clinical Research Institute, maintains the patient identifier data separately from the actual clinical and other demographic data, and the only patient level identified information that ever leaves the database is simply that the patient has a record in the database. When combining records with outside sources, patient identification information is matched against other records, such as those in the SSDMF. The follow-up information is returned from external entities and linked back to the records in the de-identified database. The externally derived data are used to supplement the data in the individual record, but these clinical, patient-level data never leave the database except in de-identified form.

Improving Care through Collaboration or Competition

With its nearly 25 years of experience providing the STS National Database, STS has considerable expertise in how a data collection and physician feedback mechanism affects surgical practice. For that reason, we have made specific recommendations to the Committee about the level of attribution at which data should be collected and incentives should be applied. In general, our approach to these issues is to use the tools available to facilitate collaboration and raise the bar for the entire specialty of cardiothoracic surgery.

If a quality-based payment system is designed to operate on the individual physician level, we fear that intra and inter-hospital cooperation and sharing of best practices will suffer. Additionally, from a purely statistical perspective, it is virtually impossible to distinguish

different levels of performance between one clinician and another because the total number of patients / outcomes / events created by the individual practitioners is far too small to achieve any meaningful interpretation. Placing incentives at a higher level can encourage collaborative learning and quality improvement that should be inherent aspects of professionalism.

Finally, placing the focus on the individual practitioner or certain specialties detracts from the team approach to patient care that always has been the hallmark of our specialty (e.g., the heart team, the cancer team, etc.). In order for such a team to function at its highest level, there must be shared responsibility for patient care and patient outcomes. Assessing care quality at the institutional, regional, or national level allows the component parts of the heart team to share accountability, ensuring the patient receives the best care from the appropriate health care provider.

Building Critical Registry Infrastructure

STS is particularly grateful to this Committee for your recognition of the utility of clinical registries in pursuit of a pay-for-quality physician payment system. To that end, we recognize that Congress faces a challenge in that many specialties do not yet have the ability to collect clinical data, develop risk-adjusted quality measures, and implement physician feedback and quality improvement programs. That said, we hope that implementation of a pay-for-quality program will not have to wait for all of medicine to be at the same place at the same time. We believe that early innovators who are able to enter into Phase II should be able to reap some reward for their efforts. For that reason, we recommend that policy makers consider ways to reward providers for incremental steps towards these quality assessment and improvement goals

while allowing those medical professionals whose specialties that already have the requisite infrastructure in place to engage in this new system as soon as possible.

Doing so will provide an incentive for others to move in a similar direction more quickly. Importantly, however, we believe that such a program can be structured so that physicians whose specialties are taking steps towards full scale implementation can reap some rewards. Short, medium, and long term infrastructure, measure, and quality assessment benchmarks should be set up as intermediate goals. For example, incremental steps towards Phase II readiness can include reporting of data to a clinical database under construction, working on various "Clinical Improvement Activities" as defined in the Committees' concept document, and receiving feedback on quality measure performance (even while such measures are being considered for approval), among others.

Corollary Potential of Developing a Clinical Registry Infrastructure

In appreciation of this Committee's work in favor of developing national clinical registry infrastructure, I wanted to point out for you some of the advancements in other aspects of health care policy facilitated by the STS National Database:

Medical Liability Reform: With respect to the Committee's express intent to remain open to the discussion of medical liability reform, we believe that the proposal to develop a clinical registry infrastructure helps to lay the groundwork for tort reform that can protect patients and providers alike. STS believes that setting standards aligned with best practices identified by specialty societies is the best way to institute meaningful medical liability reform. Quality measurement

and data on clinical risk can be used to reduce lawsuits and the cost of liability insurance, and to restore balance to the justice system.

Public Reporting: STS launched a Public Reporting Initiative in January 2011 in collaboration with Consumer Reports. As of March, 2013, 41% of Database participants voluntarily report their results for Coronary Artery Bypass Graft (CABG) and/or aortic valve replacement on the Consumer Reports or STS websites. STS is universally regarded as the medical professional society leader in these activities.

Medical Technology Approval and Coverage Decisions / Appropriate Use Criteria: The TVT Registry™ is a benchmarking tool developed to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. Created by STS and the American College of Cardiology, the TVT Registry is designed to monitor the safety and efficacy of this new procedure for the treatment of aortic stenosis. The TVT Registry was instrumental in facilitating the approval and coverage with evidence development of new medical technology, helping to bring this technology to the marketplace safely and efficiently.

Comparative Effectiveness Research: The Patient Centered Outcomes Research Institute has recognized the value of "observational research" using clinical registries to fulfill its mission. Further, registries such as the TVT Registry can be developed and augmented to collect real time data to measure outcomes in different patient populations in real time. We believe that comparative effectiveness research can help physicians, in collaboration with patients and families, to provide the right care at the right time, every time.

Determining Value of Physician Services: Congress should encourage CMS to use real, clinical data on procedural time and hospital lengths of stay collected via a clinical registry rather than time estimates which distort the relativity of the fee schedule. STS has used the time data from the STS National Database as the basis for relative value recommendations to the AMA Relative Value Update Committee. Unfortunately, the use of this type of real data has been resisted by CMS with the rationale that other specialties are not able to provide comparable data.

Conclusion

With the Congressional Budget Office's current Budget and Economic projections for 2014-2023, it is clear that Congress must act now while the cost of SGR repeal is significantly lower. Although expected growth in Medicare spending has slowed, there is no guarantee that the trend will continue. Congress has the opportunity to take SGR off the books at a significantly reduced cost and we cannot afford to let this opportunity slip by. We urge Congress to act and support the current effort by this Committee to draft legislation for that purpose that recognizes and attempts to leverage the power of clinical registries. STS wishes to thank you for the collaborative nature of your process thus far, and requests that you move forward with continued openness to stakeholder input.

Further, inasmuch as those who currently participate in the STS National Database may already be able to meet the provisions in your proposal as outlined, we welcome the opportunity to get started. Understanding that others will need to develop the infrastructure to support such a program, it is our hope that specialties will be able to jump into the pay-for-quality world when

they are ready, rather than waiting for all of medicine to get to the same place at once. To that end, STS has valuable experience in registry development that we are able to share with those specialties undertaking the task of building a registry now or in the future.

Mr. PITTS. And now recognize Dr. Foels 5 minutes for an opening statement.

STATEMENT OF THOMAS J. FOELS

Dr. FOELS. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee on Health. On behalf of Independent Health——

Mr. PITTS. Would you please turn the mike on? Thank you.

Dr. FOELS. Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee on Health, on behalf of Independent Health I appreciate this opportunity to testify before you today. My name is Dr. Tom Foels. I am chief medical officer at Independent Health, which is a not-for-profit health insurer, serving over 400,000 members in Medicare, Medicaid, and commercial insurance in the Buffalo metropolitan area of Western New York.

Independent Health is nationally recognized for its quality of services and customer satisfaction. We have consistently ranked among the top 10 percent of health plans nationally for quality based on the National Commission for Quality Insurance. Independent Health shares the belief that the replacement of the SGR with a viable Medicare physician payment policy is critical to ensure that the Medicare program will be available for generations to come. We believe that it is time to replace the fee-for-service system with a system that rewards quality outcomes and efficiency.

Now, while I represent Independent Health, I am also here with the collaborative voice of my colleagues at the Alliance of Community Health Plans, a group of not-for-profit community-based plans dedicated to improving the health of its members, the health of the communities in which they live and work, as well as to ensuring affordability of coverage.

And finally, I speak today as a primary care physician with over 30 years of clinical and administrative experience. For the past 17 years I have held various senior positions at Independent Health, the last four of which as chief medical officer. During that time, I have been deeply involved in our efforts to improve quality and affordability of health care for our community.

My experiences as a physician have taught me that transformational change is difficult, regardless of its merits. I understand the skepticism and reluctance of some physicians because I have, at times, shared it as well. But I have also come to understand that important changes need to be made now that will benefit both physicians and patients and that the transition to a value-based payment system is both desirable and workable.

Our upstate New York community, provider community, is typical of so many communities across the country with an abundance of independently practicing, non-aligned primary care and specialty care providers and hospitals. Recognizing the desire of physicians to retain their independence, Independent Health has designed its programs in a way that has led to a virtually integrated model of providers. Independent Health has helped pioneer efforts in quality improvement, primary care design, and implementation of alternative payment systems.

Much of our success is based upon the deep trust and collaboration we have purposely fostered with our provider community

throughout many years of working together. We believe there are valuable components of our quality, efficiency, and effectiveness programs that are potentially scaleable and transferrable to other communities beyond our own.

Independent Health's approach toward developing improved systems of care are based upon several guiding principles, but most importantly they are based upon the assumption that primary care plays a pivotal and foundational role in the transformation to an improved system.

Independent Health is very excited about a recent development of a new model of primary care and reimbursement which we call Primary Connections. In this program, primary care practices that are certified patient-centered medical homes are reimbursed not under fee for service, but a hybrid payment system that includes a prospective, population-based payment, a quality bonus, and a shared savings program that rewards providers for reducing the total cost of care.

The collaborative also develops strong relationships between primary care providers and specialists who compete for primary care referrals based upon transparent data, profiling their quality, and cost efficiency.

I would like to briefly share two stories from our Primary Connection model, one that represents the past and one that represents and illustrates the experience of a patient and physician under the Primary Connection model.

Imagine the year 2010, a 70-year old man with a past history of diabetes, hypertension, and coronary disease contacts his primary doctor early one morning on a Monday complaining of chest pain while climbing stairs at home. He is seen in less than an hour by his primary, where an EKG shows suspicious findings. His doctor sends him to an emergency room where he is first seen by a triage nurse, then a physician assistant, then an ER physician. No provider examining him has access to his medical records. His EKG is repeated; blood work and diagnostic studies are performed. A decision is made to admit him overnight to monitor and observe his condition. He is discharged the following morning and given instructions to follow up with his primary. The primary does not receive a report from the hospital for at least 3 days. Costs would well exceeds $4,000. Care would be fragmented. Handoffs would be poorly coordinated. And the patient and family would be worried, anxious, and afraid.

The year is now 2013. Under Primary Connections, its patient-centered care, its reimbursement system based on quality outcomes and cost effectiveness, another scenario unfolds. It is again 10:00 a.m. in the morning and the patient presents to the physician's office. Now unlike the previous scenario, the physician immediately contacts his preferred collaborating cardiologist and forwards the EKG to his review. This preferred cardiologist has demonstrated his efficiency, quality, and clinical outcomes and is chosen because of that and because the primary works under a reimbursement model that incents collaboration and new forms of patient management.

After reviewing the studies the cardiologist makes accommodations for the patient to be seen. The same blood work and diag-

nostic testing that might otherwise have been performed in the ER is completed in the cardiologist's office. The patient and family are advised he is not having a heart attack. The cardiologist and primary speak by phone to coordinate care and follow-up. Later that afternoon, the primarycare coordinating nurse calls the patient at home to be certain he is well and asks if there are questions. Total cost of care, $1,200; care coordinated and efficient; communication immediate and complete; patient and family fully informed. Primary care physician is rewarded.

In conclusion, I look forward to sharing with the subcommittee the journey Independent Health and its physician partners are now taking to arrive at this efficiency and effective system of care, as well as our longstanding successful programs to promote quality.

Mr. PITTS. Chair thanks the gentleman.

[The prepared statement of Dr. Foels follows:]

Hearing on Reforming SGR:
Prioritizing Quality in a Modernized Physician Payment System

Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

Wednesday June 5, 2013

Statement of Thomas J. Foels, MD MMM
Chief Medical Officer
Independent Health
Buffalo, New York

Overview

Independent Health (IHA) is an innovative, health solutions company with a passionate dedication to achieving its mission of providing health-related products and services that enable affordable access to quality health care. To control the unsustainable trend of rising health care costs, Independent Health has created wide-ranging community partnerships with physicians and health providers intended to achieve the triple aim of improved health, better care, and lower costs.

IHA has helped pioneer efforts in quality improvement, primary care redesign, and implementation of alternative payment systems. Our provider community is typical of many communities across our country, with an abundance of independently practicing, non-aligned primary care and specialty care providers and hospitals. We believe there are valuable components of our quality, efficiency, and effectiveness programs that are potentially scalable and transferrable to other communities beyond our own. In addition, we have identified a set of critical success factors based upon our experiences that we also believe will help guide innovation on a national level.

Included in this document are detailed descriptions of the various programs IHA has successfully implemented impacting quality and effectiveness of care, as well as a description of our efforts to build improved systems of care based upon the patient-centered medical home model (PCMH) combined with a novel, hybrid reimbursement program that aligns payment with key PCMH design elements.

About Independent Health

Independent Health (IHA) is a regional not-for-profit plan providing health benefits and services to nearly 400,000 individuals in an eight-county region the Buffalo metropolitan area of Western New York. Its affiliated physicians include an open network of approximately 1,200 contracted primary care and 2,300 contracted specialty physicians, with the vast majority practicing in independent small single-specialty group practices or solo practice settings. Two dominant hospital systems provide inpatient and outpatient care services and remain largely unaligned and independent of the physician community.

IHA is nationally recognized for the quality of its services and extraordinary customer satisfaction. IHA is currently ranked among of the top 10% of health plans in the nation for quality by the National Commission for Quality Assurance (NCQA) in its Health Insurance Plan Rankings for commercial, Medicare, and Medicaid products. IHA has achieved and retained a 4.5 Medicare STAR quality ranking since the inception of the quality recognition program. In addition, IHA was named as the top health plan in the nation for customer service for 2009 and 2010 according to the NCQA Quality Compass® and currently is the *nation's* highest scoring health plan in customer satisfaction according to the J.D. Power and Associates' 2013 Member Health Insurance Plan Study℠.

Independent Health works to create partnerships and develop initiatives throughout our community to provide a balanced approach to improve quality – accompanied by efforts to contain costs, eliminate wasteful spending, and enhance efficiencies. Much of IHA's success is based upon the collaboration and trust the plan has fostered with the provider community throughout its history.

Guiding Principles

While the Affordable Care Act (ACA) provides a framework for reform, we believe the most sustainable solutions for health care reform will continue to take place at the local level. The following are guiding principles that have governed IHA's approach toward developing improved systems of care, enhanced quality, and greater health care affordability:

- Substantive and sustainable improvement in quality and affordability of the American health care system will require movement away from traditional fee-for-service (FFS) reimbursement systems.

- Primary Care plays a pivotal and foundational role in the transformation to a sustainable high-quality, affordable health care system. Navigation of patients through a complex health system is best coordinated by providers with broad primary care based professional training who can serve as a "medical home" to their patients. Primary care is currently under-resourced and over-burdened. Immediate efforts should be made to strengthen and redesign critical components of primary care to help ensure its future success.

- Patient care is inherently "team-based." Management of preventive health and chronic disease is a shared accountability within both office-based teams and across virtual teams of care providers in multiple settings. Traditional fee-for-service (FFS) reimbursement and early first-generation quality incentives do not sufficiently align performance within or among care teams of diverse providers.

- Historically, highly integrated delivery systems (IDS) have demonstrated the ability to provide exceptional levels of coordinated, high quality, cost effective patient care. In many cases, such systems have evolved over decades and have proven difficult to replicate or sufficiently scale. "Virtually integrated networks" of collaborating providers have the potential to significantly close the performance gap in many communities over a shorter time. Primary care remains centric to the development of such virtually integrated systems and efforts should be made to align incentives among and within primary care practices to fulfill this need.

- No singular payment system is sufficient to simultaneously promote quality, efficiently, and effectiveness. A hybrid approach that balances the best attributes of various payment systems, based upon operational ease and transparent methodologies, is most likely to be effective at aligning incentives with performance.

- Successful transformation of the delivery system will be dependent upon accurate, actionable, and timely reporting, performance data transparency, and resources deployed to help educate and promote "improvement literacy" and care systems redesign with the provider community.

Experiences and Successful Programs at Independent Health

Quality Enhancement and Pay-for-Performance

IHA was among the pioneering health plans to initiate quality based reporting and payment incentive programs. Our first generation programs, which began in 2000, were primary care focused, derived data exclusively from administrative claims, and included quality process measures and to a lesser degree, utilization measures. The program was collaboratively designed with the aid of a physician advisory panel, and included meaningful monetary incentives (i.e. up to 10% of the value of the physician's current fee schedule), attainable performance thresholds, actionable reporting, and "improvement literacy" provided by a dedicated team of health plan Practice Improvement Consultants. Within the ensuing three years of this program, significant improvements were achieved in preventive cancer screening and clinical process measures related to diabetes.

As the limitations of claims-based administrative data and focus on process measures became apparent, IHA began a second-generation quality reporting and payment program in 2003. This program, named Practice Excellence[SM], supplemented administrative data with clinical data derived from the physicians' medical record, and included outcome measures for diabetes, hypertension, cardiovascular risk management, as well as expanded process measures for asthma, emphysema, heart failure, and depression. Unlike the previous program, Practice Excellence[SM] included pay-for-participation, rewarding engagement activities with Practice Improvement Consultants, as well as pay-for-performance measured against fixed performance thresholds. The financial incentive opportunity was enhanced to 15% of the primary care physician's FFS revue.

Within a 5-year period, significant improvement was demonstrated in multiple metrics, particularly those related to diabetes care. For example, blood glucose control (A1C level at goal) increased 67% above baseline and lipid management (LDL at goal) and hypertension management (Blood Pressure at goal) each increased nearly 50% over baseline. Concurrently, IHA's national HEDIS (NCQA-Health Effectiveness Data and Information Set) rankings for comprehensive diabetes care rose from the 50th percentile nationally to the 90th percentile of comparable health plans. IHA currently maintains the highest quality ranking in the northeastern United States for comprehensive diabetes care based upon HEDIS scoring.

IHA recently began a third generation quality reporting program to measure performance of chronic medical conditions in and across multiple care settings. Recognizing the prevalence of diabetes in Western New York, and diabetes as a critical risk factor contributing to multiple cardiovascular conditions, we have begun reporting diabetes process measures with both cardiologists and their referring primary care physicians. Among diabetic patients currently referred and actively managed within cardiology offices, a surprising 16% lack evidence of blood glucose testing (A1C) within the past year, 18% lack a blood lipid testing, and 36% lack appropriate medication management of coexisting kidney disease.

Cardiologists were initially resistant to assume shared responsibility for these diabetic performance metrics, insisting that clinical management of diabetes is the responsibility of the primary care physician. After meetings and discussions with both cardiologists and primary care physicians (PCP), cardiologists have begun to collaborate with PCPs to co-manage these important clinical indicators. Cardiologists are

now more actively engaged in addressing both quality and efficiency within their practices, especially given IHA's Primary Connections[SM] program, which rewards specialists that achieve better outcomes for their patients. This program is described more fully later in the document.

Critical Success Factors:

- Physicians should be involved in the design, development, and monitoring of quality based reporting and incentive programs. Early buy-in of physician attribution methodology, measurement selection, performance thresholds, and design elements for actionable reporting is critical.

- Quality metrics selected should be based upon community health priorities. Measure and incent quality based upon metrics that will have a meaningful impact, not simply those easy to measure.

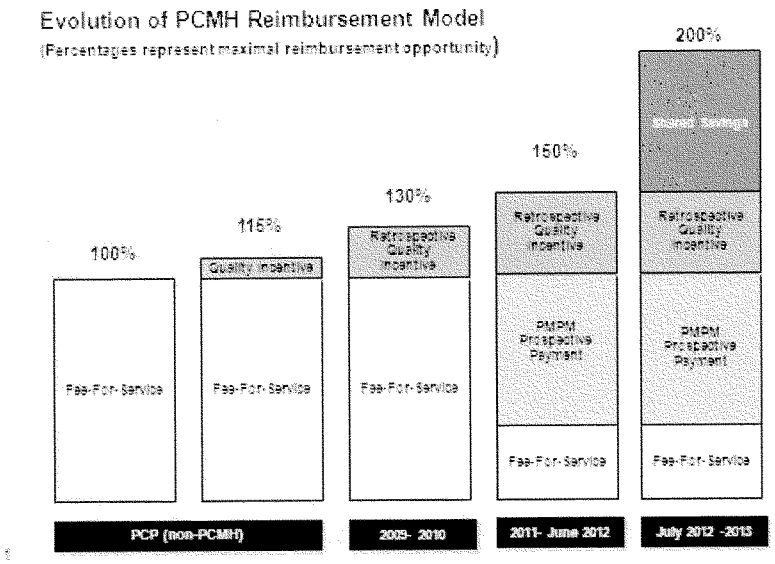
- Primary care and specialty care providers can be held mutually and collectively accountable for certain quality performance metrics that cross disciplines.

- A combination of accurate performance data, meaningful incentives, and provider education ("improvement literacy") has proven a powerful formula for success.

Patient-Centered Medical Home and Payment Reform

IHA has had a long and successful history of collaboration with the region's physician community, particularly the primary care community. In 2008, the health plan initiated discussions with key physician advisors regarding how to successfully rejuvenate and transform primary care to become a central element in the redesign of the local health care delivery system. Concurrent with these efforts, a broader national dialog was emerging regarding the concept to the "patient-centered medical home" (PCMH) and the National Commission for Quality Assurance (NCQA) was completing development of a certification process for such practices.

Following the development of design objectives and eligibility criteria, IHA accepted 16 primary care practices (120 physicians) into its PCMH Pilot Program in January 2009. An important element of PCMH was a proposed alternative reimbursement system that reduced reliance upon traditional FFS reimbursement and, instead, placed emphasis on a prospective risk-adjusted care coordination fee paid on a monthly per-member per-month (pmpm) basis. In addition, existing quality incentive programs were enhanced and carried higher performance thresholds. The intent of this payment transition was to better recognize and reward team-based care within the primary care office, reward and incent exceptional clinical quality, and transition away from the requirement for care to be reimbursed solely upon office based face-to-face encounters.



Physicians were surprisingly resistant to the proposed rapid transition away from FFS. Therefore, at the formal launch of IHA's PCMH Pilot Program in 2009, FFS was retained and enhanced "earned incentives" for quality were established. The earned incentives were based upon attaining high-threshold quality goals, completion of certification of the practice through the NCQA-PCMH program, and other factors including improved patient experience of care. Overall, practices had the potential to earn up to 130% of their former base revenue.

During the initial 24 month period, all practices attained the highest level of NCQA-PCMH certification and demonstrated moderate trends toward increased efficiency of total cost of care for the populations

they served. Quality performance measurements accelerated at a more rapid pace than other primary care practices not engaged in the PCMH Pilot Program. It proved difficult, however, for practices to engage in development of team-based care and provide substantive non-visit care, despite ongoing education and practice management consultation. There was growing awareness that retaining FFS-based reimbursement was proving a strong deterrent to practice innovation.

Following the completion of the initial PCMH Pilot Program (2009-2010), additional primary care practices meeting eligibility criteria were recruited to participate in an enhanced PCMH program that IHA developed called the Primary Connections ^{SM}. During the following 18 month period (2011-June 2012), the physician advisory panel accepted the need to transition away from a FFS based reimbursement system. During this period, FFS reimbursement was retained only for those services for which enhanced utilization was desirable, including preventive office visits, immunizations, and select office-based testing. The remaining monetary balance of the FFS revenue was converted, in budget-neutral fashion, to a prospective risk-adjusted pmpm payment. In addition, the retrospective incentive for quality and NCQA-PCMH recertification was retained and enhanced. Overall, participating PCMH practices had the potential opportunity to earn 150% more than non-participating primary care practices.

During the ensuing 18 month period, quality performance continued to advance and total cost of care diminished. Since the inception of the PCMH program in 2009, aggregate total cost of care for members assigned to PCMH practices has decreased 3.4% compared to peer averages.

Although PCMH practices had begun to impact total cost of care, the majority of medical expenses arise outside the domain of their primary care practices with expenses related to specialty care, hospital care, and laboratory, radiology and other ancillary services. Primary care reimbursement failed to reward activities related to engagement with the specialty community, development of collaborative programs to coordinate care across disciplines, or efforts to create programs to reduce potentially preventable hospital admissions and readmissions.

With this understanding, IHA developed a new hybrid reimbursement program for Primary Connections℠ practices beginning in July 2012. This new reimbursement approach now includes a shared savings component that provides an opportunity for practices to earn up to 200% of their former base revenue of four years earlier. As part of this new approach, a funding pool is established representing 65% of any saving on total cost of care compared to the previous year's expenditures of the practices. Earned shared savings therefore represent the collective as well as individual efforts of participating PCMH practices to enhance efficiency and effectiveness of care.

The development of the shared savings model has had a dramatic impact on the interaction of PCMH practices with one another (peer-to-peer collaboration), as well as generating meaningful engagement with specialists. Since shared savings opportunities are dependent upon the performance of specialists, collaborative efforts with cardiology, gastroenterology, neurology, radiology, and orthopedics with the referring primary care physician have emerged. This engagement has included efficiency and quality data reporting of specialty practices with primary care practices, as well as complete transparency among and within the specialty community. Specialty practices have now begun to compete for primary care referrals based upon published efficiency and effectiveness scores, and work within their practices

to eliminate non-value added procedures and tests, work to address avoidable hospital admissions and readmissions, reduce duplicative services and testing, prescribe generic medications where appropriate, and enhance service attributes, care coordination, and communication with referring primary care physicians.

A "ripple effect" of improvement efforts is now evident across the region's competing hospital systems as well. Since differences within negotiated hospital contract rates directly impact those specialties that are heavily hospital-based, high cost facilities risk disenfranchisement by specialties eager to improve their published efficiency indexes and willing to relocate their facility-based procedures and admissions to other more cost-effective hospitals.

As a virtual high performing network of primary and specialty care physicians and hospitals is now beginning to evolve, IHA is able to design and market tailored network insurance products at attractive premiums to employers and individuals eligible for the Exchange.

Critical Success Factors:

- FFS remains a valuable mechanism to promote utilization of important and potentially underutilized services, including preventive services.

- Prospective, risk-adjusted, population-based care coordination fees (distributed on a pmpm basis) give practices the freedom to tailor their care services to member needs and frees them from dependency upon face-to-face interactions.

- Virtual high-performing networks have the potential to emerge organically under the influence of properly designed alternative payment systems. Novel reimbursement programs focused on greater responsibility of the primary care team can have important ripple effects across the broader delivery system. Shared savings programs, even when limited to primary care practices, can have a dramatic impact upon the engagement of other important segments of the provider community (specialists and hospitals) and help communities move toward greater efficiently and effectiveness of health care delivery.

- Trust, transparency, and physician engagement in design elements of alternative reimbursement programs is critical for their successful adoption.

- Existing models of care delivery and reimbursement are potentially scalable and transferable to other settings and can be more rapidly deployed based upon know critical success factors identified in early pilot programs.

Concluding Remarks

Independent Health supports the goals of the House Committee on Energy and Commerce to reform the SGR and we applaud the bi-partisan congressional efforts to shift Medicare physician payment away from fee-for-service and toward payment that rewards performance, quality and value. Given Medicare's prominence as the single largest payer in the nation, fixing the SGR could become a powerful force in aligning incentives in a way that is consistent with the work already underway in the commercial market.

IHA has pioneered efforts in quality improvement, primary care redesign, and implementation of alternative payment systems within a provider community that is typical of many communities across our country, with an abundance of independently practicing, non-aligned primary care and specialty care providers and hospitals. We believe there are valuable components of our quality, efficiency, and effectiveness programs that are potentially scalable and transferrable to other communities beyond our own. In addition, we have identified a set of critical success factors based upon our experiences that we also believe will help guide innovation on a national level.

On behalf of Independent Health, I again thank the Subcommittee on Health for the opportunity to present these perspectives. We look forward to continuing to support and assist in this important work in the months and years ahead.

Mr. PITTS. That concludes the opening statements. We will now go to questions from the members. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Dr. Damberg, the proposed SGR revision has an initial phase with a period of payment stability, while quality-measure development takes place concurrently. What is an appropriate period of payment stability, in your opinion, in order to develop and vet measures and build the necessary quality infrastructure?

Ms. DAMBERG. As I noted in my testimony, there are an array of measures that already exist in primary care, and those are ready for market. So that transition could begin much faster than on the subspecialty side. As one of the other panelists indicated, some of the clinical subspecialties have taken significant steps to identify clinical process and outcome measures, and I think that those should be leveraged in the near term. And I think in the area where measures currently do not exist, and that space is pretty vast for the subspecialists, that process is probably going to take 3 years to bring measures to market.

Mr. PITTS. Thank you.

Dr. Rich, considering the different levels of provider readiness, how do we balance the need for a stable period enabling providers to build and test the necessary quality infrastructure while still incentivizing early innovators to move to Phase II with opportunities for quality-based payment updates?

Dr. RICH. So I would agree that a 3-year period for the embryonic novice would be important because it takes that long to develop your measures, get them vetted through an organization that would approve them, and then actually to start collecting data and look at it and using them effectively.

For those who, like us, who have measures already and we are using them already, I would suggest a tiered incentive program whereby the new payment reform would provide incentives to develop databases. If they only start out early with structural and process measures, and then develop outcome measures, that is fine. But those who have outcomes measures can start early with pay-for-performance pilots or pay-for-performance programs as we did in Virginia with WellPoint/Anthem, as well as in the public sector.

Mr. PITTS. OK.

Mr. Kramer, public feedback has reinforced the concept that it is essential for providers to receive performance feedback in order to make appropriate changes in practice improvements. To the survivor of the pickup basketball game, what does a meaningful, timely feedback process look like for providers, and what are adequate performance feedback intervals?

Mr. KRAMER. We strongly support the principle of providing feedback to physicians and other providers on the quality and affordability of the care that they provide. That should be an integral part of this redesigned payment system. And to the extent it is possible, we should move in the direction of having real-time feedback so that information that is embedded in electronic health records is accumulated and fed back to physicians on a regular basis.

I worked for many years at Kaiser Permanente, one of the pioneers in the development of electronic health records. That kind of ongoing feedback to physicians was essential. I understand that

many systems will take a while to get to that point, but that is what we should strive toward. In the interim, we should try to provide feedback as frequently as the information is meaningful in terms of volume of services that provides an adequate database for evaluation over quality.

Mr. PITTS. Dr. Foels, you state in your testimony that one of the guiding principles of IHA are, quote, "Substantive and sustainable improvement in quality and affordability of the American healthcare system will require movement away from traditional FFS reimbursement systems." Can you explain why in your opinion FFS Medicare undercuts quality and affordability in our healthcare system?

Dr. FOELS. Yes, thank you.

Yes, we believe that fee-for-service reimbursement does little to reward quality or recognize efficiency. It varies among providers by great degrees. It also inhibits collaboration across provider communities. Ultimately, the care of a patient is that of a team. It is based on teamwork within a single practice, and it is dependent upon a team across multiple specialties.

And fee for service as currently visioned and currently practiced does not promote any collaboration among providers, and hence we strongly believe that a new system of reimbursement that may involve some degree of hybridizing the best parts of multiple ways to reimburse may be much more effective.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady, Dr. Christensen, for 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

And thank you for your testimony.

As an African-American physician who practiced for more than 20 years, I know that many racial and ethnic minority providers, providers in rural areas, as I once did, work in communities and treat patients who have long been underserved by the healthcare system and detrimentally affected by the social determinants of health that create, sustain, and even exacerbate the health disparities. As a direct consequence, some patients simply present with more challenges than others, and that needs to be taken into account as we develop these systems. And so as we seek to assess provider quality and efficiency in a reformed Medicare payment system, we will undoubtedly struggle with how to account for these gaps.

So how should we be thinking about addressing these racial, ethnic, gender, and rural disparities as we move to incorporate quality performance measurement into a new Medicare physician payment system, and how can we assure that the Medicare payment reforms do not leave those providers who serve the Nation's most medically and financially needy in harm's way by ignoring the upstream variables that directly affect patient outcomes?

So anyone can answer, but maybe I would begin with Dr. Damberg by asking her if her pay for improvement along the gradient begins to address that.

Ms. DAMBERG. I think absolutely. And as I noted, the way in which you structure the translation from actual performance to the payment can be modulated along that performance curve, such that

you more heavily incentivize folks who are at the lower end of performance, and generally those folks are struggling with some of the very issues you identify.

So I think that the primary thing that you want to try to avoid happening is you are going to under-resource those providers. So allowing them to earn incentives for each increment of improvement I think will help mitigate that problem.

The other thing that I think is really important is trying to align incentives across providers. And I think if you look at what is going on in ACOs that are really linking providers across the continuum of care, as well as with social service agencies in the community, because I think there is recognition that it is not just health care that influences whether somebody comes back into the system. And so, again, I think there is really sort of an elephant in the room around larger payment reform, not just working at the margins, which is what incentives overlaid on fee for service really look like.

And so if you look at the Blue Cross Blue Shield of Massachusetts Alternative Quality Contract, where they have aligned incentives, it is a global payment, providers have worked very hard and have closed the disparities gap. So I think there are models out there that really have demonstrated that they can improve care for these disadvantaged patient populations.

Mrs. CHRISTENSEN. Dr. Rich? And I was going to ask the Thoracic Surgeons and maybe Independent Health, have they grappled with this and addressed it?

Dr. RICH. And the STS has long recognized that there are disparities in care. In our database we collect data on Afro-Americans, Hispanics, as well as Asians. We look very carefully at disparities in care for women and for socioeconomic status. And my first answer or response is that we need to measure it and inform providers whether they are addressing these needs or not.

I think to change it you could do what we did at CMS for hospitals and provide a disproportionate share payment, DSH payment, that allows providers to seek out the communities that need them the most, and to get an added incentive to their fee-for-service payment.

Dr. FOELS. And if I might add, and build off the two previous remarks, I, too, am very sensitive to the fact of the gap in disparities, which is not closing nearly as fast as anyone feels comfortable. And I concur with Dr. Damberg's comments that it is important to recognize that inner-city, urban, and rural providers have different starting points for their quality and they should not be punished for that. And there are scoring mechanisms and evaluation mechanisms, reporting mechanisms that would allow their incremental improvement and support.

Mrs. CHRISTENSEN. Thank you.

My time is almost up so I will yield back.

Mr. PITTS. Chair thanks the gentlelady.

Recognize Dr. Burgess 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Rich, thank you for being here. You are a practicing cardiothoracic surgeon, is that correct?

Dr. RICH. Yes.

Mr. BURGESS. So when you drive to work in the morning, do you tell yourself, boy, I hope I am average today?

Dr. RICH. No.

Mr. BURGESS. No, you go to work to do your best work every day.

Dr. RICH. That is right.

Mr. BURGESS. This is why I have always had a little bit of trouble with the concept of pay for performance. We are goal-directed individuals as physicians. We always go to work to do our best job. We never go into a patient's room expecting to be slightly above average, or hopefully not below average. No, we go in to do our best work. So we all need to recognize we are dealing with a highly motivated population of providers, and somewhat at our peril if we damage that motivation that exists amongst the Nation's physicians. And that is why it is so important to get the SGR reform because it is damaging to the psyche of America's doctors.

Now, I woke up this morning to the paper who said that they were very dismissive of the hearing we have today. The quote in the paper is that the draft that we have in front of us doesn't tackle some of the biggest outstanding issues, such as how to measure quality. So I really liked your comments. In your written testimony you said on behalf of the Society of Thoracic Surgeons, I would like to thank you for a very thoughtful proposal. And I agree with you. I think it is a thoughtful proposal. I think the committee and the committee staff have done a very good job of going to the provider community and soliciting their input as to what these performance metrics would be. Do you agree with that?

Dr. RICH. Oh, absolutely. Having sat at CMS and seeing other thoughts and legislation coming out of here, I think this is probably the most thoughtful, well-rounded, and sought after for input proposals out there. I was really impressed at the questions and some of the principles that were out there regarding the SGR reform.

Mr. BURGESS. Can you say that again for the press? You were very impressed?

Dr. RICH. I think they did a great job.

Mr. BURGESS. All right. Well, and let me just ask you, on the issue of CMS, you do reference in your testimony that it is so important that the registries have access to clinical data from CMS. CMS, as we learned over the past several weeks as they releasing some hospital data, I mean, they have got a lot of data, and it would really help you and your specialty in developing these performance metrics, it would really help you to have access to that data, is that not correct?

Dr. RICH. Absolutely. We have access to data that is really financial data. There is a little bit of clinical data in the CMS database, but more financial. Now, when ICD–10 comes out there will be more clinical data. But bringing that financial data into the patient record and matching that with the clinical experience has been an enormously powerful tool for us in Virginia. We have been able to see how quality improvement reduces costs. We have been able to look at maintaining quality and reduce resource consumption and provide the same level or better levels of care.

It is a very powerful tool to have, and access to it has been a little troubling recently. We are trying to do that on a national scale,

the STS is, and we are having difficulty because we have to go every time and ask for a special exception.

Mr. BURGESS. So is that the bottleneck, the fact that you have to go every time and ask for the specific data?

Dr. RICH. It is one of the bottlenecks.

Mr. BURGESS. Are there other bottlenecks that you could identify for the committee. Because we would like to help you, we would like to facilitate that exchange of data, because I believe you are on to something, and I think when you do have the data sometimes you will discover things that you weren't even thinking of as a way to embark on a cost-saving measure. So I want you to have the data and I want you to have access.

Dr. RICH. No, I appreciate that. So another bottleneck has been getting the Social Security Death Index data. That has been shut down because of, I guess, legal issues. And so in the past we were always able to track our outcomes and look at those who have died and figure if we have done a good or a bad job, you know, if they have died 7 months later. So that is a bottleneck.

Mr. BURGESS. It is a clinically identifiable endpoint, correct?

Dr. RICH. Usually. Sometimes people argue about it. But——

Mr. BURGESS. Just before my time expires, and I may ask you in writing to get back to us with some of those bottlenecks.

But, Dr. Foels, I need to ask you, you spent some time discussing the fee-for-service aspect of the system and why you don't think that should endure. And yet, in your testimony, no singular payment system is sufficient to simultaneously promote quality, efficiency, and effectiveness. And I said in my opening statement, whatever we do here, it has to allow for the entire panoply of practice options that are out there, allow them to exist and to thrive and, in fact, flourish.

So I would just tell you, I think the committee has done a good job as far as allowing a fee-for-service model to continue. As someone who has practiced OB-GYN, I mean, there is not a lot of Medicare practice in your average OB-GYN practice, but there is some and it is an important part. And if I have got to join an ACO or deal with bundled payments in order to continue to see those patients, I may well say enough is enough, and I am just going to exclude those patients from my practice. But if you allow me to have a fee-for-service model for compensation for those patients, I may be more apt to continue. And there are other examples I could give you, but in the interest of time, do you have a comment on that?

Dr. FOELS. Yes, you raise several points, one being that we may need to embrace a variable model for those individuals, those organizations, those physician communities that want to move quicker and faster toward development of virtual high-performing systems.

You also pointed out the fact that the, in my opening comments, that there is no singular payment system that isn't without its benefits or its perversities, so trying to blend the best of all together is effective.

One of the interesting footnotes in our experience is our application of the hybrid payment system to primary care physicians and its subsequent impact on specialty and hospitals that are still practicing under fee for service. And I would be welcome to describe that in further detail. But the takeaway message here is sometimes

altering a payment system within one sector of the provider system can have effective and beneficial impacts on other sectors that remain under fee for service.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The chair thanks the gentleman, and now recognizes the distinguished ranking member emeritus of the full committee, Mr. Dingell, for 5 minutes for questions.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy. I commend you for holding this hearing. It is a fine example of good bipartisan, bicameral progress. And it is my hope that it will lead to repealing the fatally Sustainable Growth Rate, SGR, and replacing it with a system that makes good sense for our healthcare system and for our physicians.

We have broad agreement on the goals and now we must come together in a bipartisan manner to work hard and find out what is the proper solution for this problem.

These questions are for all of our witnesses and will be both friendly and mostly yes, or no.

First question. At the end of 2012, Congress passed legislation to prevent a 26.5 percent reduction in physician payment rates. This short-term fix was signed into law last year and cost about $25.2 billion. Is that correct? Yes or no?

Dr. RICH. Yes.

Mr. DINGELL. Thank you. I was afraid I wasn't going to get a volunteer down there.

This year, the Congressional Budget Office found the cost of freezing physician payments for 10 years is $138 billion, more than $100 billion more than their previous projection. I believe this demonstrates the urgent need for the Congress to act.

Now, again, to each witness, do you believe that Congress should repeal and replace the SGR this year?

Ms. DAMBERG. Yes.

Mr. KRAMER. Yes.

Dr. RICH. Yes.

Mr. DINGELL. Sir?

Dr. FOELS. Yes.

Mr. DINGELL. Sir?

Dr. FOELS. Yes, I think initiatives should begin.

Mr. DINGELL. Now, in your analysis, did this system improve quality outcomes, yes or no?

Ms. DAMBERG. Could you clarify which system?

Mr. DINGELL. I am sorry?

Ms. DAMBERG. Could you clarify which system you are referring to?

Mr. DINGELL. Well, I am sorry. We will just lay this one on Dr. Foels and make that easier.

Dr. Foels, did the system improve quality outcomes, yes or no?

Dr. FOELS. I believe the existing fee-for-service system turns a blind eye to quality and efficiency.

Mr. DINGELL. OK. Now, your Independent Health system recently implemented a system that shifts away from the traditional fee-for-service reimbursement. That is correct, isn't it?

Dr. FOELS. That is correct.

Mr. DINGELL. And in your analysis, you found that this new system did improve outcomes, right?

Dr. FOELS. Yes, it did, medically.

Mr. DINGELL. All right. Now, do you believe that the reforms made by the Independent Health are a good example that the Congress should or could follow when reforming SGR, yes or no?

Dr. FOELS. Yes.

Mr. DINGELL. Now, there are many other private groups across the Nation that are experimenting with innovative payment models which promote quality care over quantity of care in an effort to make our healthcare system more efficient. I heard a great deal of comment relative to this point today. And it is my feeling we should use these efforts as building blocks. Congress must ensure any new physician payment model does not work counter to other successful innovations that are already in place.

Now, these questions are for all witnesses. Ladies and gentlemen, do you believe the Congress should look at the innovations and changes being made in the private sector when considering reforms to SGR?

Ms. DAMBERG. Yes.

Mr. KRAMER. Yes, absolutely.

Dr. RICH. Sure, yes.

Dr. FOELS. Yes.

Mr. DINGELL. I am running out of time, so I am not going to ask you to do that at this time, but if you would submit for the record some suggestions of what you feel might be useful, I believe it would be valuable and helpful to the committee.

Now, I guess I am going to conclude by pointing out that I think that this committee is on the right track. I am hopeful that it will continue to have an inclusive bipartisan process that will solve this problem which is making a huge mess for all of us, and I think that we can no longer kick the can down the road and that now is the time for the Congress to act.

So, Mr. Chairman, I thank you for your work today and for your leadership, and I am hopeful that this will lead us towards a better conclusion to the situation we confront. And I yield back 27 seconds. Thank you.

Mr. PITTS. The chair thanks the gentleman and now recognizes the chair emeritus of the full committee, Mr. Barton, for 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman. I want to commend you and the full committee chairman for starting this process. I think this is something that, given good will on both sides, we might actually could do, and if we are able to accomplish it, it will be a significant achievement of the committee. This is something that is long overdue. Go back to Chairman Dingell's chairmanship, my chairmanship, Mr. Waxman's chairmanship, we have fought with this and wrestled with it, and because of the expense and the way the Budget Act is, when we get down to the lick-log we have always had to back off. So I hope that this time your efforts and Mr. Upton's efforts with Mr. Waxman and others do bear fruit.

I just have one general question to the panel. It is the issue of balanced billing. It is currently prohibited. I am a proponent of whatever system we move to, that it should be something to be al-

lowed. It makes sense. It allows physicians, providers to bill for those services that are not reimbursable. And I would just like the panel's general position on whether we should include some provision for balanced billing.

Dr. RICH. So I think balanced billing, it is a touchy topic. I think it should be discussed and it should be vetted through the provider community as well as your committees. There is a way to sort of balance bill already in the Medicare system, and that is just to be a nonparticipant, but there are caps on the amount that you can balance bill a patient. So it is not very much. It is 105 percent of Medicare. And it doesn't take many patients not to pay their bill before it doesn't work. So balanced billing has been something that people have talked about and there likely is value in having discussion and perhaps introducing it into the legislation.

Ms. DAMBERG. While this is not my particular area of expertise, your comments, I think, highlight another deficit around aligning incentives across the healthcare system, and that is price transparency. So I think to the extent that you are considering any kind of balanced billing provision, I think that that has to go hand in hand with full disclosure of prices for patients, because I know on various occasions I have gone into the fee-for-service market where they no longer take health insurance, and when you ask physicians to tell you what the cost of the visit is going to be, they can't tell you that, and they often refuse to tell you that.

Mr. BARTON. Anybody else wish to comment?

Dr. FOELS. I would agree with the two previous statements. I think, to Dr. Damberg's point, the ability to capture balanced billing and include that in the efficiency profile of the physician for complete transparency would also have to be discussed.

Mr. BARTON. OK. I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green, for 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing. And like all of us, for 16 years now, we have been trying to figure out what we are going to do with the SGR, and this is an important step in that effort. I thank our witnesses for being here.

In the interest of transparency and opportunities for public stakeholder engagement are vital to quality measure development and approval process. Currently, mechanisms such as the National Quality Forum endorsement process that measures application partnership input and pre-rulemaking and rulemaking solicit and incorporate multistake stakeholder feedback can help. In addition, the Secretary of Health and Human Services is in charge of the National Quality Strategy, which it is a national overarching strategy to guide quality measurement activities and identify gaps in the current framework.

First, Mr. Kramer, I would like to hear your thoughts on the current state of the quality measurement oversight in the Nation's quality agenda. Do you believe we are on track and what more can be done to drive the quality improvement and measurement?

Mr. KRAMER. Thank you for the question. I will speak on behalf of Pacific Business Group on Health, but I am also a member of the board of directors of the National Quality Forum as well as Na-

tional Priorities Partnership that measures application partnership, but I will speak on behalf of PBGH.

I think it is fair to say that the current process is to develop, endorse and prioritize and put into use performance measures, are not getting the results we want. I think this opinion is shared fairly broadly by purchasers, patients, providers, and health plans.

That being said, there are some elements of the current structure and process that I think we can build upon. In particular, the National Quality Strategy, I think, represents a robust, well-vetted process to develop a clear set of priorities for the Nation. But we need to speed up the development of the process of developing and using measures at all steps of the pipeline.

At the front end, measure development, Congress needs to invest in the development of patients-centered measures to complement the measures that are currently in use. These measures represent a public good of enormous value. For a very small investment, the payoff, in terms of improved health and health care, is enormous.

The next step in the pipeline, measure endorsement, we need to streamline the process for reviewing proposed measures and getting input from all stakeholders. National Quality Forum has already begun to make improvements in the endorsement process through the work of all stakeholders. I hope we can build upon that.

Mr. GREEN. With respect to reforming SGR, in all honesty, if we reform the SGR with the goal of making sure we are paying for, you know, quality and measurements, I think we will see that input. But with respect to reforming it, are there current mechanisms that are both substantive and nimble enough to meet the policy framework in the discussion draft of the legislation? Is this legislation something that makes that possible?

Mr. KRAMER. I think this legislation will be a significant stimulus to development of better measures. It needs to be, I would recommend strongly, that it be paired with investment in development of quality measures and a clear direction to CMS to ensure that the measure endorsement process is streamlined, efficient, and involves all stakeholders.

Mr. GREEN. OK. I only have a minute.

Mr. Kramer and Dr. Foels, should participation in clinical improvement activities be included as a component of performance-based payment? If so, how could this be structured to support and incentivize meaningful quality improvement in a way that is not otherwise captured?

Dr. FOELS. Well, I think that is probably one of the most critical areas to address when addressing this issue of quality measurement, is how will it be reported, how will it be actionable, and trying to look for the process by which systems of care can be reengineered to deliver that quality.

To an earlier comment today, no physician goes in intending each morning to deny care to a particular percentage or to do less than what is absolutely best, but it is often a system of care that they provide in their office or among physicians that functions such that that is the byproduct. And so I think we need to continue to think about the ability to apply these measures on systems with deep col-

laboration, learning improvement, and share best practice across this.

Mr. GREEN. I only have a couple of seconds, but I want to make sure that investing in health information technology, medical home certification and use of clinical decision support tools, that could be used as part of the performance-based payment, I would hope, because that seems like where we are going.

Dr. FOELS. Exactly to my point. Clinical decision support would be a new system of care delivery that would close those gaps.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognize gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Real quickly, Mr. Kramer, I am interested in your opening statement, you talked about surgery and checking. Wouldn't it also have been nice to know, be able to search for fees? For fees or the cost. Or did you ever, after you went through the whole operation, did you know the total cost?

Mr. KRAMER. Absolutely. You raise an excellent point. I focused in my opening comments on the quality measures for the surgery I was undergoing, but an essential element for any patient is to also know the price. Building on Dr. Damberg's earlier comments about the importance of price transparency, this is one of the areas where consumers are looking for information and it is simply not available, whether in Medicare or in commercial insurance.

Mr. SHIMKUS. And I was just going to say, because Dr. Damberg, Ph.D. Doctor, not to diminish, but you did mention transparent in the answer to one of the questions as being a pretty key component.

Ms. DAMBERG. That is right. I do think that consumers very much want that information, particularly as, you know, insurance products change, and even in the Medicare program consumers face more and more out-of-pocket expenses. And, you know, having them be exposed to more cost-sharing helps align the incentives to the consumer about appropriate use of care, but again, that has to go hand in hand with transparency on prices so that they can make those.

Mr. SHIMKUS. And I really buy that, especially in the preventive care model. If you can really use transparency and you are encouraging people in wellness, you know, however the transparent system is, and encouraging people for generics versus, you know, the name brand, I mean, there is a lot of things you can do. But if the consumer is not in the game because it is a healthcare debate, then you lose all that additional thought process.

In rural America, there is access issues, and inner-city issues, as was highlighted earlier, where Americans will pay for quality, we know that, or assumed quality. There are, Dr. Burgess is gone, but there are cases of problems in the healthcare system with some providers who are not—I mean, in any organization there are some problem individuals who disparage and hurt the entire group. And my concern would be then erased because of available funding requirements having to have a lesser choice in quality is a concern. So there is a need to protect that both, I think, in inner-city regions

and also the rural care. But I am very interested in this reform proposed, and we have section 2 and subsection (h), which talks about providers paid under alternative payment models.

And so the question would be, I would like first to Dr. Foels, understanding the premise of the question, can you tell me how using alternative payment models can help fix this system and be beneficial?

Dr. FOELS. Yes. There are several ways. You know, our firsthand experience with our Primary Connection model is to retain fee for service where there is the potential for the underutilization of services. So fee-for-service reimbursement is very effective, for example, in encouraging preventative care visits, immunizations, and so forth.

The perversity of fee for service is that it recognizes, by and large, only face-to-face encounters and only those that occur between a physician or midlevel practitioner, and it doesn't recognize all of the very effective and beneficial work that can be delivered by a care team of nurses. It does not recognize telephonic interaction. It does not recognize electronic interaction with patients, which can be very effective. So we developed a component of a prepaid allocation to the practices that was not visit dependent or necessarily provider dependent but was tightly adherent to outcomes.

The third piece here, in savings, really gets back to that earlier issue of price transparency, so allowing a primary care physician to be rewarded for efforts with their collaborative team of specialists or hospitals to avoid redundancy of testing, to find those components of the system that operate the most efficiently and effectively, and to steer patients in those directions.

Mr. SHIMKUS. And, Mr. Chairman, just follow up just on that answer.

Shared savings, what do you mean by shared savings?

Dr. FOELS. Well, our model of shared savings for primary care is upside only, so it does not include any punitive downside, and it is measured on the total cost of care for the population, total population of patients assigned to that primary care group, and any incremental savings off a previous year's budget are shared proportionately back to them.

So again they are rewarded for the hospitalization that could have otherwise been avoided, which is also a quality issue as well as a cost-effective issue regarding alternatives.

Mr. SHIMKUS. OK. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

And now recognize the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Well, thank you, Mr. Chairman. I really appreciate you calling this hearing today on this important topic.

And I appreciate the witness testimony very much. You have made some very constructive recommendations. And I think the general parameters are clear. That is the easy part. We want to permanently replace the Medicare physician payment formula, this SGR that is very poor public policy, and replace it with a new payment model that improves the quality of care and lowers the cost of Medicare. And that is very easy to state, but it is much harder to get done.

But I know that we can do this. Just look at the report from the Medicare trustees last week. The reforms that we adopted in the Affordable Care Act are helping to reduce the growth in spending in Medicare already. Health spending in Medicare is expected to grow at a slower rate now than the overall economy in the next several years. So that is good news, and it does give us an opportunity to take some of the more difficult steps in payment reform.

But I have to say, I was very surprised in the Republican discussion draft, because I think we are so far beyond the discussion draft. It doesn't provide us with any real direction on payment reform, and I think that is unfortunate. Unless we change it substantially, the way it is crafted now, it will keep us wedded to the SGR and that poor public policy of temporary patches and outdated spending patterns.

I think better model to look to is the bipartisan bill H.R. 574 that I am a cosponsor of. It was drafted by Congresswoman Allyson Schwartz and Congressman Joe Heck. It is called the Medicare Physician Payment Innovation Act of 2013. It provides greater detail.

And when you compare the two, if you look at the current discussion draft now, I don't like that it has upfront cuts to providers. It doesn't really provide any innovation in what we need to do. We should be incentivizing physicians to transform their practices and participate in these innovative payment models. And what this discussion draft does, it says you can opt in if you like. And that is why I think it is too squishy.To use a technical term, it is kind of wimpy. And we can do a lot better. We have the experts here that can help us get there.

If you look at H.R. 574, it repeals the Sustainable Growth Rate permanently, stabilizes the current payment system, it institutes interim measures to ensure access to care coordination, it gives that important boost to primary care that I think everyone agrees on, we can build on the reforms in the Affordable Care Act. And then what it does, it says we are going to aggressively test the models and evaluate these payment models. It provides a very significant transition period, and as Dr. Rich recommended, the focus on best practices and the clinical registry.

So I would recommend to my colleagues to put out a real discussion draft where we can start to get to the more difficult decisions. One of those, what a number of you have mentioned, some of the high cost areas. We know we need to boost primary care and align doctors and have them work together better, but there are some certain high cost areas. You said there are 10 to 12 we should focus on. And, Dr. Foels, you said it has been difficult in transition, but you have arrived at some interesting payment systems.

Could you all highlight some of the specific areas, high cost, that are going to need greater transition periods or you think we should focus on that are crying out for reform?

Ms. DAMBERG. I think you are asking a broader question than just around measurement. So when I was talking about the 10 to 12, these are clinical specialties that if you look at sort of the majority of care that seniors need, it falls into areas such as cardiology, gastroenterology, endocrinology, neurology. And recognizing that, you know, we are in this sort of space where there is a vacu-

um of measures at the moment, and the realistic implementation of these programs, I think the idea should be to focus on where most of the action is in Medicare and focus the measure development work in that space in the near term.

So that can be used in any payment model that exists in the Medicare program. And one of the comments that is in my longer testimony is that whatever happens in the context of the SGR reform should work to align with programs that exist throughout Medicare, including the incentive program for meaningful use of electronic health records. There is a significant amount of alignment and coordination that can happen there, both as physicians and the LNC work with her, electronic health record vendors to ensure that the EHRs have the functionalities to capture the data that clinicians need to manage care and to report out these measures and to build in those clinical decision support tools to help physicians manage to appropriate care. So those exist in any system and that is something we should be working for across the entire Medicare program.

Mr. PITTS. Gentlelady's time has expired.

The chair recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Thank you, Mr. Chairman. I just want to make sure, and I am particularly focused on the two physicians who are here, this basically puts the onus on the academiesand colleges of medicine, various subspecialties, upon you to provide quality standards of best clinical practices. Is that the way you read this? OK.

And also that the specialties then are to develop on the front end the standards of protocols for best practices and apply those. Is that the way you read this as well? I want to make sure I am understanding this the same as you.

But I also understand that different specialties are farther advanced than others in terms of really establishing protocols. Am I correct on that? Dr. Rich, am I correct on that?

Dr. RICH. Yes.

Mr. MURPHY. Now, would you see this, in terms of quality measures, that basically this is a payment model that is based upon that if you adhere to the standards and protocols established by the medical specialties, that would be considered a quality measure? In other words, if they said for this diagnostic workup or for this diagnosis, once these results are in, this treatment plan, this is the protocol you follow and that would be the standard by which payment would be attached.

Is that your understanding, Mr. Rich?

Dr. RICH. Yes.

Mr. MURPHY. Now, what happens if a provider feels the need to vary from that protocol? Does this bill adequately address that yet or do we need some more work in that area?

Dr. Rich.

Dr. RICH. So I think, yes. So we work as a specialty society to develop on an evidence basis guidelines, and we go out to our membership and say get with the guidelines and here are the guidelines for these, you know, procedures that you are doing. So you are absolutely right.

The bill doesn't address discretion that physicians have in using technologies and drugs that are what we would call off-label use. And when I was at CMS, we discussed this at great length, even into the Secretary's office, and the message back to me was that we didn't want to interfere with the discretion of the physicians who are taking care of these patients to use a technology or drug within a certain patient. It can be abused. And so I don't think it goes far enough here in the legislation.

Mr. MURPHY. Well, let me ask you this, too, and Dr. Foels, as well as you can answer this. Then would it be—I mean, just other issues here—that, for example, if a person is board certified in a certain specialty, that they—perhaps one of the ways we could word this—is that person would be granted a little more latitude. So, for example, if you are recommending something as a thoracic surgeon, and someone else who is a practitioner, it is not within their area but they are following your protocol, that your recommendation, because you are board certified in the area, if you are varying from that protocol, might that be some other wording we could look at, or whatever that is. I am asking the both of you if you have any suggestions, we would appreciate that.

Dr. FOELS. Well, to comment on the board certification. That has evolved significantly in the past decade. Most recertification in a medical specialty involves quality assessment improvement efforts within your practice, so I think board certification is much more of a tangible marker of quality and improvement.

To your earlier comment about guideline, I would concur with Dr. Rich that there are very appropriate times where a guideline is not the path that should be taken with a particular patient. The frequency with which that occurs has potentially predictable ranges, and I think that the guideline adherence can be measured within certain degrees based on that.

Mr. MURPHY. Let me ask this, too. In terms of a payment model, I can understand how this could work if you have, for example, a hospital-based employee, where you have a large number of physicians and providers, a wide range of specialties practicing, because then the hospital could receive or the network could receive a global payment for that patient that covered life. If someone, however, is in a private practice, how do you work out the payment systems and still have enough incentive for people to work as integrated, coordinated care team. I am asking anybody on the panel because that is a key question.

Dr. RICH. So you could do global payments. We did in Virginia, we did it in our hospital with independent practices. It is just an agreement, a transparent agreement that you can have, and we worked on that.

Mr. MURPHY. Who controls that payment then? I mean——

Dr. RICH. So in Virginia, it was the hospital. The payment flowed down to the hospital and then they distributed it under agreement to the providers, and the providers were selected out depending on their quality and their reputation in the community.

Mr. MURPHY. I am a psychologist by training, and I am on some hospital staff, but if a physician refers to me from another hospital and I am not part of the hospital staff, how do they work out that payment system? And I know I am out of time, but that is some-

thing, I think, we really have to work out in terms of this, how we handle. And it does make reference to people who are nonphysician providers, but that is something we would appreciate your input on.

Thank you for the time, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now goes to the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

Thank you all for being here for this important discussion. I have long been a supporter of fixing the SGR and am happy we are continuing that conversation. Before I get to my questions, I just want to highlight, as we continue on this series of hearings addressing the SGR, I want to make sure we do not forget to address other items as well, like therapy caps that have historically moved alongside the yearly doc fix and share the common purpose of ensuring access to critical care for our Nation's seniors, and the opportunity to finally address the GPCI and other geographic payment inequalities that leave so many providers, especially those in my district, unfairly reimbursed and seniors with really fewer options.

Now, switching gears, as we focus today on quality, I would like to take a broad look at our health system. There has been a lot of talk in here on this committee about the role of doctors in the healthcare system, very appropriate, but as I have said before, I truly believe if we are going to really move to a more comprehensive prevention-focused system of care, we need to look at the full picture of our healthcare system. This is especially critical when it comes to addressing quality.

Most of the new delivery models like patient-centered medical homes and accountable care organizations emphasize team-based care, and they recognize the critical role and value of nonphysician providers. As such, I think it is important to acknowledge the role of other healthcare providers like nurses, nurse practitioners and physician's assistants in this conversation as well.

So, Dr. Foels, you state in your testimony that management of preventive health and chronic disease is inherently team based, which I agree. Could you expand on how diverse providers could be incorporated into any reformed Medicare payment system and what are your thoughts about their role and how they might improve quality and value?

Dr. FOELS. Well, I can perhaps briefly reflect on my earlier comment on an existing fee-for-service reimbursement system, which does not really recognize team-based care to any great degree. A large portion of preventive care can be delivered by nurses or advanced practice nurses who can identify missed opportunities for preventive services, make those arrangements. This does not require the time of higher licensed individuals. One of our mantra is always practicing to the top of your license.

Mrs. CAPPS. Right.

Dr. FOELS. And I think it is fairly true that nurses are inhibited today, in part by the payment system, from practicing to their full extent.

Mrs. CAPPS. Thank you. I agree.

And I want to return now to Cheryl Damberg. Under the proposed revision of SGR, which emphasizes best quality practices, nonphysician providers paid under the Medicare payment system are also expected to be rated on quality measures.

In your testimony, Dr. Damberg, you highlighted how we must enlist providers as true partners in defining the measures for which they will be held accountable for as teams and providers. In your opinion, do nonphysician providers need unique measurement sets compared to physician providers, and what role do you believe they should play in defining these measures?

Ms. DAMBERG. Well, let me start with the latter part of your question. Absolutely, they should be involved. And I think with all of the changes that going on in health care right now, practices are rethinking how they use people. But I want to note that what drives measurement is it is patient focused, so the patient's health needs determine what measure gets applied. And so if these other nonphysician providers are qualified to deliver that care that the patient needs, then those same measures would apply. So it is not clear to me that you would develop a set of measures that, say, apply to nurse practitioners, but rather the measures are developed around the patient and his or her needs.

Mrs. CAPPS. I see. That is intriguing, and I guess I would have to say it is pretty novel. Do you see glitches in or challenges in going from the way we do it now to something like this?

Ms. DAMBERG. I actually don't think it is inconsistent. If you look at the care that, you know, if you go to your physician practice site that you hope that they are delivering, you hope that that care is appropriate for you, given your gender, your age, and your health conditions, right? And the way in which measures are constructed, it really reflects that.

So, you know, if you are a diabetic, they are looking to control your blood sugar and your lipid levels, as well as your blood pressure. So I think it is really an issue of, you know, getting the right measures that focus on the major clinical issues that face patients in our healthcare system.

And then in the context of constructing those measures, you designate who are the appropriate specialties, and some of those may be nonphysicians, who should be held accountable for delivering that care.

Mrs. CAPPS. I see some other people nodding. I know my time is up. Is there a general agreement with this? Yes?

Mr. KRAMER. I would just say that example of good team-based care, which involves nonphysicians as well as physicians, is the intensive outpatient care program piloted by Boeing and adopted by a number of other large employers for taking care of very sick people with multiple medical conditions. It has been very successful in involving all members of the team, working to the top of their license. It has been done in a more affordable way, getting better clinical outcomes, better patient experience, better provider experience, and lower costs overall. Be glad to share the additional information.

Mrs. CAPPS. I would appreciate that if you include that in the record.

Mr. KRAMER. Yes, it is included in the supplemental materials we have submitted to the committee.

Mrs. CAPPS. Excellent.

Mr. PITTS. The gentlelady's time has expired.

The chair now recognizes the gentleman, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Chairman. Thanks for convening this. And I agree with our distinguished chairman emeritus, Mr. Dingell, working together bicameral, bipartisan, trying to solve an issue that whenever we get to the countdown of SGRs in the past, that is what I hear about when I go home, is from physicians and people in the medical field. And so it is important that we are doing this and doing it way early and getting ahead of it before we get to that point. So it shows that things are working, and hopefully we can work to get a solution. So I appreciate that very much.

And to follow from my friend from California was talking about, just measurements and qualities, and, you know, a large number of the quality measures in use today were developed following scientific processes to ensure their continued importance, scientific acceptability, which is important, usability, feasibility for reporting. However, there are many more measures in widespread use that fail to meet or require additional resources to meet these criteria for national reporting.

And Dr. Damberg, what process or processes could be enacted that would ensure quality measures or measurement sets are developed with high scientific rigor, maintain currency to the latest evidence-based clinical practices, and are relevant to new care delivery systems?

Ms. DAMBERG. So if CMS were taking the lead on measure development, I think what they have to do is institute a process where they work with measure developers who understand the scientific requirements and steps in a measure development process, which includes reviewing the evidence, holding panels with clinical experts that can include physicians and nonphysicians, to ensure that the underlying science is right, and then working to develop a draft measure specification that you go out and test and validate.

So they need to set up a rigorous transparent process to do this. And I think that it should involve clinical subspecialists and primary care physicians in identifying what those performance gaps are. And if you go out and you talk to physicians, they know where the gaps in care are, and so I think by linking the clinical specialists with the performance measure developers, I think you can have a robust development system that will create confidence in the system.

Mr. GUTHRIE. Well, thanks. And I am also on the Telecom Subcommittee of this great committee, and we are dealing with trying to update things, and telecom is changing so fast, where there is a system that doesn't happen.

So I guess also ask, in health care, my lifetime, they have gone from 6 weeks of recovery from gallbladder surgery to outpatient care. So just as those things, as we innovate and develop, the system has to be there and develop with that.

Ms. DAMBERG. Yes, the system has to be nimble enough and there have to be resources available to allow for annual re-review of measures and updating as necessary and retiring as necessary.

Mr. GUTHRIE. Well, thank you.

And, Dr. Foels, how would these processes ensure that quality measures evolve with data accumulation and advancement in measure development science and appropriately account for the relative value of measures as they relate to other measures and use? I think I just used measures as every part of speech.

Dr. FOELS. Well, you know, I actually want to build off Dr. Damberg's comments in that regard and at the same time address the issues you have raised.

So there are a couple of layers deeper that also have to be fully explored, examined and monitored, and one has to do with the methodology for attribution and accountability. I think the other take-forward lesson we have learned from our community is that, although various metrics are—certain of them are very attractive because of their ease of operational measurement, aren't terribly important because the community is already achieving reasonably high rates of success. And so prioritizing the measures to which are most important and impactful is also going to be, I think, a critical byproduct of whatever group is assigned this task.

Mr. GUTHRIE. Well, it is amazing how innovative we are in medicine, you know, from cancer drugs to where it killed all cells to get the cancer cells to where they are trying to—in Louisville, University of Louisville, is a doctor there pioneering going to individual, where they actually get just the cancer cells, as you all know better than I. I just want to make sure that whatever system we have, innovation and processes that allow innovation and keep up as we change are in place. So I appreciate that very much, and I yield back 10 seconds.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I have some questions for you, Dr. Damberg. Optometrists, podiatrists, optometrists, chiropractors have all been recognized by Congress within the definition of physician providers in the Medicare statute. Those medical providers follow the same rules and policies as other physician providers who deliver high quality services to the Medicare population.

For example, these providers face the same threat of reimbursement cuts under the SGR as M.D.s or D.O.s. Using the same rules for all providers included within the physician definition allows Medicare patients the freedom to choose among licensed healthcare providers for covered services.

I have concerns that the discussion draft actually would undermine a patient's access to the provider of their choice by allowing the Secretary to establish separate quality update incentive programs for optometrists, podiatrists, chiropractors than those established for M.D.s and D.O.s, and it seems to me this could result in providers who perform the same services being assessed by different quality standards and receiving different payment adjustments.

So let me ask you if you think it is important for every physician provider treating the same problem to be measured using the same quality measurement system and eligible for the same quality update incentives?

Ms. DAMBERG. I actually do. I think, again, per my earlier remarks, the clinical care that is delivered should be focused on the patient's needs, and whatever provider is addressing those needs should be held accountable. And I recognize that there are variations across health systems in how they deploy personnel. So I know firsthand, when I had my bunion surgery at Kaiser, I had a podiatrist who was involved in that. So, again, I think it is very important that the same set of measures apply as relevant.

Ms. SCHAKOWSKY. So talking about the patient, by having different quality measures and incentives, do you think that that could affect their access to quality care and their choices?

Ms. DAMBERG. Do I think it could affect Medicare beneficiaries?

Ms. SCHAKOWSKY. Yes, different, if we had different quality measures, might it not affect them?

Ms. DAMBERG. It is not clear to me that it would necessarily affect access to care. I mean, I think potentially the risk around access more generally in any incentive-based program comes when incentives get so large that they distort behavior, and particularly in the context of outcome measures you have not accounted for underlying patient factors that attribute to the outcome such that physicians or other types of practitioners may choose to avoid treating patients.

Ms. SCHAKOWSKY. OK. And currently, don't optometrists, podiatrists, chiropractors follow the same criteria right now and successfully report the same quality measures as M.D.s and D.O.s?

Ms. DAMBERG. In the measurement programs that I have been involved with, I have not seen evidence that they are reporting those measures. So I don't have any knowledge of that firsthand.

Ms. SCHAKOWSKY. OK. Another quality initiative being implemented in Medicare is the electronic health record incentive program, which provides incentive payments, as you know, to physician providers as they adopt, implement, upgrade, demonstrate meaningful use of the her technology. Do you know if optometrists, podiatrists and chiropractors are included in this program?

Ms. DAMBERG. I do not know that.

Ms. SCHAKOWSKY. OK. And let me see if—I think these all deal with those. You may not know the answer to this. The answer is yes, actually. Like these quality initiatives, isn't it important for the quality update incentive program being proposed for Medicare to require all physician providers in the Medicare program, including those other providers I listed, to use the same standards and receive the same incentives for the same services? I think it is another way of asking the same question.

Ms. DAMBERG. The answer should be yes, they should be held accountable to the same standards. I would be loathe to set up two different incentive systems. I just think the complexity of it and sort of the challenge is in sending very different signals. If anything, what we want to be doing is be creating greater alignment across physicians, other practitioners in the ambulatory care setting as well as aligning incentives across the system in which the

patient travels. So aligning incentives between physicians and hospitals, that is so very critical. And again, the extent to which this bill can help push that ball down the field a bit more would be very helpful.

Ms. SCHAKOWSKY. Mr. Chairman, I just want to say how much I appreciate the tone of this hearing and this discussion, and I hope we could have more like it. Thank you very much.

Mr. PITTS. The chair thanks the gentlelady.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

I appreciate all of you being here today, and I know there is some good questions that you already answered, and I am going to yield the rest of my time to Dr. Burgess for additional good questions.

Mr. BURGESS. And I thank the gentleman for yielding.

Mr. Kramer, let me just ask you a question. In your testimony, you talked about incentives and providing—building incentives into the structure, but oftentimes, here in the people's House, we end up talking about making something punitive rather than providing an incentive. Can you speak to that and the differential between those two activities, building in an incentive versus building in a punitive activity?

Mr. KRAMER. I will offer my opinions on this, although maybe it is best answered by a psychologist. But I think that my experience and experience of our members at PBGH is that positive incentives for doing the right thing are very powerful. There are occasions, however, we want to put in place a mechanism to avoid bad things, and it may be that in some situations that some kind of penalty would be appropriate.

For example, we want to avoid infections, you know, high rates of infection, we want to avoid high rates of mortality, we want to avoid high rates of unnecessary hospital readmissions. There may be some situations like that in which a penalty would be appropriate, but I think in most cases they can be restructured as a positive incentive. So the negative side of infections is infections are too high, therefore reward progress on reducing infections and frame it as a positive incentive, I think that could be most effective in moving us in a direction so that we get the results we want.

Mr. BURGESS. You know, my old epidemiology instructor from Southwestern Medical School used to tell me that in order to adequately measure something you had to eliminate fear, and the providers must not be in fear; otherwise, they are not going to be as forthcoming with you when they have problems. And that is one of the difficulties I see in constructing a system that is more punitive than one based on incentives. So I agree with you, and certainly the prescription drug or the providing for electronic e-prescribing, it wasn't part of the healthcare law, it was part of the stimulus bill, you are actually going to build some resentment toward e-prescribing because of the fact that it is a reimbursement reduction if that doesn't happen, rather than building in an incentive. And I hope we can be sensitive and careful about that as we construct this.

Dr. Foels, I just want to continue our discussion on the fee-for-service aspect for a moment where we kind of got cut off by time, but I do feel so strongly that in our reform of the SGR, you have to allow the—I mean, a lot of physicians of my age group, fee for service is what we have always known. We are goal directed. It is an incentive to which we respond. And to just start out with the premise that we are going to eliminate all fee-for-service practice in many ways I fear will only harden those people who would be resistant to the new payment models. And I would just encourage us, as we think about this, there has to be a place for the fee-for-service physician in the new Medicare model, in the new SGR, whatever is the follow-on from the SGR. I always use the example of Muleshoe, Texas, literally a one-stoplight town with one GP, and it is hard for him to be an ACO. I mean, I guess he can call himself ACO, but it is hard for him to be an ACO because he is just a country doc working in a little town and he gets paid for his services.

I think you have to allow him the ability to continue to practice. Do you disagree with that?

Dr. FOELS. I agree with your point. I think, again, there are systems of care that are all various levels of maturity and depths of integration across the country. Many of them will be willing to accept a more advanced payment system early on. Others——

Mr. BURGESS. And I agree with you, but it should be their choice. It should be their choice when they go into that system. And if the guy in Muleshoe can't do it, we can't exclude him because he is all they have got, correct?

Dr. FOELS. And to your earlier point, too, about the accommodation of physicians to a new system of payment, we have probably over a century of experience in the United States with a fee-for-service system, so it is something that everyone is extremely accustomed to and our systems of payment are all operationally designed around it. And we even found, in our own experience, despite our deep collaboration with our primary care community, that they were not immediately willing to transition to a new care model until we profiled them under how they would actually perform under that and we made the methodology completely transparent. But that took an additional year or two for them to be willfully accepting of the change.

Mr. BURGESS. So that is an educational endeavor.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady from North Carolina, Mrs. Ellmers, for 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman. I appreciate so much the opportunity to be participating in this subcommittee hearing on SGR reform. I think that it is something that is vital to healthcare reform into the future.

And I thank our panel for being here and giving your input as well. I certainly associate myself with many of your comments on best practices, Dr. Damberg, especially when we are talking about making improvements with science-based, real information that will actually improve our healthcare system.

That brings me, Dr. Kramer, to one of the other discussions that was just taking place. We were talking about whether there is

room or should there be room for penalties, essentially, I will call it that. And one of my big concerns is that many times physicians are placed in a position because there is a new best practice that is established, may or may not be science based, but Medicare will require that they adhere to that, and it may end up in a bad patient outcome, an increase in infection rate or something else.

In your words, how would you address that? How can we avoid that situation happening where a physician possibly may be penalized or cannot participate in an incentive program because there is some best practice that is put in place? How could we address that?

Mr. KRAMER. I would answer by saying that if we keep the focus on the patient, and the results, the outcome, the clinical outcomes to the patient and the patient's experience in those outcomes, that will address many of the underlying problems that currently exist. So, for example, rather than focussing on whether a clinical best practice was followed or a clinical guideline was followed, rigid adherence to that can sometimes lead to bad results, the inappropriate results.

Mrs. ELLMERS. Yes.

Mr. KRAMER. So rather than focussing on rigid adherence to the clinical practice guideline——

Mrs. ELLMERS. It should be patient centered. Patient outcome.

Mr. KRAMER. Patient centered. What happened to the patient? Was that best for the patient? Did it get the right results? That is what physicians are working toward, that is what drives them as individuals, and that is what we ought to be rewarding.

Mrs. ELLMERS. Thank you. I appreciate you saying that. That is my opinion as well.

Dr. Damberg, in the draft of our legislation that is definitely ongoing, we are going to be taking in so much more feedback to make sure that what we put in place is an actual working model that will work in the real world and not just in theory. In your testimony, you talk about the collaboration between CMS and establishing a process where measures can be developed between clinical specialists and correcting that performance gap area. In your opinion, how important is this relationship between CMS and medical providers in maintaining that value-based performance?

Ms. DAMBERG. So I think for this program to be successful CMS and the physicians have to work in a very close partnership, and that partnership starts with the measure development process, but it extends way beyond that to CMS trying to figure out how to support physicians regardless of what type of practice they are in, but I would say especially focused on the kinds of practice that Mr. Burgess was talking about, which are, you know, the smallish practices that may be miles away——

Mrs. ELLMERS. Right.

Ms. DAMBERG [continuing]. From big centers where they can work with other partners to develop capacity. I think that there is a lot of work that needs to go on, on the ground, to develop capacity in practices so that they can achieve the results that we want them to. And there are various entities in communities across this country who are already working with providers.

And I think that CMS should look to leverage those partnerships with community players, and I also think that CMS should look

very carefully at private commercial health plans who are also investing substantial resources to work with community providers and build capacity. And I think if they could align the deployment of those improvement resources and work in partnership, that would be a huge help to providers. And I think there are lots of incentives in place for that to happen because many of the commercial health plans participate in Medicare Advantage and are at risk financially for a quality bonus payment themselves.

Mrs. ELLMERS. Thank you. I appreciate your comments.

And I see that I have run out of time. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentlelady.

Now recognize the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I appreciate it. And I thank the panel for their testimony. I have a couple of questions.

Start with Dr. Damberg. You talk about a continuum of performance. Should we target a percentage for performance of quality measures? For example, should the average physicians meet 75 percent or 85 percent of performance measures? If the averages are above the targeted percentage, should we recalibrate the metrics every 5 years or so to adjust the metrics and increase the standard of care?

Ms. DAMBERG. So you are talking about where to set these performance thresholds?

Mr. BILIRAKIS. Sure.

Ms. DAMBERG. Yes. So there are several different ways in which you can establish benchmarks. One is to use national performance benchmarks that are already in place. If you look at the National Committee for Quality Assurance, they have many benchmarks already for ambulatory care measures.

But there are more sophisticated methods. I would call your attention to my testimony where I reference a report by a statistician named William Rogers and Dana Safran at Blue Cross Blue Shield of Massachusetts, and I am not going to go mathy on you, but they used the beta-binomial distribution to set this. And in essence, where they set the top threshold tends to remain very stable over time, and it sets up sort of the optimal performance that can be delivered safely. Because I know one of the previous questions was around, you know, are we going to not give physicians some flexibility around the care they provide? I don't think we personally want to drive everybody to 100 percent, because I think there are some reasons why patients should not get care.

Mr. BILIRAKIS. All right, thank you very much.

This is for the entire panel. Do you support quality measures tailored to specific diseases such as diabetes and Parkinson's? And if so, how do you develop quality measures for rare diseases? These are hard to diagnose diseases with small populations. If we do develop metrics for specific diseases or conditions, how do we responsibly develop measures for these conditions when research may be somewhat limited? Whoever would like to address it first.

Mr. KRAMER. We do need to develop better measures for disease conditions, both common conditions, unfortunately common conditions, such as diabetes, as well as rare conditions. I think a number of those measures already exist, or are in the process of being de-

veloped and through the endorsement process. I think the National Quality Forum has done a reasonably good job of bringing together clinicians, patients, patient-advocate groups, as well as other stakeholders to find the best measures, encourage measure developers to put those forward, and to build on what is already there so that those measures are in place and are available and the outcome results are available to clinicians for their clinical quality improvement efforts, to teams, who are often in a very good situation to manage the care for someone with chronic conditions, but also to patients so that they can identify the best providers and participate in their care.

Mr. BILIRAKIS. Anyone else?

Dr. RICH. Definitely should have measures for disease conditions. So when I was at CMS in 2008 we did an analysis of the three biggest cost buckets for Medicare populations, and depending on what decile of Medicare patient you were looking at, it was always congestive heart failure, coronary artery disease, and cancer. And you could reverse the order depending on how old the patient was. But that represented somewhere around 45 to 47 percent of the healthcare dollar that we spent at Medicare. And if you are going to create disease-specific measures you should start there, and I think that would be what Mrs. Castor would want to hear as well.

I do think that there is a team approach to taking care of people with coronary artery disease. Myself, a cardiologist, PCP, all care for these patients, the same for heart failure, and creating a robust set of measures for a disease-specific entity like that across specialties and cross into primary care.

Ms. DAMBERG. May I add one more point?

Mr. BILIRAKIS. Yes, please.

Ms. DAMBERG. I think that the other thing that I would keep in mind is, right now we have some one-off measures, so in the area of diabetes. I would encourage development of measures with an entire episode of care. So if you think of hip replacement surgery, you know, you may start in the ambulatory setting, you transition into the hospital and then you may end up in post-acute care. And so we need to look at this larger bundle of measures that hang together to cut across that continuum.

Mr. BILIRAKIS. Anyone else, does anyone disagree with the disease-related measures, or specific measures?

Dr. FOELS. If I could just reiterate a point that was made earlier, that a particular quality measure does cross disciplines. It follows the patient. And we have had some recent experience with applying diabetic measures to cardiologists who are also caring for those patients, and we know diabetes is a strong risk factor for coronary disease.

And it is important that the cardiologists are also a participant in improving diabetes care as well. It may not be an area to which they feel they should naturally be measured, but we feel as an integral part of an entire team that cares for that particular chronic condition, it would be appropriate to apply measures in that regard.

Mr. BILIRAKIS. I have one more question, Mr. Chairman.

Mr. PITTS. Go ahead.

Mr. BILIRAKIS. Just briefly. What about patients? Should patients groups have a role or input into the process when determining these measures?

Mr. KRAMER. Absolutely, yes. Patients is why we are here. We are here to take care of people who are beneficiaries of Medicare. And more broadly, if it is done right for Medicare, can help our entire healthcare system. By keeping a patient focus, finding out what is important to them in terms of their outcomes, making sure we have measures of those outcomes, and then providing rewards to physicians and care teams to achieve those outcomes, that will do what is right for the patient. If it is done right for the patients, it will work for the rest of us.

Mr. BILIRAKIS. Thank you, Mr. Chairman, I yield back.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Mr. CASSIDY. Thank you, Mr. Chairman.

First, Dr. Rich, I will just say that there is a T-surgeon, Gene Berry, that first acquainted me with your data set on quality. Very impressed with it. I just thought about it ever since. So let me compliment your society and my local doc who acquainted me with that.

Mr. Kramer, I enjoyed your remarks. If you are the guy that broke your face playing basketball, I got to tell you, man, your hair is a little gray to be up there on the court. But that said, you know. Listen, we do have to be patient focused.

Now, I will say that solutions in Washington tend to be big. Affordable care organizations are huge. And as a doc who is thinking that oftentimes you are going to have a four- or five-person practice in which, unless you figure out how to align the patient with the interest of that four- or five-person practice, you are not really going to serve those patients best.

Then, Dr. Foels, I was impressed that your organization seems to have been somewhat entrepreneurial adapting. My thinking is that we need something, we call it in this legislation an alternative payment model, where you take that entrepreneurial group of docs, whoever they might be, and you allow them to come up with a different model that none of us have thought about, but in their circumstances works for their patients and for their practice better than anything else, and that CMS, frankly, would be required to approve unless they could show why they should not, as long as the folks doing the model were willing to take the risk. Any thoughts on that?

Dr. FOELS. Yes, I would concur. Our participation with other like plans, regional, not-for-profit insurers that also have deeply collaborative efforts with the community, are moving toward—and we do that work through the Alliance of Community Health Plans and share a lot of excellent work across disciplines. But what we have found, although we work toward a common goal, we have taken different approaches, and many of those approaches have all been equally successful.

Mr. CASSIDY. Yes.

Dr. FOELS. But there are significant and slight differences among them that we need to recognize are regional.

Mr. CASSIDY. I totally get that. If your final outcome is giving access to high-quality medicine at an affordable cost, there may be different goals depending upon the practice and upon the patients. So, one, compliments you all for doing so. And, two, I hope this legislation enshrines that.

Dr. Damberg, one thing—I could have asked this of many of you—one thing that has been occurring to me though, I am liver doctor who takes of cirrhotics, I am always struck that primary care doesn't want to touch that cirrhotic once they have cirrhosis because it is such a fragile patient. So what do you think, I have tried to coin a phrase called, not primary care physician, but principal care physician. If you take someone like a nephrologist caring for the renal failure patient, she is really the principal care physician even though she is not, quote, the "primary care physician." Cancer doctors. Patients with heart failure. And really trying to align a payment model to recognize that once someone has CHF no one touches that patient unless the cardiologist first blesses the touching. Does that make sense? I see Dr. Rich nodding his head.

Do you all have any thoughts on this principal care concept? Dr. Damberg, I started it with you.

Ms. DAMBERG. So let me ask you a question back.

Mr. CASSIDY. Yes.

Ms. DAMBERG. Are you considering this person—hopefully this is not too much of a value-laden term—almost like a gatekeeper for that person's care in terms of coordinating the management?

Mr. CASSIDY. The principal care physician would then take on the responsibilities currently ascribed to the primary care. It just recognizes that if somebody has cirrhosis——

Ms. DAMBERG. Something very complex.

Mr. CASSIDY [continuing]. They become the one who becomes the coordinator, they become the hub off which everyone else radiates.

Ms. DAMBERG. Yes. No, I actually think there is potentially some value in that. I think we are looking to primary care, and particularly medical homes, to coordinate a lot of care, but there may be care that is sort of outside the purview of primary care where I think it could be useful to set up someone who would be——

Mr. CASSIDY. I think if you look at Medical Advantage's special needs programs, most of those folks are probably not managed by primary care in an urban setting. They are managed by some gal, some guy who happens to be a specialist in their condition.

Mr. Kramer, from the business perspective any thoughts you have?

Mr. KRAMER. Yes, I think this makes sense. I think a term that we actually use, informally, is accountable care physician. I think it gets at the same thing. There is a physician that may be a specialist, may be a primary care physician, but for certain kinds of patients it would make sense for the specialist to be the accountable physician for the care that is delivered to that patient working with his or her team.

Mr. CASSIDY. So if there was a payment model in which—an alternative payment model in which a group of gastroenterologists would take on the risk bearing of a group of cirrhotics pre-transplant patients, they would then become the accountable physician, if you will, at risk, and then coordinating the care, being the pri-

mary care doc for a group of fragile patients. You all are nodding your head yes.

Mr. KRAMER. And rewarded for the quality and the total resources used on behalf of those patients.

Mr. CASSIDY. Yes. Well, thank you for your input.

I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Dr. Christensen has a unanimous consent request.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. Yes, I ask unanimous consent to insert into the hearing record a paper from the National Senior Citizens Law Center and a letter from AFSCME, both on balanced billing.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the record.]

Mrs. CHRISTENSEN. Thank you.

Mr. PITTS. All right, that completes our first round. We will do one follow-up per side.

Dr. Burgess, 5 minutes for follow-up.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Damberg, let me just ask you, can you discuss at all to the extent that providers are dealing with measure reporting, quality improvements, and financial arrangements to link quality payment, is this something that is ongoing that you have observed?

Ms. DAMBERG. So, yes, indeed. I would say the majority of physicians, at least in primary care in this country, have ongoing measurement reporting of some sort and payment tied to performance. In the clinical specialty areas, it tends to be tied to, again, the set of measures that have been identified, whether that is care for diabetes or cardiac-type measures. In some cases those physicians' payments are also tied to performance currently.

Mr. BURGESS. Just specifically in the primary care world, so those measures have already been developed. Are we going to——

Ms. DAMBERG. They have been developed. They are in widespread use. Many of the pay-for-performance programs in the private sector have actually been in operation since about 2003. So it is a long period of time.

Mr. BURGESS. But do you think it is possibly to integrate them into whatever happens in the Medicare world?

Ms. DAMBERG. Absolutely, and I think the CMS should be looking to align the measures. So the ambulatory physicians are already accountable through their health plans for the Medicare Advantage measures. Those measures represent a really strong starting point, and that you are basically not asking those physicians to do something different.

Mr. BURGESS. Why do you suspect that there has not been wider involvement of that or wider institutionalization of that?

Ms. DAMBERG. Of the fee-for-service side of Medicare?

Mr. BURGESS. Well, on the Medicare Advantage side where it does seem like you have got happy providers, you have got happy patients, the cost is less. Why is there not wider adoption of that within the Medicare system itself? Because there does seem to be some resistance to the Medicare Advantage model.

Ms. DAMBERG. Well, I think if you look at the physician value-based payment modifier program, that is essentially trying to move

down that path with physicians across the board within Medicare. So even absent the SGR, that work is in process. And again, I think it is going to be the primary care physicians who are first out of the gate on that because of the existence of measures.

Mr. BURGESS. Yes, in many ways, if the SGR could not be reformed, if we didn't have the favorable CBO score winds at our back, it has always seemed to me that Medicare Advantage may offer a way forward on whatever happens with SGR down the road. Is that a fair observation?

Ms. DAMBERG. I think possibly. I do think Medicare Advantage has been a leader, and it is not surprising because much of the measure, the performance measurement work that has gone on historically has been on the managed care side even in the commercial sector. But even private payers recognized they were not getting value out of the providers on the fee-for-service side, and so they shifted those programs into play in fee for service.

Mr. BURGESS. Very well. Let me just ask a question, generally, and anyone can feel free to answer or not. But should the quality improvements undertaken by a physician or a practice, should the quality improvements themselves be included as a component of whatever performance-based payment is adopted? If you have a doctor who realizes that at the start of the year they are not performing as well as they might, and improves their performance, can that be taken into account, the fact that they have improved their performance?

Dr. RICH. Yes, absolutely, I think. And if you look at the hospital value-based purchasing program, it is written into that. So you can have targets, we can have absolute targets, or you can have a quality improvement incentive. So you can't take a low performer and expect them to get to 90th percentile in 1 year, so you ought to be able to reward them to go from the 10th to the 30th percentile as an incentive to keep trying.

Mr. BURGESS. And just as a practical matter, you think that is something that should be included in whatever follows on from SGR?

Dr. RICH. Yes, absolutely.

Mr. BURGESS. Mr. Chairman, I shouldn't do this, but I actually want to recognize Dr. John O'Shea, who is here in the audience. He has had a big hand in helping us get to where we are today, and we were sorry to lose him, but at the same time, we are grateful to have had the association in the past couple of years where he has been so instrumental in getting this tough problem moved along. So I will yield back my time.

Mr. PITTS. The chair completely agrees with that statement. Thank you very much.

The chair recognizes Dr. Christensen for 5 minutes for a follow-up.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman, and I don't think I will take all of 5 minutes. But this is a little bit of a different question. But we have not been able to fix malpractice, do malpractice reform. And I wonder if the panelists think that the reforms that we are talking about, and comparative effectiveness research and some of the other provisions could lower the risk of lawsuits and perhaps even the cost of liability insurance?

Dr. RICH. I do. I think if you get providers to participate in clinical registries and quality improvement programs, I think that would be recognized, not only by insurance companies to lower your cost, but just in general I think it would help the healthcare system to reduce complications and reduce lawsuits.

Mrs. CHRISTENSEN. OK. Well, a lot of what we are talking about in terms of reform relies a lot on primary care physicians. Do you have any concerns that we are not producing enough family physicians, or primary care physicians, or do you think we are on target for where we need to be with primary care physicians? And if not, what do we do until we get there?

Dr. FOELS. If I may comment, I have very deep concerns about the adequacy of the primary care physician workforce. When, again, one steps back and thinks about a viable, vital primary care team, it takes the discussion to a little different level above and beyond recruiting interested residents in a primary care professional track. I think there is considerable work that has yet to be realized in making this an attractive specialty.

I think the reengineering of primary care alone, and the ease of work through efficient systems of care that will evolve, which I hope will evolve over very short periods of time in primary care, will again make this a very attractive discipline. And to my early earlier comment, I think we are still underutilizing the valuable talents of nursing staff to provide care, and a reform payment system would be a valuable contribution toward moving in that direction of, again, designing a viable, vital primary care team.

Mrs. CHRISTENSEN. Thank you.

Anyone else?

Ms. DAMBERG. I also share that concern, and I think one of the issues that hasn't been addressed here, but I know is being talked about is reweighting the payments such that, you know, if we are going to talk about incentives, right now I think the incentives in the system in terms of the payment structure really go against going into primary care as a specialty. So I think we need to look at ways to correct some of those imbalances in payments.

Mrs. CHRISTENSEN. Thank you.

Mr. Chairman, I don't have any other questions, so I will yield back my time.

Mr. PITTS. All right. Chair thanks the gentlelady.

That completes our questioning. I am sure some members will have additional questions. We will submit those to you in writing. We ask that you please respond promptly.

And as I stated in the opening statement, we are seeking substantive feedback on ways to complete this legislative draft. I would encourage all interested parties to submit their comments to the committee by next week.

I remind the members, they have 10 business days to submit questions for the record, so they should submit their questions by the close of business, Wednesday, June 19th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:17 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. RALPH M. HALL

Mr. Chairman, I would like to commend you for all the hard work that you have done, including the coordination with the Ways and Means Committee, to bring us to this point where we can have a meaningful hearing on the Sustainable Growth Rate issue. This is a complex issue, and the stakeholders are many, but it is an issue that we must resolve before the end of the year.

As we move forward in this process, we are going to need to resolve not just the important details of the "doc fix" issue, but also the need for spending offsets to assure that the legislation does not have a significant impact on our budget. In that regard, I would like to suggest one budget savings that might be included as an offset in this bill. It is the language of H.R.1076, which is legislation that I have introduced along with Mr. Olson and others. Our bill would assist political subdivision health care pools by giving employees in these pools the same premium tax credits and cost sharing assistance that will be available in the new health care exchanges. But the employees in these health care pools would only get the assistance on one condition—if they can show that doing so would save the federal government money.

Most states have one or more of these health care pools. In Texas, we have one for small towns and one for county employees. In our case, the health care plans offered in these pools are expected to be less expensive that those that will be available in the exchanges. So keeping these employees where they are—in less expensive plans that provide the same quality of coverage—means that the value of the tax credit will be less, and the impact on the federal budget will be less.

Mr. Brady, who Chairs the Ways and Means Health Subcommittee, has asked CBO for a score of this language. When we get that score and find out how much budget savings the language will generate, I hope we can consider including it in this bill as an offset.

I look forward to working closely with the Chairman on this idea.

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

I would like to thank the Chairman for holding this hearing. Today's discussion will focus on some of the critical questions the Committee must address as we look to finally solve the problem of the broken Medicare Sustainable Growth Rate formula which has been plaguing Medicare for too long.

It's clear from this and others hearings we've held on the topic that there is broad consensus on the need to fix this problem, and even consensus on which direction we need to move and the broader policy goals that will get us there. The question is how to get there, and, like all things, the devil is in the details.

The Affordable Care Act provided a good foundation and charted the right path forward. Through its support for new delivery and payment models like accountable care organizations, bundled payments, medical homes, and initiatives that boost primary care—it moves us in the direction of improved quality, efficiency, and value.

I am pleased that the Chairman has reached out to us to try to move forward in a bipartisan fashion. Our discussions so far have been largely fruitful. The early-stage, draft legislative language released by the Chairmen adheres to these shared policy goals on which we've reached broad agreement.

However, thoughtfully crafting legislative language that effectuates these goals is a challenge—one that we are doggedly attacking in collaboration. All policies have consequences, some are apparent and some are unforeseen (as we've painfully witnessed with SGR). And this is precisely why this hearing is important, but also why we need to continue to refine, vet and develop the concepts that will move us from a volume based system to a value based system of physician payments.

With that in mind, there are three key challenges that I'm interested in hearing about today: (1) Recognizing that fee for service medicine will remain a part of our health system, how do we best deal with incentives that drive volume at the expense of value; (2) How do we get physicians to accelerate the move to new delivery system models that can improve care without compromising cost; and (3) How do we make sure we don't throw the baby out with the bathwater—for example, CMS has been working to build a solid array of quality measurement programs, and has been working to develop new models—we don't want to be starting from scratch.

I am glad to see the Chairman continuing to move forward on this issue early in this Congress, and we look forward to continuing to refine these policies through a bi-partisan approach.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you Chairman Pitts. I commend you for your continued commitment to addressing Medicare's flawed sustainable growth rate (SGR) payment model. Over the past few weeks, our staff have come together and had meaningful conversations on this topic. While I have not signed on to the discussion draft before us today, I can assure you that the Democratic staff are still working to find a permanent fix to the SGR, and look forward to continuing to work with the Republican staff to do so.

As I have said before, fixing the SGR system is one of my top priorities. For too long, Congress has passed short-term fixes to override arbitrary cuts to physician payments generated by the SGR formula. It is not fair for physicians or their beneficiaries to continually be faced with uncertainty, and these short-term fixes are not financially sustainable. It is time for us to come together in a bipartisan manner to repeal and replace the SGR formula.

We can all agree that the current SGR system is unstable, unreliable, and unfair. I also believe that, broadly, we all have the same goals for what an SGR fix will look like. However, getting these goals into legislative language is a complicated task. With so many moving parts, it is critical that we fully understand the consequences of each provision and gather views from all stakeholders. This is not a process that should be rushed. Let's work together to make sure we get this right.

A new payment model should focus less on volume of services provided, and instead rely upon improved outcomes, quality, safety, and efficiency. By focusing on these goals, we can improve patient experience and reduce the growth in health care spending simultaneously. While there may still be a need for a fee-for-service option within the future payment system, a new system must better encourage coordinated care while incentivizing prevention and wellness within the patient.

The Affordable Care Act established a number of new provider arrangements under Medicare, such as new Accountable Care Organizations (ACOs), which encourage cooperation and coordination among providers, hospitals, and suppliers, so that patients receive high-quality, efficient, and cost-effective care. As we work to replace the SGR, we should look to these programs as a starting point for developing a payment model that moves away from traditional fee-for-service and toward a system that focuses on quality and outcomes.

I look forward to hearing from our witnesses today about their perspectives on the best way to prioritize quality and address the flawed SGR, and I look forward to continuing to work with my colleagues and all stakeholders to finally find a permanent fix.

Thank you.

NSCLC
National Senior Citizens Law Center
PROTECTING THE RIGHTS OF LOW-INCOME OLDER ADULTS

Balance Billing Prohibition-A Crucial Protection

The prohibition against balancing billing is a crucial protection. Without it, low income Medicare beneficiaries will be cut off from access to their Medicare benefit.

Individuals who receive Medicare and Medicaid services, known as dual eligibles, cannot afford Medicare's 20% co-pay for services. Dual eligibles are universally acknowledged to be an extremely vulnerable and medically fragile group. 85% of have incomes below 150% of the federal poverty line.[1] In general, the Medicare program covers 80% of Medicare approved charges, and Medicare beneficiaries are required to pay the remaining 20% of the Medicare-approved fee-for-the service.[2] Because Medicaid payment rates are very low and state Medicaid programs are only required to make copayments up to the Medicaid rate, Medicaid usually fails to pay the difference.[3]

With balance billing protections, these individuals maintain access to the Medicare benefits that they or their spouse has earned. They can continue to see Medicare providers knowing that they will not be subject to bills they cannot pay and ultimately collection proceedings. Without balance billing protection, dual eligible individuals are afraid to see Medicare providers and amass medical debt that they cannot pay.

Balance billing is a bedrock protection. Without it, a low income Medicare beneficiary is effectively cut off from access to their Medicare benefit.

The balance billing protection as currently defined is inadequate because many Medicare providers still are unwilling to accept patients without full Medicare reimbursement. One positive development is the Section 1202 Affordable Care Act provision that sets Medicaid rates for primary care at the same level as Medicare.[4] The provision is important as it has the effect of giving primary care providers who serve dual eligibles the full Medicare payment. But that ACA provision sunsets in two years and only applies to primary care. A better long-term fix is needed to ensure continued access to needed care. Until then, the balance billing prohibition is a crucial protection.

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[1] Jacobson, G., Neuman T., & Damico, A., (April 2012). Medicare's Role for Dual Eligible Individuals, *Kaiser Family Foundation Medicare Policy*, 2. Retrieved from www.kff.org/medicaid/upload/2186_06.pdf.
[2] Center for Medicare Advocacy, Medicare Part B. Retrieved from http://www.medicareadvocacy.org/medicare-info/medicare-part-b.
[3] Burke, G., & Prindiville, K., (November 2011). Improving the Qualified Medicare Benefit Program For Dual Eligibles, *National Senior Citizens Law Center*, 6. Retrieved from www.nsclc.org/wp-content/uploads/2011/11/Improving-QMB-for-Duals-Brief.pdf.
[4] Public Law 111-152, "Health Care and Education Reconciliation Act of 2010."

Alliance of Specialty Medicine

Testimony for the Record
Before the House Energy and Commerce Committee
Subcommittee on Health
Hearing Entitled
"Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System"

Wednesday, June 5, 2013

Chairman Pitts, Ranking Member Pallone, members of the Committee, and honored guests, the Alliance of Specialty Medicine (the Alliance) would like to thank the House Energy and Commerce Committee for the opportunity to provide feedback on its May 28, 2013 draft legislation. The Alliance strongly supports your intent to repeal Medicare's sustainable growth rate (SGR) formula and to replace it with a payment system that places greater emphasis on quality and efficiency. The Alliance is a coalition of medical specialty societies representing more than 100,000 physicians and surgeons dedicated to the development of sound federal healthcare policy that fosters patient access to the highest quality specialty care.

Our written testimony will not only detail some outstanding questions and concerns regarding the Fee Schedule Provider Competency Update Incentive Program, which the Committee proposes as Phase 2 of its Medicare payment reform proposal, but also briefly outline our suggestions and principles for SGR reform. We would be happy to discuss our concerns and principles with you, as well as any other questions you may have going forward.

The Alliance again thanks the Committee for the opportunity to provide feedback and looks forward to working with you to refine this legislation and work toward a permanent and meaningful solution to the flawed physician payment system.

Many of the Alliance's specialty society member organizations currently have, or are in the process of developing, physician-driven quality improvement initiatives, including the development of clinically-relevant performance measures based on evidence-based guidelines, the management of clinical data registries and enhanced maintenance of certification (MOC) programs. While more work remains, these physician-driven initiatives often result in a more accurate snapshot of specialty care and produce more relevant feedback to specialty physicians than current federal initiatives, which lack sufficient flexibility to accommodate different specialties and care settings, rely on measures that are inadequately risk adjusted and not necessarily linked to better patient outcomes, and divert significant resources away from direct patient care due to administrative complexities.

Taking these experiences into account, the Alliance appreciates the opportunity to share with the Committee the following outstanding questions and to offer potential solutions regarding the Fee Schedule Provider Competency Update Incentive Program, which the Committee proposes as Phase 2 of its Medicare payment reform proposal:

- **The manner in which the update adjustment would take into account quality assessments is a significant issue that remains undefined.** It is critical that the Committee clarify this point and

then seek public feedback on its recommendation. Quality programs must rely on positive incentives rather than penalties to encourage participation and trust in the system and to ensure that physicians can continue to invest in quality improvement infrastructure and provide patients with the access to care that they deserve. Physicians should not have to start out from a negative and then have to "claw" their way back up to a payment rate that still may not even cover the cost of practice.

- **The manner in which the base payment will be determined and updated is another critical issue that is undefined**. The Alliance supports the use of the Medicare Economic Index (MEI), which is more predictable than the SGR or other mechanisms, and more accurately captures the true costs of providing physician services.

- **Any system that replaces the SGR should incentivize participation in quality programs rather than reward or punish physicians based on flawed ranking systems.** Publicly available rankings provide little value in terms of educating the public or promoting quality care unless they reflect substantial and verifiable differences in quality. Unfortunately, the methodologies to accurately make these assessments remain flawed. Much work still needs to be done to ensure risk adjustment and attribution methods are fair, statistically valid, result in unambiguous comparisons, and do not lead to cherry picking of less risky patients or otherwise impede patient access to care. As such, we urge the Committee to instead consider a system that recognizes and rewards continuous quality improvement rather than one that pits physicians against each another. Evidence demonstrates that quality is improved when physicians are provided confidential feedback in a non-punitive environment. For educational and improvement purposes, confidential feedback reports may include information regarding how a particular physician or physician group compares to national or regional benchmarks, however, **we strongly oppose head-to-head comparisons**. Additionally, the methods used to make any comparisons must be transparent and clearly described.

- **The Alliance strongly believes that, if updates are to be based on quality evaluated through a newly proposed structure, existing programs and associated penalties need to be repealed and replaced with programs that more accurately and meaningfully reflect the care provided by a range of physician practice types as provided by the respective societies.** Our current understanding of the May 28th language suggests that the competency updates would piggyback on existing federal quality programs, such as the Physician Quality Reporting System (PQRS) and Electronic Health Record (EHR) Incentive Program. In particular, language giving the Secretary the authority to "coordinate the selection of quality measures…with existing measures and requirements, such as the development of the Physician Compare Website" and "with measures in use under other provisions of section 1848" leads us to believe that existing programs would remain in place and that the competency update would create additional responsibilities for physicians that could further erode patient-centered care. The Alliance has serious concerns about expanding upon what are already administratively burdensome programs that rely on metrics of questionable value and include future penalties that, when combined, could reduce physician's payments by almost ten percent. Similarly, in the section discussing methods for assessing performance, the Secretary is given the authority to incorporate methods from comparable physician quality incentive programs. This is concerning because the methods employed under current programs are seriously flawed, have undergone little testing, and often result in inaccurate assessments, which breeds frustration and mistrust among physicians. **As such, we urge the Committee to include language to ensure that the PQRS, EHR Incentive Program, and the Physician Value-Based Payment Modifier (VBM)**

Program are repealed and replaced by any new SGR replacement programs incorporating physician quality.

- **The proposed quality measure development process remains vague.** While we are pleased that the quality measure development process would rely on best clinical practices, and that the Secretary may consider measures developed by medial specialty organizations, there is little detail about the standards that measure developers would be held to when translating evidence into measures of accountability. Current standards, such as those used by the National Quality Forum (NQF), are often too resource intensive to justify specialty society investment, too lengthy to allow for timely implementation, and too rigorous to accommodate the testing of more innovative approaches to quality improvement, such as reporting to a clinical data registry. We encourage the Committee to preserve specific current minimum standards -- such as transparency, minimum sample sizes, basic auditing and data integrity/validation criteria, and ongoing evaluations of the effectiveness and feasibility of measures -- without being overly prescriptive and limiting the development of more innovative measures or approaches to quality improvement.

  At the same time, there is no need to reinvent the wheel and waste resources. In cases where a specialty has already invested in the NQF process and NQF-endorsed measures already exist, those measures should be used to the extent that they are supported by the relevant medical specialty society.

  We also question who would meet the definition of "other relevant stakeholders" eligible to develop measures. Measure development must be led by relevant clinical experts, who are most familiar with the clinical literature and best equipped to decide on the most appropriate strategies for treating specific diagnoses, procedures, and patient populations. While multi-disciplinary input is important, it is critical that this process be driven only by clinicians with relevant clinical and topical knowledge.

- **The language requiring the Secretary to select a "sufficient number" of quality measures for potential inclusion in each peer cohort is vague and inadequately reflects measure intensity and relevance.** In terms of the provisional core measure set, it is unclear how the Secretary will ensure that each peer cohort is being held to a similar level of accountability in terms of range of measures, measure complexity, and reporting burden. While there is language giving the Secretary authority to assign different scoring weights based on the type or category of quality measure, this seems to relate more to the calculation of the composite score for individual physicians within a peer cohort rather than differences between measure sets across peer cohorts. For example, a single measure evaluating whether a specialist reported regularly to a clinical outcomes registry may require heavy investments in data collection tools and the collection of more numerous and more robust data points, including outcomes, than individual process of care measures which often require little more than the checking of a box to indicate that things such as smoking cessation counseling were offered. Therefore, we urge you to adopt mechanisms to ensure that all peer cohorts are held to a similar level of accountability even if their measures differ in number, type or focus.

- **The requirement to develop core competencies appears unnecessary and duplicative of current requirements of the certifying boards.** We do not fully understand the rationale for including yet another layer of unnecessary regulatory requirements. The medical profession already fulfills a

series of requirements aimed at ensuring compliance with various core competencies. This starts during a physician's medical residency training, with the requirements set forth by the Accreditation Council for Graduate Medical Education (ACGME) and the individual specialty Residency Review Committees (RRCs), and continues with initial board certification and maintenance of certification, pursuant to the requirements of the American Board of Medical Specialties (ABMS) boards. We believe that the process for developing meaningful quality measures and other quality improvement programs can move forward without creating the additional process of defining core competency categories.

- **The timeline for solicitation of public quality measure input remains undefined.** We urge you to legislatively require that the public comment period related to quality measures be open for at least 90 days and that the final response include a discussion regarding all of the comments received, similar to the current regulatory process.

- **The timeline for finalizing measure sets remains undefined.** Measures should be finalized at least one year before the first day of a performance period. Similarly, the Secretary should provide confidential feedback reports to physicians, including new fee schedule providers, for at least one year before holding them accountable for performance.

- **It is unclear how the Secretary will ensure widespread publication of core measure sets in specialty-appropriate peer-reviewed journals should a journal refuse to publish such information.** Most peer-reviewed journals have independent editorial processes and medical organizations, therefore, have no control over what gets published in these journals. Thus, we urge you to define alternative mechanisms that may be used to ensure that physicians who will be held accountable by these core measures are appropriately informed of the programmatic requirements. The Secretary and local Medicare carriers should be responsible for providing this basic information. Certainly, the specialty society members of the Alliance are also willing to use our available communication tools to educate physicians about applicable quality measures, processes and programs that would qualify for the quality portion of their payment.

In addition to the specific questions outlined above regarding the May 28th proposal, the Alliance believes that the following elements are critical to any physician payment reform proposal and urges the Committee to embrace the following principles:

- Repeal of the SGR, followed by a minimum 5-year period of stability in Medicare physician payment;
- Positive financial incentives for higher quality care rather than penalties and withholds;
- Physician-led quality improvement that allows the medical profession and medical specialties to determine the most appropriate and clinically relevant quality improvement metrics and strategies for use in future quality initiatives;
- Flexible criteria that allow physician participation and engagement in delivery and payment models that are meaningful to their practices and patient populations, including FFS;
- Legal protections for physicians who follow clinical practice guidelines and quality improvement program requirements;
- Repeal of the Independent Payment Advisory Board (IPAB); and,
- Allowing for voluntary private contracting between physicians and Medicare beneficiaries.

Finally, in the attached appendix, the Alliance has outlined the extent to which a majority of its member organizations are engaged in quality improvement activities, including participation in national multi-stakeholder coalitions; engagement in public and private payer quality recognition programs; and the development of quality measures, health information technology (HIT) products, and clinical data registries.

Thank you again for taking into consideration our written comments.

Alliance of Specialty Medicine

Sound Policy. Quality Care.

The Alliance of Specialty Medicine, a coalition of 13 national medical specialty societies representing approximately 100,000 physicians and surgeons, appreciates the opportunity to provide Members of Congress and their staff with a snapshot of specialty society quality improvement activities. Specialty societies are engaged in a variety of efforts to improve both quality and efficiency in health care and have developed robust infrastructures to support specialist engagement in those activities. Through this work, specialty medicine has found that there is no "one-size-fits-all" approach to raising the bar on quality and that the optimal model will depend on the clinical context. As such, the Alliance firmly believes that the long-term potential to close the gap on quality and achieve better value in health care lies in the ability to accommodate multiple aligned quality improvement strategies. We urge Congress and public and private payers to support flexible approaches to quality improvement, which recognize activities that are clinically relevant to specific physician practices and meaningful to individual patients, rather than any singular approach.

Below we outline the extent to which a majority of Alliance member organizations are engaged in quality improvement activities, including participation in national multi-stakeholder coalitions; engagement in public and private payer quality recognition programs; and the development of quality measures, health information technology (HIT) products, and clinical data registries.

American Academy of Facial Plastic and Reconstructive Surgery

- Exploring the development of a clinical data registry
- Few quality measures are available for AAFPRS members in existing quality programs
- Implemented an educational portal to facilitate lifelong learning, including CME tracking, MOC and clinical research

American Association of Neurological Surgeons/Congress of Neurological Surgeons

- Established the National Neurosurgical Quality Outcomes Database (N^2QOD)
- Engaged in enhanced MOC activities
- Regularly produce, review and endorse evidence-based clinical practice guidelines
- Developed the Self-Assessment in Neurological Surgery (SANS)
- Participates in the ACR Appropriateness Criteria program for diagnostic imaging
- Promoting development of episode-of-care payments for two common neurosurgical conditions
- Several quality measures are available for neurosurgeons in existing quality programs, but they are not meaningful indicators of quality
- Exploring opportunities to collaborate with EHR vendors
- Members of the NQF, AMA PCPI, SQA, and PEHRC

American College of Mohs Surgery

- Exploring the development of a clinical data registry
- Collaborated on the development of Appropriate Use Criteria (AUC) for Mohs Surgery
- Few quality measures are available for ACMS members in existing quality programs
- Members of the NQF and AMA PCPI

American Gastroenterological Association

- Launched the AGA Digestive Health Outcomes Registry, which is integrated into gGastrov4, a certified EHR technology
- Developed Practice Improvement Modules (PIMs) for Procedural Sedation/Patient Safety, which is now included as part of the ABIM Approved Quality Improvement (AQI) Pathway
- Launched the Bridges to Excellence IBD Care Recognition program through the Health Care Incentives Improvement Institute (HCI3)

- Participating in the ABIM Foundation's Choosing Wisely Campaign
- Developed a bundled payment model for screening colonoscopy
- Several quality measures are available for AANS/CNS members in existing quality programs
- Members of the NQF, AMA PCPI, AQA Alliance, and PEHRC

American Society of Cataract and Refractive Surgery

- Participating in the development of a clinical data registry with the American Academy of Ophthalmology and other ophthalmic organizations
- Established the Integrated Eye Care Delivery Model, which serves as a medical "eye care" home
- Many quality measures, including outcomes measures for all of the major eye care conditions, are available for ACSRS members in existing quality programs
- Members of the AMA PCPI and IHE Eye Care

American Society of Echocardiography

- Exploring the development of a clinical data registry
- Developed Appropriate Use Criteria (AUC), in collaboration with other imaging medical societies and subspecialty societies, for a variety of imaging modalities effort to guide physicians in determining a rational, quality approach to the use of diagnostic imaging
- Participating in the Image Gently Campaign
- Participating in the ABIM Foundation's Choosing Wisely Campaign
- Several quality measures are available for ASE members in existing quality programs
- Members of the AMA PCPI, IHE Cardiology and DICOM

American Society of Plastic Surgeons

- Launched the Tracking Operations and Outcomes for Plastic Surgeons (TOPS) clinical data registry, and a PQRS Registry with CECity
- Engaged in MOC activities
- Collaborated with EHR vendors on HIT solutions for plastic surgeons
- Several quality measures are available for ASPS members in existing quality programs
- Members of the AMA PCPI and SQA

American Urological Association

- Launched a PQRS Registry with CECity and developing a clinical data registry
- Participating in the AMA's NQRN and the National Registry Coalition
- Participating in the ABIM's Choosing Wisely Campaign
- Several quality measures are available for AUA members in existing quality programs
- Exploring opportunities to collaborate with EHR vendors
- Members of the NQF, AMA PCPI, SQA and PEHRC

North American Spine Society

- Developing a clinical data registry
- Participation in the ABIM's Choosing Wisely Campaign
- Development of clinical guidelines and appropriateness criteria for spine
- Several quality measures are available for NASS members in existing quality programs
- Members of the AMA PCPI

Society of Cardiovascular Angiography and Interventions

- SCAI members participate in the NCDR clinical data registry
- Engaged in MOC activities
- Several quality measures are available for SCAI members in existing quality programs
- Members of the NQF and IHE Cardiology

ACRONYM KEY

ABIM – American Board of Internal Medicine
AMA PCPI – American Medical Association Physician Consortium for Performance Improvement
DICOM – Digital Imaging and Communications in Medicine
EHR – Electronic Health Records
HIT – Health Information Technology
IHE – Integrating the Healthcare Enterprise
MOC – Maintenance of Certification
NQF – National Quality Forum
AMA NQRN – American Medical Association National Quality Registry Network
PEHRC – Physician EHR Coalition
SQA – Surgical Quality Alliance

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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June 26, 2013

Dr. Cheryl L. Damberg
Senior Policy Researcher and Professor
Pardee RAND Graduate School
1776 Main Street
Santa Monica, CA 90401-3208

Dear Dr. Damberg:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 5, 2013, to testify at the hearing entitled "Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Friday, July 12, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

TESTIMONY

Physician Payment Reform

Designing a Performance-based Incentive Program

Addendum

Cheryl L. Damberg

RAND Office of External Affairs

CT-389/1

July 2013

Document submitted on July 12, 2013 as an addendum to testimony presented before the House Energy and Commerce Committee, Subcommittee on Health on June 5, 2013

Published 2013 by the RAND Corporation
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The RAND Corporation

Physician Payment Reform:
Designing a Performance-based Incentive Program
Addendum[2]

Before the Committee on Energy and Commerce
Subcommittee on Health
House of Representatives

July 12, 2013

The subsequent questions and answers found in this document were received from the Committee for additional information following the hearing on June 5, 2013 and were submitted for the record.

The Honorable Joseph R. Pitts:

1. **In your testimony, you state that "value-based payment programs seek to incentivize providers to innovate and redesign care delivery to drive improvements in quality and how resources are used (i.e. costs)". Do you believe that payment reforms like those envisioned in the committee legislative framework hold the potential to improve the quality and value of the Medicare program for seniors?**

Since the committee's framework has specifics yet to be filled in, it is difficult to accurately predict what the effects would be. The ability to improve quality and value in the Medicare program is contingent on the value-based payment program design, which will affect how physicians and the organizations in which they work respond. So yes, I believe that with the appropriate design, incentivizing physicians to deliver the right care will help to improve the quality and value of the Medicare program for seniors. The design of the program is critical in encouraging providers to innovate and redesign care delivery. For example, in the context of the emerging Accountable Care Organizations (ACOs), the providers (physicians and hospitals) in the ACOs are collaborating and working across their individual care-setting silos on care redesign to ensure they hit the cost and quality targets for which they are now jointly accountable. The joint accountability is a key design feature. In this case, incentives are aligned across the system to ensure that providers are working to achieve the same goals--better quality and better value for the patient and the payer. This is a sea change from what has historically been occurring in the delivery of

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[2] This testimony is available for free download at http://www.rand.org/pubs/testimonies/CT389z1.html.

health care, where heretofore each physician and hospital has been working independently without regard to the actions of others, often resulting in duplication of services with little or no value to patients and patients falling through the cracks as they transition between providers and health care settings. These have cost and quality implications for patients, and for the government as the payer of care. In the context of SGR reform, holding physicians accountable for their performance can lead to improvements in care and overall value. Ensuring that the measures for which providers are financially accountable are evidence-based (so that providers agree they are important because studies show taking the action leads to benefit for the patient) or focus on important patient outcomes can lead to improvements in the reliability of the care patients receive and the outcomes they experience. In a recent Expert Panel on value-based purchasing (comprised of providers, payers and researchers) that I conducted for the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services, there was consensus among the experts that we should hold physicians and hospitals accountable for the outcomes we seek and that if we do, the providers would determine what actions to take (through innovation, coordination with health and social service community providers, and care redesign) to work towards achieving those outcomes, as multiple factors besides selected processes of care may influence them. Outcome measures should include both clinical and cost (measures of overuse of services) dimensions; including costs as part of what is measured and how providers are paid is critical to ensure that services are efficiently delivered. Physicians who make decisions about treatments have a central role to play in helping to ensure that health care remains affordable for patients and other entities (employers, government agencies) that pay for care.

While my comments focused on embedding performance-based incentives into the existing FFS payment model as part of the SGR reform, I would underscore for the subcommittee that more wholesale payment reform is required to move us beyond the current payment structure that incentivizes physicians to do more, often with little to no clinical benefit or that may even harm the patient. Transitioning physicians to performance-based pay (in lieu of the SGR) is the first step in a larger journey towards restructuring the underlying incentives in health care in order to deliver value. The incentive structures I discussed at the subcommittee's hearing on June 5 work at the margin rather than on the base payment. While physicians over the next 3-5 years gain greater comfort with measurement and incentives within the FFS structure, I would encourage Congress to support CMS and local communities to conduct more wholesale payment reform innovations across the United States, allowing payers, physicians, and other stakeholders in communities to innovate to advance the delivery of high value health care. Experiments such as the Blue Cross Blue Shield of Massachusetts Alternative Quality Contract, which sets a global payment for care and provides performance-based incentives, represent an important step in this direction.

2. **Your testimony outlines the need for "meaningful" payments to help drive value-based payments. You also mention that incentives on the order of 5 or 10% would be needed to**

drive meaningful improvement in the system. However, right now the financing of the Medicare program is weak and I don't envision that Congress could pass a 10% increase for providers (or even a 5% increase) during these times. Are there other ways to structure incentive payments without having to rely on a 5 or 10% bonus to providers for practicing quality care?

The implementation of value-based purchasing programs in the United States has emphasized budget neutrality, unlike the implementation of pay for performance in the United Kingdom, which involved new money on top of a raise for primary care physicians. In the context of no new money, this means that the funding for incentives would come from withholds—either from existing payments or from envisioned updates to payment—or from savings. In the private sector over the past decade, payers held back a portion of anticipated payment updates (e.g., if the year-to-year increase was to be 4%, then 2% would be guaranteed and the other 2% would be held back and paid out based on performance) and over time accrued more money at risk. Increasingly private payers are moving towards shared savings approaches to funding the incentive pool, with providers first needing to hit quality targets and then if they hit cost targets, they receive a portion of the savings (typically 50% of the savings).

3. **You state that many primary care providers have already been exposed to the kinds of performance measures outlined in the draft legislative framework. In your opinion, are the types of programs envisioned in the committee's legislative framework achievable goals for the Medicare program and providers? Also, do you believe they are goals that will improve the lives of seniors and taxpayers?**

Private sector and Medicaid plans have been experimenting with pay for performance for much of the past decade, and most of the measures in those programs focus on primary care. Because physicians typically see a mix of patients from different payers, the concept of pay for performance is not new to primary care physicians. The subcommittee has outlined a general framework that I believe builds an important path forward for moving providers towards accountability for quality (and hopefully cost)—for both primary care and subspecialists. I do believe the framework sets out achievable goals for Medicare and providers, and that these will benefit seniors and the taxpayers. A central piece of the work over the next five years is the development of measures for each specialty that address important performance gap areas and that target areas that benefit patients in terms of their health and functioning. Additionally, addressing areas where care is delivered with little or no value will help seniors—who are exposed to therapies that may actually harm them—and will help ensure the viability of the Medicare program, which must focus on controlling health spending.

4. **While primary care and some specialty groups have a long standing history of measure development and performance, others unfortunately lag behind. Do you believe that all provider groups adopting a system of quality measurement will be good for the provision of care in this country, and do you believe that provider specialties which are advanced in these areas might be able to help those who lag behind?**

There are many clinical subspecialties that have not developed performance measures, while some have made significant progress (Oncology, Cardiology, Cardiac Surgery, and Orthopedics). Without doubt, the sub-specialties that have made advancements in measure development, measurement and reporting through clinical registries, and that make use of that information for quality improvement, can be a resource for the specialties that lag in these areas.

Measure development efforts by the American Medical Association's Physician Consortium on Performance Improvement (PCPI) could be a foundation to support development of measures for those subspecialties that are currently lacking measures. Also, the recent efforts by the American Board of Internal Medicine Foundation (ABIMF), in partnership with clinical specialty societies, to generate recommended areas to reduce the overuse of services provides another opportunity that could be leveraged to support subspecialists in the transition.[3]

I would note that the current process of measure development being deployed through the Medicare program requires modification to support the work envisioned by the proposed legislation. As I have stated, it will be critical to pull physician leaders together from a particular specialty to identify areas of evidence-based practice and areas where performance gaps exist, and to pair them with measure developers who can work in concert with the clinicians to develop robust, valid measures.

5. **Your testimony touches on an important point. It is not whether we measure per se but really how meaningful the measure is and what it is measuring. In a system like that envisioned by the draft legislative framework, how do you believe Congress and CMS should ensure that measure development and application are meaningful both now and in the future?**

For measures to be meaningful, they must be based on scientific evidence that taking the action (e.g., providing beta blockers for those who have had a heart attack) will lead to better patient outcomes (i.e., lower mortality). We should not be asking physicians to provide care that has no clinical benefit to the patient. Similarly, we should hold physicians accountable for providing care that has little/no benefit (e.g.,

[3] Choosing Wisely: an initiative of the ABIM Foundation. 2012 [updated 2012; cited 2012 October 29th, 2012]; Available from: http://choosingwisely.org/.

per the Choosing Wisely and other specialty recommended areas related to overuse of health care services that are low value). So, CMS should first require that the measures it selects for focus are evidence-based. Secondly, CMS should move toward measuring outcomes that both physicians and patients agree are important and that can be influenced by the actions of the health care system. The value of outcome measures is that they transcend time; they are important now and will be in the future. As such, they will require less modification than process measures, which are tied to clinical evidence that can change year to year given medical advancements. For measurement of outcomes to be meaningful to physicians, it must account for differences in the sickness level of patients across different physicians. Otherwise, physicians will have incentive to remove sicker patients from their panel of patients in order to perform well on the measures. Third, the development of measures needs to occur using a scientifically rigorous process that is transparent, inclusive of physicians and other stakeholders, and ensures the reliability and validity of measures that become the basis of payment. Measure development is a science. It requires careful review of the scientific evidence to identify areas that define high quality care (which form the measure concept), vetting the evidence and concepts with clinical expert panels, specification of the concept using various data sources (e.g., claims data, electronic health records (EHRs)), field testing the measures across an array of providers with different data systems, assessing the measurement properties (reliability, validity of the measure), and finalizing the specification for uniform application across physicians in different settings. Because of the high stakes application of measures for payment and for driving provider performance, the measure development work should undergo a peer review process—meaning that the work of the measure developers and clinical panels should be published in clinical journals or in other publications that rely on a similar review process. Transparency of the process and underlying science will enhance the face validity of the process and the acceptability by the clinical community.

6. **The legislative draft puts a heavy emphasis on best practices as decided by medical specialties and primary care as the bed rock upon which measures should be founded. Your testimony also states that CMS should establish a process where measure development experts work with clinical specialties to identify performance gap areas and work to address those as measures. In your opinion, how important is this iterative relationship between CMS and medical providers around developing and maintaining a system of value-based performance?**

Those who measure and those who are measured need to be involved together in developing the system of value-based performance—so I would say the iterative relationship is critical. Successful VBP programs employ this partnership and it extends beyond identifying/developing measures to working in collaboration to improve. Fundamentally, this is the concept behind ACOs, which have the payer (i.e., CMS), physicians and hospitals all at the table working together to solve the problem. This relationship

will be critical to the success of new value-based performance payment systems. Physicians will offer important insights on patients who should be excluded from a measure, what is a reasonable performance target (given other factors that influence the result), and where the performance gaps are. They have deep knowledge of the science and this information is critical to developing a measure that is meaningful. For example, recent research conducted by Dr. Eve Kerr at the University of Michigan (Ann Arbor Veteran's Administration) shows that performance measurement should be moving towards "risk-based" measurement to avoid over treating patients; her work is showing that physicians are working to get HbA1c levels in diabetics below values of 7 and 8, often with little clinical benefit to the patient and substantial side effects. Such knowledge emanating from clinicians engaged in quality of care is vital to the construction of sound measures that Medicare can advance in the context of VBP. Medicare can best work to change physician culture by helping physicians understand that Medicare is working *in partnership* with physicians to do this, rather than simply imposing change on them. Development of the measures is the first step in building a partnership built on credibility and respect.

7. **Do you believe Medicare can benefit from thought leaders like Independent Health and others who are currently employing new models of care delivery in the marketplace?**

Absolutely! There are important innovations in play throughout the country and the Medicare program (which faces more statutory and regulatory constraints that impede its ability to experiment quickly and nimbly) should actively monitor and seek to learn from innovation that is occurring in the private sector. Much is being learned on the ground by organizations like Independent Health, Dartmouth Hitchcock, Aurora Healthcare, Hill Physicians, Sharp Healthcare, Geisinger, Mayo Clinic, Intermountain, etc., and unfortunately most of these insights are not being published. CMS should engage in annual outreach efforts to providers and payers around the country to learn from the innovations that are happening that could inform what Medicare does.

8. **How important is meaningful, timely feedback on performance for such a system to work?**

To take quality improvement action, physicians will need timely feedback on their performance and how they vary compared to peers. Generally, the sponsors of incentive programs are not in the business of providing real-time information; instead, that has fallen to the organization within which the physician works because the organization is better equipped to provide real time information. If the VBP program in the physician fee schedule were to establish fixed performance benchmarks that are known long in advance of the performance measurement year, physicians could periodically monitor their own performance throughout the year to get more immediate feedback. A key challenge in American healthcare is that most providers (save for systems like Kaiser and Geisinger) do not have ready access to a dashboard of performance indicators to tell them how they are doing in managing their patient

population. I fundamentally believe that embedding VBP into the physician fee schedule and other performance-based payment innovations (ACOs, bundled payments, medical homes) will work to change this; over the last decade, Kaiser has transformed itself to have a dashboard of performance indicators to be able to respond to VBP—such as in the Medicare Advantage star rating program. Increasingly, in the context of ACOs, health plans are partnering with health systems (physicians and hospitals) to provide daily reports to alert physicians that a patient's situation is worsening (so at risk for hospitalization) or that the patient has been admitted to the hospital or emergency department. Such data are valuable to the physician practice so they can intervene quickly to manage the patient in the most appropriate setting. Similarly, some integrated health systems are providing real time feedback to physicians on their performance (e.g., monthly), flagging areas where performance is lagging or signals a problem. While ideally real time data monitoring and feedback would be universal in our health system, that is not a near term reality. However, as electronic data systems improve and CMS is able to leverage data submissions from physicians on a more frequent basis, there is potential to develop systems where CMS could generate more timely feedback reports (relative to benchmarks)—such as on a quarterly basis.

The Honorable John Shimkus:

1. **Page 21 of the legislative framework released last week calls for the development of a "process by which physicians, medical societies, health care provider organizations, and other entities may propose" Alternative Payment Models for adoption and use in the Medicare program. Do you believe that model development from private payers and providers like those at Independent Health can lead to reforms that could benefit patients, providers, and taxpayers?**

I believe that physicians should have flexibility to participate in alternative performance-based payment models, be they ACOs, medical homes, bundled payments for episodes of care, or other models that have not yet been developed—and that these should "qualify" physicians as meeting the requirements of VBP as they will be measured on a set of performance measures. There is much innovation going on nationally in the private sector, such as at Independent Health, and as these types of models emerge and show benefit, CMS should consider ways to embed similar features into the Medicare program. Private payers, working with local providers, have greater flexibility and nimbleness to innovate, and the lessons from these experiments could yield benefits if applied in Medicare.

The Honorable Gus Bilirakis:

1. **In your testimony, you talk about a continuum of performance. Should we have a target percentage for performance of quality measures? For example, should the average of**

physicians meet 75% or 85% of performance measures? If we do use targets for performance measures and the averages are above the target percentage, should we recalibrate the metrics every five years or so, to adjust the metrics and increase the standards of care?

I encourage the committee to examine the way in which targets are set in the Alternative Quality Contract (Blue Cross Blue Shield of Massachusetts), where targets are set based on empirically derived cut points based on the data.[4] In this program, they pay along the continuum, so providers are rewarded for each increment of improvement. The highest level benchmark is set for what is best in class and is achievable, based on the actual performance of peer specialty physicians. They have found the highest level tends not to change over time (unless there is a significant change in the underlying therapy). Congress or the Secretary should set a minimum performance threshold below which no incentives would be paid. Performance targets do need to be periodically reviewed and reset; however, the Medicare program should seek stability and thus only change targets as necessary. Specifically, a framework should be put in place that allows for measures to be updated as needed. There are some measures in place now that are being achieved by almost all physicians. As measures top out, CMS should be empowered to retire those measures and implement new ones that allow physicians to continue to improve and be rewarded by such improvements.

Another approach for setting cut points is to use national benchmarks—such as the National Committee for Quality Assurance's (NCQA) Health Employer Data Information Set (HEDIS) measure benchmarks. The highest level benchmark can be set for what is best in class and is achievable, based on the actual performance of peer specialty physicians.

I am unclear on the portion of your question about "should the average of physicians meet 75% or 85% of performance measures." You may be asking about the use of a composite measure that aggregates information across a group of measures. For example, a composite could be constructed by adding together all measures for which a physician "passes" the measure divided by all the measure opportunities. In this case, you would arrive at the percent of all opportunities achieved. There is ample literature on composite construction, and I would be happy to discuss this topic with the subcommittee if this is an area of interest.

2. **How much of these quality measures should be developed for the physician in general or should we have measures for specific diseases? There are hard to diagnose diseases with**

[4] Safran, DG et al. Evaluating the Potential for an Empirically-derived Standard of Performance Excellence in Ambulatory Patient Care Experience Measures: Analysis in Support of NCQA's Efforts to Develop a Physician Recognition Program in Patient-Centered Care. October 2007.

small populations. If we do develop metrics for specific conditions, how do we responsibly develop measurements for these conditions when research may be more limited?

Performance measures should be "patient-driven." By that I mean that the patient's health care needs define the measure. For some measures, multiple physicians could be accountable for the same measure (such as the management of high blood pressure where a primary care physician and a cardiologist could be accountable). Many of today's measures have a disease or condition focus such as for diabetes, heart attack, or congestive heart failure. In these instances, there are multiple evidence-based processes of care and intermediate outcome measures that form a collection of measures for diabetes or heart disease. What generally drives performance measurement are the following things: 1) prevalence of a condition; 2) treatment impact (meaning that there is evidence that doing X will result in improved outcomes—better functioning and maintenance of health, lower comorbidity, and lower mortality); 3) identification of a gap in care (i.e., underuse); and 4) variation across physicians in care delivered with no demonstrable effect on outcomes (i.e., areas of potential overuse of services).

You flag two critical problems in the area of performance measurement. The issue of small numbers: generally measurement has focused on areas where there is greater prevalence of the problem in the patient population. Unless there is an opportunity for large impact from addressing care for less prevalent conditions, the focus hasn't been on these types of clinical problems. In the future, this may change as electronic health records provide a vehicle for providing clinical decision support to ensure that patients with less common problems still receive evidence-based care. One strategy for dealing with small numbers is to create a composite measure (see above) from all the possible measure areas for a given physician; this approach aggregates information across all care provided by the physician. This may be a potential approach for clinical subspecialists who deal with less common health conditions. Developing measures that are reliable at the individual measure may not be possible, but when aggregated across multiple measures, we may be able to get a good signal on the overall quality of care provided by the physician.

3. **How much input should patient groups have and what type of input into the process should they have when determining these measures?**

Patients are an important stakeholder group that should be consulted at various stages in what gets measured. Patients routinely identify issues such as access to care, coordination, communication, and costs as key concerns. Currently, patient groups are involved in the NQF's National Priorities Partnership, which identifies core areas for measure development. CMS could similarly engage patients at the front end of the process to identify key areas for development.

4. **Should the system evolve to allow a direct feedback loop to the doctor? For example, the physician would know that they were paid X because they did or did not do Y to patient Z. Do we want that granular a system, or should the information and payment be done on a more aggregate level?**

As I mentioned in my response to Chairman Pitts, (see question 8, above), to take quality improvement action, physicians will need timely feedback on their performance and how they vary compared to peers. Generally, the sponsors of incentive programs are not in the business of providing real-time information; instead, that has fallen to the organization within which the physician works because the organization is better equipped to provide real time information. If the VBP program in the physician fee schedule were to establish fixed performance benchmarks that are known long in advance of the performance measurement year, physicians could periodically monitor their own performance throughout the year to get more immediate feedback. A key challenge in American healthcare is that most providers (save for systems like Kaiser and Geisinger) do not have ready access to a dashboard of performance indicators to tell them how they are doing in managing their patient population. I fundamentally believe that embedding VBP into the physician fee schedule and other performance-based payment innovations (ACOs, bundled payments, medical homes) will work to change this; over the last decade, Kaiser has transformed itself to have a dashboard of performance indicators to be able to respond to VBP—such as in the Medicare Advantage star rating program. Increasingly, in the context of ACOs, health plans are partnering with health systems (physicians and hospitals) to provide daily reports to alert physicians that a patient's situation is worsening (so at risk for hospitalization) or that the patient has been admitted to the hospital or emergency department. Such data are valuable to the physician practice so they can intervene quickly to manage the patient in the most appropriate setting. Similarly, some integrated health systems are providing real time feedback to physicians on their performance (e.g., monthly), flagging areas where performance is lagging or signals a problem. While ideally real time data monitoring and feedback would be universal in our health system, that is not a near term reality. However, as electronic data systems improve and CMS is able to leverage data submissions from physicians on a more frequent basis, there is potential to develop systems where CMS could generate more timely feedback reports (relative to benchmarks)—such as on a quarterly basis.

5. **Is it possible to use physician quality measures to encourage patients to better follow a doctor's plan to manage diseases? For example, a newly diagnosed diabetic getting a follow up call by the doctor reminding them to check their blood sugar or reminding them to schedule an appointment with a nutritionist. Should these metrics be limited to what is done inside the physician's office?**

The question you raise seems to refer to use of patient incentives. VBP programs tend to focus on incentives for the physician to do the right thing; however, patients have a significant role to play, and some parties are experimenting with the use of patient incentives to encourage their engagement.

6. **Should the quality measures be weighted? If there are 10 things that a doctor can do to increase their performance measure, should they be rated equally for payment bonuses or weighted to account for time or difficulty?**

There is no single correct answer here. The use of weights can signal "importance" and thus direct provider attention to areas deemed more important by payers and other stakeholders. For example, the Medicare Advantage program places more weight on outcomes, intermediate weight on patient experience measures, and the lowest weight on process measures. These are "policy" derived weights. Weighting of measures can be used to encourage greater focus or as you note, provide some accounting for level of difficultly. Weights can also be empirically derived (using tools such as factor analysis), based on which measures are providing the strongest signal on performance (i.e., those measures where the reliability of measurement is greatest). The advantage of empirically derived weights is that the program sponsor can work to minimize the risk of misclassifying a provider's performance by increasing the reliability of the composite measure. Some VBP programs have chosen to assign weights to different measure domains in determining payouts, such as 50% on clinical, 20% on patient experience, and 30% on safety. In this case, these represent the values of the stakeholders involved in the program. The use of weights is a policy option that should be left to the discretion of the Secretary, who should consult with affected stakeholders. Note that in any measurement system, even if all measures receive a weight of 1, if there are more diabetes measures (let's say they represent 5 out of a total of 10 measures), then de facto they will account for 50% of the total weight in an equal weight scheme.

The Honorable John D. Dingell:

1. During the hearing, you agreed that Congress should look at the innovations and changes being made in the private sector when considering reforms to SGR. Would you please list some suggestions of what you feel might be useful?

The types of changes being envisioned in reforming the SGR at this stage are reflective of early pay for performance (P4P) efforts over the past decade, where physicians were paid differentially (at the margin) for a set of measures. Much has been learned from these P4P experiments---and I would encourage Congress to examine the California Integrated Healthcare Association P4P program and the P4P efforts by private plans in Massachusetts. In California, the program is evolving to include costs, and it will now be called the value-based pay for performance program; in this program providers have to hit both cost

and quality targets and incentives will be based on shared savings. Such an approach could be considered in SGR reforms, once an established program of performance measurement is put in place (the first building block). In the near term, if Congress wants physicians to focus on helping to reduce health spending, measure development needs to prioritize the development of measures of overuse. Additionally, physicians need to understand where they deviate in the delivery of care and what factors contribute to them being high cost outliers (after controlling for the difficultly of their patient mix). These are the types of actions that are in play by numerous private payers and provider organizations—such as United Healthcare, Blue Cross Blue Shield of Massachusetts, Kaiser, Mayo Clinic, Aurora Healthcare, the Palo Alto Medical Foundation (and Sutter Medical Group). In constructing the bill, Congress should outline the path for physicians and set expectations that measurement in the early term may focus on closing quality gaps (underuse of services), but over the longer term focus on cost reduction through variation reduction and reduction in the overuse of low value services. This is the focus in the private market, and ACOs are working aggressively on these areas to ensure they meet targets to secure shared savings.

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June 26, 2013

Mr. Bill Kramer
Executive Director for National Health Policy
Pacific Business Group on Health
221 Main Street, Suite 1500
San Francisco, CA 94105

Dear Mr. Kramer:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 5, 2013, to testify at the hearing entitled "Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Friday, July 12, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Attachment 1 - Additional Questions for the Record
Responses from William E. Kramer,
Executive Director for National Health Policy
Pacific Business Group on Health
July 24, 2013

The Honorable John Shimkus

1. **Page 21 of the legislative framework released last week calls for the development of a "process by which physicians, medical societies, health care provider organizations, and other entities may propose" Alternative Payment Models for adoption and use in the Medicare program. Tell me, do you believe that model development from private payers and providers like those at Independent health can lead to reforms that could benefit patients, providers, and taxpayers?**

   Response: Yes. Private health plans, provider groups, employers and other organizations have developed a wide range of innovative provider payment models. The best of these provide appropriate incentives for improved quality, patient experience, appropriateness and efficiency of the services provided. These models benefit patients, purchasers and taxpayers by encouraging providers to deliver services that result in higher value – better quality and lower cost. The innovative payment models also reward physicians who are delivering superior medical care.

   Note: See response to the question from The Honorable John D. Dingell, Attachment 2, for more details regarding innovative private sector payment programs.

The Honorable Gus Bilirakis

1. **How much of these quality measures should be developed for the physician in general or should we have measures for specific diseases? How do we develop quality measures for rare diseases? These are hard to diagnose diseases with small populations. If we do develop metrics for specific conditions, how do we responsibly develop measurements for these conditions when research may be more limited?**

   Response: We need both general and specific measures.

   - General performance measures are needed to compare physicians regardless of their specialties and of the specific disease being treated. First, patients expect the same high quality of care from any doctor integrally involved in treating their condition. For example, a patient treated by a primary care physician for diabetes should expect to get the same care as a patient treated by a specialist. Otherwise, there is one standard for primary care physicians and another standard for pulmonologists. A patient-centered approach is to apply measures to all physicians that may be caring for patients with a particular condition. Otherwise, we are not getting a true picture of quality, and variation across peer groups is accepted. Second, general measures of performance are needed by patients and purchasers to evaluate the overall quality of care provided by an individual

physician or medical group. For example, patients choosing among competing ACOs want to know whether the ACO's physicians, as a group, are rated high for coordinating the care of their patients. This is important information regardless of the specific disease or condition, especially for patients who do not have an existing or chronic condition.

- Specific performance measures for certain conditions are also needed. For example, a prospective mother will want to know which obstetricians have the best clinical outcomes for deliveries. If the patient has had a previous C-section delivery, she will want to know whether the obstetrician is likely to recommend another C-section vs. a vaginal birth. Specific information like this would be masked by general performance measures.

2. **How much input should patient groups have and what type of input into the process should they have when determining these measures?**

Response: Performance information is a public good, and it should be developed in order to meet the public interest. Measures that are used in this program should include those that are relevant and meaningful to purchasers and consumers. These types of measures are often lacking in measures developed solely by provider organizations. For more information, refer to *Ten Criteria for Meaningful and Usable Measures of Performance*. While physician involvement is critical in this process, the ultimate stakeholders are those who receive and pay for medical care.

Patient representatives can bring the authentic voice of the patient into the process of defining and evaluating quality. Patients often make trade-offs that differ from those made by clinicians. Research shows, for example, that patients often choose more conservative treatment options when using shared decision-making tools and when considering end-of-life care. Excellent methods exist for scientific measurement of patient outcomes and preferences that should be included in the measurement development process. Patient organizations should be asked to help define "quality" for a given condition and to encourage patients to contribute their own data to the quality measurement process, through surveys and patient-reported outcome measures.

3. **Should the system evolve to allow a direct feedback loop to the doctor? For example, the physician would know that they were paid X because they did or did not do Y to patient Z. Do we want that granular a system, or should the information and payment be done on a more aggregate level?**

Response: In response to a question from the Committee during the June 5 hearing, I stated that, ideally, physicians would receive real-time feedback on their performance as well as real-time decision support tools. For example, a primary care physician would be able to see, every day, how many of her or his patients had acceptable blood pressure levels. The physician would also be able to see the expected costs of diagnostic and treatment options, e.g., lab tests, imaging and prescriptions, before making decisions in the best interests of the patient. Current reporting methods, however, often have a very long lag – sometimes as much as a year after services are delivered. Retrospective

reporting with long lags is not very useful to clinicians who are working every day to improve the care they provide.

Including the amount the physician would be paid for every decision is problematic. Physicians have an obligation to serve their patients, and information about the likely outcomes and potential risks – as well as costs and resource use – should be paramount when making decisions. We support frequent and convenient provision of aggregate cost and resource use data to physicians, but do not recommend patient-specific cost data that may influence physician judgment.

4. **Is it possible to use physician quality measures to encourage patients to better follow doctor's plan to manage diseases? For example, a newly diagnose diabetic getting a follow up call by the doctor reminding them to check their blood sugar or reminding them to schedule an appointment with a nutritionist. Should these metrics be limited to what is done inside the physician's office?**

Response: Yes, quality measures should be used to encourage better follow-up care. For example, managing blood glucose levels is essential for diabetic patients. Measures should not be limited, however, to what is done in the physician's office. Managing a chronic condition like diabetes requires communication and an effective partnership between the physician and the patient, much of which happens outside the visit to the physician's office.

Physicians should be rewarded for achieving superior outcomes -- e.g., do their diabetic patients have acceptable blood glucose levels -- not "process" measures such as follow-up calls or reminders. There are many ways to achieve good outcomes; overreliance on standardized process measures may deter important innovation, fail to recognize local health care market and populations differences, and lock in the care processes of today that may not be the most useful and effective tomorrow.

Public reporting and payment programs should focus on outcomes and other patient-centered performance measures. Improvement will result from providers' efforts and innovative approaches to achieve superior outcomes.

5. **Should the quality measures be weighted? If there are 10 things that a doctor can do to increase their performance measure, should they be rated equally for payment bonuses or weighted to account for time or difficulty?**

Response: Yes, it is appropriate to consider different weights for performance measures. The relative weights, however, should be based on importance to patients, not the time or difficulty involved in achieving high levels of performance. The public interest should be paramount in selecting and using performance measures in Medicare physician payment programs.

Attachment 2-Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable John D. Dingell

1. **During the hearing, you agreed that Congress should look at the innovations and changes being made in the private sector when considering reforms to SGR. Would you please list some suggestions of what you feel might be useful?**

   Response: Large employers have supported innovative approaches to physician payment, such as the Intensive Outpatient Care Program (IOCP) piloted by Boeing and adopted by other large employers.[i] The IOCP is a primary care-led, high intensity care management model for high-risk populations. The California HealthCare Foundation (CHCF) provided the funding to develop this groundbreaking model of delivering care as a strategy for reducing costs while maintaining or improving quality. The designs and financial projections underwent a peer review panel of subject matter experts and leaders of traditional and more innovative practices. Key features of the model include:

   - A focus on high-risk patients, i.e., the 5-20% who incur the highest costs.
   - Each site creating a new ambulatory intensivist practice.
   - Shared care plans, increased access, and proactively managed care.
   - Copays for the initial intake visit were waived; there were no other benefit changes.
   - Sites were paid a case rate per member per month (pmpm) to cover non-traditional services; otherwise, the sites continued to be paid based on traditional fee-for-service contracts.
   - The sites received a portion of the savings in total medical expenses.

   The Boeing Company initially implemented a pilot of this model in Seattle. Over a two-year period, Boeing achieved improved health outcomes (28% reduction in hospital admissions, 16% increase in mental functioning on the SF-36), 20% reduction in costs, and increased patient access to care.[ii] [iii]

   Following the success of the Boeing pilot, PBGH worked with CalPERS and Pacific Gas & Electric Company (PG&E) to replicate the model in rural Northern California with the Humboldt del Norte Foundation Medical Group. This program targets the top 20 percent of patients in terms of relative health risk. PBGH is now expanding the IOCP to the Medicare population. Under a grant from the CMMI, PBGH is rolling out this model to 17 medical groups in California, covering 23,000 Medicare patients, demonstrating commitment to public and private sector alignment.[iv]

   Other PBGH members are experimenting with models for accountable care organizations (ACO). For instance, CalPERS implemented an ACO-like pilot with Hill Physicians Medical Group, Dignity Health and Blue Shield of California that introduced a shared

savings model for improving care coordination and quality for 42,000 HMO beneficiaries in the greater Sacramento area. Early results showed a $15.5 million cost reduction annually due to a 17% reduction in patient readmissions and shorter lengths of stay.[v] Five months later, those results were updated to reflect $20 million cost reduction over the two years of the program, largely due to a 22% reduction in hospital readmissions.[vi] [vii]

Large employers know, however, that these innovations do not have the scale to drive system-wide change and improve health care across the nation. It is important to have the collaboration of the federal government - the nation's largest health care purchaser -- in transforming the way health care is delivered. Working together is also important to large employers to avoid the shifting of costs from the public to the private sector. In some markets, cost shifting from Medicare to private payers can be as high as 40%. [viii] [ix] [x] Instead, we should pursue strategies to improve quality while lowering the overall cost of care.

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[i] Additional information about the IOCP program can be found at http://www.pbgh.org/iocp.

[ii] Milstein, A and Kothari P, Health Affairs, October 20, 2009. Accessed at http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/

[iii] This model was also highlighted in Atul Gawande's "Hot Spotters" article in the New Yorker, and documented on the Agency for Healthcare Research and Quality (AHRQ) Health Care Innovations Exchange. http://www.innovations.ahrq.gov/content.aspx?id=2941. Additionally, Steve Jacobson, MD and Jennifer Wilson-Norton of The Everett Clinic presented on "Connecting Providers and Managing High Risk Beneficiaries" at the CMS ACO Accelerated Development Learning Session on September 16, 2011, https://acoregister.rti.org/docx/dsp_lnks.cfm?doc=Module 3B. Connecting Providers Managing High Risk.pdf.

[iv] http://www.pbgh.org/key-strategies/paying-for-value/28-aicu-personalized-care-for-complex-patients.

[v] CalPERS Press Release. (2011, April 12). Press Release: April 12, 2011. Retrieved February 21, 2012, from www.calpers.ca.gov: http://www.calpers.ca.gov/index.jsp?bc=/about/press/pr-2011/april/integrated-health.xml.

[vi] CalPERS Agenda Item 4. (2011, October 18). Agenda Item 4 Memo to the Members of the Health Benefits Committee. Retrieved February 21, 2012, from www.calpers.ca.gov: http://www.calpers.ca.gov/eip-docs/about/board-calagenda/agendas/hbc/201110/item-4.pdf.

[vii] Blue Shield of California Press Release. (2011, September 16). HHS Secretary Kathleen Sebelius Reviews Key Pilot Program Tied to Health Care Reform Goals. Retrieved June 3, 2013, from www.blueshieldca.com: https://www.blueshieldca.com/bsca/about-blue-shield/newsroom/sebelius-reviews-aco-pilot-programs.sp.

[viii] W Fox & J Pickering. Cost Efficiency at Hospital Facilities in California: A Report Based on Publicly Available Data. Milliman. Oct 2007.

[ix] Analysis of Hospital Cost Shift in Arizona. The Lewin Group. March 2009.

[x] Health Care Trends in America. BlueCross BlueShield Association. 2009 Edition.

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June 26, 2013

Dr. Jeffrey B. Rich
Mid-Atlantic Cardiothoracic Surgeons
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600 Gresham Drive, Suite 8600
Norfolk, VA 23507

Dear Dr. Rich:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 5, 2013, to testify at the hearing entitled "Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Friday, July 12, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

The Society of Thoracic Surgeons

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July 12, 2013

Honorable Joseph R. Pitts
Chairman
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

Thank you for the opportunity to present my testimony on behalf of The Society of Thoracic Surgeons (STS) and thank you for your thoughtful questions. As you know, STS is the largest organization representing cardiothoracic surgeons in the United States and the world. Founded in 1964, STS is an international, not-for-profit organization representing more than 6,600 surgeons, researchers, and allied health care professionals in 85 countries who are dedicated to providing patient-centered high quality care to patients with chest and cardiovascular diseases, including heart, lung, esophagus, transplantation, and critical care. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

Additional Questions for the Record
The Honorable Joseph R. Pitts

1. From your testimony, it appears that the Society of Thoracic Surgeons have been doing measurement development and promotion for years. Do you believe that specialties that may not be as advanced as thoracic surgery can catch up?

Yes, in fact many specialties are already in the process of developing their own, specialty-specific clinical registries. Importantly, we believe that implementation of a pay-for-quality program should not wait for all of medicine to be at the same place at the same time. We recommend that policymakers consider ways to reward providers for incremental steps towards these quality assessment goals outlined in Phase II of the Committee's discussion draft, while allowing those medical specialties that already have the requisite infrastructure in place to engage in this new system as soon as possible and reap some reward for their efforts.

Short, medium, and long term infrastructure, measure, and quality assessment benchmarks should be set up as intermediate goals, shortening the "period of stability" for those able to meet those steps. For example, incremental steps towards Phase II readiness can include reporting of data to a clinical database

under construction, working on various "Clinical Improvement Activities" as defined in the Committees' concept document, receiving feedback on quality measure performance (even while such measures are being considered for approval), or observing process or structural measures that have been approved or are in the process of being approved by a consensus-based entity, among others.

2. How beneficial can a system of primary care and specialty-specific quality and efficiency measures be to our seniors, taxpayers, and the Medicare program as a whole?

The fundamental principle underlying the STS database initiative has been that engagement in the process of collecting information on every case, robust risk-adjustment based on pooled national data, and feedback of these risk-adjusted data to the individual practice and institution will provide the most powerful mechanism to change and improve the practice of cardiothoracic surgery for the benefit of patients and the public. In fact, published studies indicate that the quality of care has already improved as a result of research and feedback from the STS National Database.

For example, ElBardissi and colleagues studied 1,497,254 patients who underwent isolated primary Coronary Artery Bypass Graft (CABG) surgery at STS National Database-participating institutions from 2000 to 2009. They found that:

- Patients received more indicated care processes in recent years, including a 7.8% increase in the use of angiotension-converting enzyme inhibitors preoperatively and a significant increase in the use of the internal thoracic artery (88% in 2000 vs. 95% in 2009).
- The observed mortality rate over this period declined from 2.4% in 2000 to 1.9% in 2009, representing a relative risk reduction of 24.4% despite the predicted mortality rates (2.3%) remaining consistent between 2000 and 2009.
- The incidence of postoperative stroke decreased significantly from 1.6% (2000) to 1.2% (2009), representing a relative risk reduction of 26.4%.
- There was also a 9.2% relative reduction in the risk of reoperation for bleeding and a 32.9% relative risk reduction in the incidence of sternal wound infection from 2000 to 2009.

In addition, participation in initiatives that rely on data from the STS National Database have proven that access to information on patient outcomes helps physicians to identify best practices in quality and efficiency that can help save money and critical resources. For example, funded by the National Heart Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH), the ASCERT (American College of Cardiology Foundation-The Society of Thoracic Surgeons Collaboration on the Comparative Effectiveness of Revascularization Strategies) study was designed to examine the comparative long-term effectiveness of Coronary Artery Bypass Graft (CABG) and percutaneous coronary intervention (PCI) revascularization strategies in real world populations, including specific subgroups of patients such as those with diabetes, severely impaired heart function (low ejection fractions), chronic lung disease, and kidney dysfunction. ASCERT examined 86,244 patients undergoing CABG and 103,549 patients treated with PCI. The study uses data from STS Database and ACC registry along with CMS Medicare Provider

Analysis and Review (MEDPAR) data. STS views the ASCERT study as a paradigm for a comparative effectiveness research enterprise based on linked clinical and administrative data. Clinically robust, broadly generalizable data from thousands of patients, linked with longitudinal outcomes from claims data, could quickly and cost-effectively answer a broad range of questions. The results of these studies will be a unique and innovative source of information for patients, providers and various third party payers concerning the potential long-term results of different treatments in specific subgroups. Such information could feasibly be used to change how physicians treat their patients, patients experience their treatments, and payors reimburse for care.

At the regional level, the Virginia Cardiac Surgery Quality Initiative (VCSQI) has demonstrated that improving quality reduces cost. For example, using evidence-based guidelines derived from an analysis of data from the STS National Database combined with patients' claims data, VCSQI has generated more than $43 million in savings through blood product conservation efforts and more than $20 million by providing the best treatment to patients with atrial fibrillation at the right time.

3. You mention in your testimony the importance of linking administrative and outcome data for providers in the field. How important in such a process as outlined in the Committees legislative framework will it be for providers to have timely access to their own performance data? How early and often in the process of measurement should such access happen?

The issue of linking robust clinical data with resource utilization data such as Medicare or private payor claims information is an essential part of any program that attempts to improve quality and efficiency in health care. Clinical data registries have previously been limited to short-term outcomes. To mitigate this limitation, STS has linked our clinical registry data to administrative sources such as CMS MEDPAR to obtain long term clinical outcomes and long term data on resource utilization. Clinical registries provide detailed diagnostic and therapeutic data (including data about risk factors and severity of disease) not present in administrative databases, while administrative databases provide information about long-term outcomes and cost not present in clinical databases. Linkage of clinical and administrative databases is essential for the assessment of resource use and value (quality/cost). The linkage of clinical data with resource utilization data provides the mechanism to risk-adjust both clinical outcomes and resource utilization and thereby to assess the value of care being delivered. We anticipate that feedback of these linked clinical and resource utilization data to the practice/institutional level will be associated with further improvements in both the quality and cost, i.e., value of cardiothoracic surgical practice. We urge that the CMS MEDPAR data be made available on a regular basis to qualified registries that have robust patient privacy protections and formalized standards for assessment of providers' performance that relies on *both* clinical and claims data, such as the STS National Database.

A significant roadblock to the acquisition of long-term survival data has recently been established by the Social Security Administration. In November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the Social Security Death Master File (SSDMF). There are continuing efforts to further restrict access to

the SSDMF so as to "protect" those listed in the file from identity theft. Balanced against these legitimate privacy concerns is the value of the unique survival information that can be provided from the SSDMF data. Linking clinical registries to the SSDMF allows for the verification of 'life status" of patients who otherwise would be lost for follow up after their treatment, and as indicated previously, this longitudinal survival data is vital in assessing the long term efficacy of many treatment algorithms for important diseases, including heart disease, cancer, and many other chronic diseases.
Research based on this information helps physicians to provide information to today's patients and families to help them with shared decision making. Outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term benefits of medical procedures. It is important to note that STS, through its contracts with the Duke Clinical Research Institute, maintains the patient identifier data separately from the actual clinical and other demographic data, and the only patient level identified information that ever leaves the database is simply that the patient has a record in the database. When the follow-up information is returned from external entities, such as the SSDMF, it can be linked back to the records in the de-identified database, but the flow of information is only in this direction. The externally derived data are used to supplement the data in the individual record, but these data never leaves the database except in de-identified form.

Importantly, STS believes that meaningful quality measures and rewards for physician performance cannot be applied simply to administrative data, including claims data, reported by hospitals and physicians alone. While administrative data provide information on longitudinal medical treatments and resource utilization across settings of care and by various physicians, their clinical accuracy have been shown to be poor, and they exclude pertinent information on patient risk factors, disease severity, and clinical outcomes. This critical information is only found in clinical datasets where there is input of clinical data by clinicians. Publication of claims data, without the clinical context and robust demographic information essential to risk-adjustment, could have extremely harmful effects. For that reason we oppose current efforts by the administration to provide general public access to Medicare Claims data and request significant revisions to S. 1180 and/or any similar legislation that is considered in the House.

Finally, in responding to this question, we feel it is important to define the terms physician-reported data, physician performance based on quality measures, and physician feedback reports. I have provided an example of a physician data entry form (available here: http://www.sts.org/sites/default/files/documents/STSAdultCVDataCollectionForm2_73_Annotated.pdf) and a physician feedback report (available here: http://www.sts.org/sites/default/files/documents/pdf/ndb2010/Report_OV_General_5-37.pdf). You will note that the data collection form records raw data drawn from a patient's chart. Quality measures provide statistically and clinically relevant ways to interpret those data. The feedback report uses these data and measures to generate analyses across the specialty, allowing cardiothoracic surgeons to compare themselves against national aggregate data in a statistically valid and clinically credible fashion. We wish to again emphasize the motivational power of this type of feedback data in influencing physician practice.

4. Your testimony and past feedback to this committee raised a concern about the sharing of best practices should a system of quality measurement be linked to payment in the wrong way. Do you have any recommendations for appropriate ways to apply such measurement that would not negatively impact the sharing of best practices among providers?

While the creation of a reward/penalty system of physician reimbursement is not inherently wrong and could potentially be an effective method of improving health care quality and efficiency, it is the method of implementation that is logistically problematic. If such a system is designed to operate on the individual physician level, intra- and inter-hospital cooperation and sharing of best practices will almost certainly suffer. In addition, from a purely statistical perspective when low frequency events are being evaluated, it is virtually impossible to distinguish different levels of performance between one clinician and another because the total number of patients / outcomes / events created by the individual practitioners is far too small to yield any meaningful interpretation. For example: 95% of 25 patients equals 23.75 and 92% of 25 patients is 23 (essentially no difference). However, 95% of 10,000 patients equals 9500 and 92% of 10,000 is 9200 (a much more easily appreciated difference). On the other hand, a national or perhaps regional construct will enhance cooperation and "cross-fertilization" of information. Cardiothoracic surgical examples of these structures include not only the STS National Database efforts, but also state and regional efforts such as the Virginia Cardiac Surgical Quality Initiative, the Michigan STS collaboration on adult cardiac surgery, and the Northern New England Cardiovascular Study Group. Placing incentives at a higher organizational level (e.g. state, region, or national) can encourage collaborative learning and quality improvement that should be inherent aspects of professionalism and can avoid incentives to "game the system" or to refrain from sharing knowledge and clinical experience. We believe that using competition to create economic winners and losers among physicians can only lead to reduced cooperation, collaboration, and information sharing that we all believe is essential to improving the practice of medicine.

Finally, placing the focus on the individual practitioner detracts from the team approach to patient care that is the hallmark of many of the advances in medicine and surgery of late. For example, in order for the heart team, which consists of the cardiothoracic surgeon, cardiologist, anesthesiologist, and advanced practice nurses and physician assistants (among others), to function at its highest level, there must be shared responsibility for patient care and patient outcomes. Similar relationships exist throughout medicine including the multidisciplinary team of heath care providers necessary to provide optimal care to patients with cancer and many other diseases. Assessing care quality at the institutional, regional, or national level allows the component parts of the health care team to share accountability, ensuring the patient receives the best care from the appropriate health care provider.

STS believes that any new, alternative payment methodology should align incentives along specialty or disease process lines at the regional or national level. This type of payment system would foster and incentivize physicians to act as members of a profession and fulfill their professional responsibilities to collaborate and share knowledge and practices with their peers. There are several alternatives to current Medicare physician and hospital payment mechanisms

which could advance these goals, including specialty-specific conversion factors for physician payment and global payments to hospitals and physicians for specified procedures such as isolated coronary bypass procedures. STS believes that the most powerful and reliable method to affect physician practice is to engage physicians in the collection of outcomes data on the services that they provide, and to provide meaningful, risk-adjusted feedback that allows them to compare these outcomes to those of their peers. We believe that the reimbursement system should promote physician practices that exemplify the profession's responsibilities to not only improve the quality of the care that is given to patients but also to wisely allocate societal healthcare resources. We also believe that responsible professional organizations provide important database and educational resources that can provide the infrastructure to support the needed improvements in physician practice and resource utilization.

5. How important will specialty specific clinical registries be for a process such as the one outlined in the Committee's legislative framework? Could such a registry serve as a source of continual physician feedback and data as some have stated will be so important?

The STS National Database is an example of an initiative that was designed precisely for the purposes described in this question. It is our strong belief that specialty-specific registries are the most appropriate source of this information and the best tool available to meet the goals of physician payment reform that achieves quality improvement. Peer pressure is an important factor in changing practice, and the closest medical peers are members of the same specialty. Most physicians identify directly with their specialty and also with their specialty or sub-specialty societies. We also believe that these databases should be independently and randomly audited, as the STS database has been for several years, in order to provide credibility and comfort to the American public and to payors in the validity of the data.

Any modernization of the physician payment system should ensure that individual medical specialties can—and have incentive to—control the growth rate of their services and payments by identifying the most effective and appropriate treatment for the patient. At the very least, specialties should not be penalized if their quality and value improvement activities result in lower Medicare utilization and expenditures. As the STS National Database and registries of other specialties have demonstrated, feedback of credible, risk-adjusted outcomes data encourages physicians to change their practice patterns to achieve better outcomes, more efficient care delivery, and thereby, increased patient value. The following should be included in any Medicare physician payment reform initiatives:

- Mandate and incentivize the development and utilization of specialty- specific clinical data registries;
- Require the Centers for Medicare and Medicaid Services (CMS) and other payers to make administrative (cost and claims) data available to registries for use in their analyses so that resource utilization becomes an outcome variable to be assessed in the same manner as traditional clinical outcomes such as mortality or complication rates. The STS believes that the improvement in clinical outcomes without significantly reducing out- of-control medical resource utilization is ultimately self-defeating ;
- Address barriers imposed by federal and state privacy regulations including, but not limited to the inability of our clinical registry to also collect administrative claims data

and "outcomes" data contained in the SSDMF. Preventing the STS and any other legitimate specialty specific data registry from having access to information as to the patient's final outcome (i.e. mortality) severely limits the power of clinical registries. Of course, the onus of protecting the privacy of patients should be required of the specialty societies and has been demonstrated for years by the STS National Database and its sound method of data encryption;

- Allow physicians to share the savings generated by their quality improvement efforts and consider providing economic incentives and disincentives at higher levels than the individual physician or practice.
- Utilize audited clinical registries and other resources to generate comparative effectiveness research; and
- Consider significant changes to reimbursement systems for both hospitals and physicians that promote wise use of resources and improved clinical outcomes.

STS urges Congress to consider quality incentive programs that encourage the coordination of Medicare claims data with existing clinical registries to enhance patient monitoring and physician performance, and improve quality. Without linking the administrative data collected by health plans and CMS with the clinical information reported by clinicians, patients cannot be effectively monitored. By using linked longitudinal registries, physicians can more broadly monitor patients for readmissions or care transitions. Similarly, longitudinal patient histories allow physicians to assess the long-term success of surgical or other medical interventions. The successful linking of the STS database with CMS administrative data in Virginia, for example, has led to a clinical/financial tool that brings quality improvement and cost containment to reality through a focus on reductions in costly complications and the redesign of care delivery models in order to promote high quality efficient care.

A new STS public reporting initiative was launched in September 2010. By January, 2011 more than 20% of Adult Cardiac Surgery Database participants began to voluntarily report their heart bypass surgery performance score to the public on www.sts.org[1]. As of July 2013, approximately 43% of Database participants are voluntarily reporting their results for Coronary Artery Bypass Graft (CABG) and/or aortic valve replacement on the Consumer Reports and/or STS websites, and STS is universally regarded as the leading professional society in these activities.

6. While primary care and some specialty groups have a long standing history of measure development and performance, others unfortunately lag behind. Do you believe that all provider groups adopting a system of quality measurement will be good for the provision of care in this country, and do you believe that provider specialties that are advanced in these areas might be able to help those who lag behind?

As outlined previously, STS strongly believes that this process of collection of reliable outcomes data, central risk adjustment, and feedback is a strong motivator for practice improvement. We believe that these same principles apply across all areas of medicine. In some disciplines, the outcomes may be more difficult to precisely define, but we believe that outcomes measurement

[1] http://www.nejm.org/doi/pdf/10.1056/NEJMp1009423

must be an integral part of quality improvement. STS and other surgical groups are recognized as leaders in this type of activity, but there are multiple other examples including collection of data on the treatment of cystic fibrosis and childhood cancers, to name a few. This approach is not new, but its expansion across all areas of medicine will require the appropriate incentives and support to overcome the important financial and motivational barriers that exist.

STS as a professional society, and our individual members who have experience in working with the STS National Database are eager to help in the effort to proliferate best practices in clinical data collection and analysis to bring about a change in how care is provided in this country. We believe that we have the tools to ensure that the right patients receive the right care at the right time, every time.

The Honorable John Shimkus

1. Page 21 of the legislative framework released last week calls for the development of a "process by which physicians, medical societies, health care provider organizations, and other entities may propose" Alternative Payment Models for adoption and use in the Medicare program. Do you believe that model development from private payers and providers like those at Independent Health can lead to reforms that could benefit patients, providers, and taxpayers?

While we appreciate that the current proposal, and the preponderance of our comments to date have addressed Medicare Fee For Service (FFS) payments, we feel strongly that the health care system should begin to move away from FFS and towards models of payment that promote provider collaboration in the treatment of a single patient. STS members are committed to the concept of team-care as exemplified by the heart team and cancer team. For example, STS worked to build the heart team concept into CMS's coverage with the evidence development decision for Transcatheter Aortic Valve Replacement therapy (TAVR). TAVR is covered for the treatment of severe aortic stenosis when furnished according to an FDA-approved indication. The TAVR National Coverage Decision requires that two cardiac surgeons have independently examined the patient and the patient is under the care of a heart team: a cohesive, multidisciplinary team of medical professionals that includes a cardiothoracic surgeon and a cardiologist. We have learned from cardiothoracic surgeons who practice in other countries that the heart team is so valued that the heart team actually receives payments for time spent consulting about the best treatment option for a given patient. While we may still be a few steps away from such an integrated payment system, STS members are committed to the practice of patient oriented care and STS is very supportive of the Alternative Payment Model proposals. The STS recognizes the inevitability and enormous value of the concept of a bundled payment initiative.

However, we also recognize the need to stabilize the FFS system before such wholesale reforms are able to take place inasmuch as some specialties are not able to accommodate a full transition, as yet. More importantly, however, the true value in the Committee's proposal is the commitment to the development of a robust clinical registry infrastructure that is critical to quality-focused reforms. Without such an infrastructure, physicians, who use evidence-based medicine as the basis for their daily practice, will have no ability to document their outcomes and

compliance with evidence based medicine. We have focused our efforts at the specialty level, primarily because that reflects the organizational structure of much of medicine. It is not difficult to envision linkage of specialty level data along disease entity lines, much as the STS and ACC have linked their data in the ASCERT trial comparing the effectiveness of coronary bypass and percutaneous catheter based treatments for coronary artery disease. The critical issue is constructing a system and a professional ethic that emphasizes the collection of robust clinical and resource utilization data.

The Honorable Cathy McMorris Rodgers

1. Phase II of the House Energy and Commerce, health Subcommittee's proposal to repeal and replace the flawed Sustainable Growth (SGR) formula requests that providers submit "clinical practice improvement activities" to the HHS Secretary for approval. Clinical practice improvement activities are defined as activities that improve care delivery and, when effectively executed, are likely to result in improved health outcomes.

It has come to my attention that other medical providers are already using clinical decision support tools (embedded with medical specialty society appropriateness criteria) as an example of a clinical improvement activity. These tools are both software and web based.

One example is in the area of advanced diagnostic imaging. Clinical decision support tools, designed and used by radiologists, have demonstrated savings of health care dollars by reducing inappropriate utilization; reduction of patient exposure to unnecessary radiation; better care coordination; and shared decision making between the doctor and patient.

In light of this doctor-initiated success, please comment on the merits and concerns about using such technology in other areas of medicine.

Do you think it is feasible to consider this use of clinical decision support tools as one tool in the tool box of improving quality in healthcare?

Clinical decision support tools, and the evidence-based development of such tools, are an invaluable asset to the practice of medicine. However, these tools should never be construed as usurping a physician's medical expertise and judgment. Yet it is the critical interplay between the physician's judgment and the various clinical support tools available to him/her that is emerging as the new construct for medical care. The STS believes that the various clinical support tools (e.g. the ACC/AHA Guidelines for Coronary Artery Bypass Graft surgery and Percutaneous Coronary Intervention [stent/angioplasty]), are meant to augment and not supplant the physicians' decision making expertise.

The STS Risk Calculator is a publicly available, web-based tool that is used by surgeons to determine the best course of treatment, particularly when faced with a frail patient or one who has comorbid (i.e., co-existing) conditions. With millions of patients in its data repository, the STS Risk Calculator is so powerful that it is frequently cited in FDA approval and CMS coverage decisions as a criterion for the appropriate use of a treatment or therapy. For more

information about the STS Risk Calculator, please visit: http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models

The Society has developed several dozen risk-adjustment models for cardiothoracic surgery, all of which were derived using granular clinical data from thousands of patient records. STS has also developed sophisticated quality performance measures in all three sub-specialties of cardiothoracic surgery (Adult Cardiac Surgery, General Thoracic Surgery, and Congenital Cardiac Surgery), and 32 of these measures have either been endorsed or are in the process of being considered for endorsement by the National Quality Forum. In 2007, STS began developing a family of composite performance measures for the major procedures in CT Surgery, each one of which encompasses multiple domains of quality (e.g., mortality, morbidity, adherence to process measures). STS began this initiative with a composite measure for CABG, one of the most common cardiac surgical procedures. We have begun adding one new procedural composite measure each year (e.g., isolated aortic valve replacement, aortic valve replacement combined with CABG, mitral valve repair, etc.). The goal is develop a portfolio of these multidimensional composite measures that, in aggregate, will provide a broad perspective on the quality of a cardiac surgical practice."

In 2012, the STS National Database formed an Appropriateness Task Force. The goal of this task force is to map the variables in the STS National Database to specific guidelines recommendations and appropriate use criteria for coronary revascularization and CABG, as developed jointly by the American College of Cardiology, American Heart Association, and the Society of Thoracic Surgeons. Once this mapping is accomplished, it will be possible to immediately determine from the patient's medical history and coronary artery symptoms/anatomy, as entered in the STS Database, whether the patient meets nationally accepted recommendations for surgery. This information, in addition to patient-specific risk estimates from the STS National Database, will be extremely valuable elements of truly informed consent and shared decision making.

In the context of the Committee's proposal, STS believes that utilization of clinical decision support tools, or even steps towards adoption of clinical support tools, should be considered "Clinical Improvement Activities." We would suggest that such activities could be used to allow physicians to ramp up to full Phase II implementation, allowing the committee to reward providers who attempt to advance from Phase I more quickly.

Clearly, encouraging providers to engage in certain Clinical Improvement Activities will help to set a level playing field among providers and specialties. This variable will be an important component of the program at its inception and provides a mechanism for policy-makers to signal recognition of innovations in health care delivery that they deem to be useful for future quality improvement. Like the quality measures, the list of clinical practice improvement activities can be updated regularly to promote growth and improvement. We support the proposal that physicians have the ability to choose from a menu of clinical practice improvement activities.

The Honorable Gus Bilirakis

1. How much of these quality measures should be developed for the physician in general or should we have measures for specific diseases? How do we develop quality measures for rare diseases? These are hard to diagnose diseases with small populations. If we do develop metrics for specific conditions, how do we responsibly develop measurements for these conditions when research may be more limited?

Risk adjustment for rare procedures is difficult because of the limited numbers of patients to develop risk adjusted models. However, in these situations, one can still collect clinical data including patient demographics and risk factors, as well as outcomes and processes and structures. These aggregate data can, when done on a national basis, contribute to assessing performance, but in particular add information that could be useful in improving treatment quality and value.

Quality measures for the treatment of rare diagnoses, therefore, are best developed from national aggregate data, as exemplified by the STS National Database. The STS National Database was established in 1989 as an initiative for quality assessment, improvement, and patient safety among cardiothoracic surgeons. The STS National Database has three components—Adult Cardiac, General Thoracic, and Congenital Heart Surgery and is organized around specific procedures within all three of those categories. The Database houses more than five million surgical records and gathers information from more than 90% of the approximately 1,100 groups that perform cardiac surgery in the United States. Anesthesiology participation is available within the Congenital Heart Surgery Database and will be added to the Adult Cardiac Surgery Database in 2013. In 2011, the Database expanded to include international participants; currently, Brazil, Israel, Turkey and Jordan have surgeons participating in the Database. STS also operates the STS/ACC TVT Registry™ in a joint effort with the American College of Cardiology (ACC)[2].

In general, the STS National Database provides:

- a standardized, independently audited, nationally benchmarked tool for assessing the care of patients undergoing cardiothoracic operations;
- the opportunity to participate in national quality improvement efforts for cardiothoracic surgery that have an impact at the local, regional, and national levels;
- a mechanism to target specific areas for clinical practice improvement;
- the ability to investigate regional and national practice patterns in cardiothoracic surgery; and
- the ability to conduct clinical and comparative effectiveness research using national aggregate data sets.

[2] The TVT Registry™ is a benchmarking tool developed to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. Created by The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the TVT Registry is designed to monitor the safety and efficacy of this new procedure for the treatment of aortic stenosis. https://www.ncdr.com/TVT/Home/Default.aspx

We feel that the best way to organize a clinical registry, particularly as it relates to cardiothoracic surgery, is to develop it around specific procedures. Doing so facilitates the risk adjustment and public reporting models highlighted above. To the extent that a procedural model is not accessible for other specialties or primary care providers, disease-specific or other models may be usefully employed. Disease and procedure-specific registries are the building blocks, and these registries can be linked together to provide more comprehensive assessments of physicians, groups, hospitals, or systems.

The STS believes that it is the concept of a national data registry with continuous physician feedback that 1) allowed us to realize enormous success in improving care within our own specialty, and 2) becomes a blueprint for the creation of similar national data registries that will positively affect clinical care in other medical disciplines. Instead of focusing on outcomes following coronary artery bypass, the primary care physician might be more interested in guidelines for the treatment of community-acquired pneumonia and more importantly with the continuous feedback that helps him/her assess clinical effectiveness with better outcomes and decreased utilization of precious medical resources. The medical oncologist might be able to, for the first time, have an objective yardstick to measure not only how the patients are doing as compared to national standards but also how he/she is performing relative to medical peers.

We also believe that the physicians who best understand individual disease processes are in the best position to determine the most clinically relevant quality and outcomes measures, and we believe that external random audit processes will be essential for public and payor credibility. We recognize that there must be input and oversight from outside the specialty, but existing organizations, such as the National Quality Forum and the AMA PCPI that can provide this type of oversight. A measure that is appropriate for a cardiothoracic surgeon will surely not be appropriate for a primary care provider, but each medical and surgical specialty should determine clinically relevant outcomes to measure and should engage in the collection of outcomes data on important clinical diseases.

2. How much input should patient groups have and what type of input into the process should they have when determining these measures?
Input from patients is critical in the new era of health care delivery. The existence of national data registries and all of the clinical decision making tools is designed to facilitate the concept of shared decision making between the medical team and the patient. Significant improvements in quality outcomes will simply never be fully realized without meaningful patient participation in medical decisions.

Clinical registries can and should track outcomes that are uniquely important to patients such as use of metrics for patient satisfaction, quality of life, and adequacy of communication with providers, etc. As outlined in question 1, STS believes that a medical specialty should not be the sole developer of quality outcomes measures, and that patients and other interested parties should be able to participate in providing input on the types of outcomes to be measured. However, STS believes that each specialty or sub-specialty should be given the responsibility to receive input from patients and other interested groups and develop outcomes measures.

3. Should the system evolve to allow a direct feedback loop to the doctor? For example, the physician would know that they were paid X because they did or did not do Y to patient Z. Do we want that granular a system, or should the information and payment be done on a more aggregate level?

The STS National Database and related initiatives (public reporting, physician feedback reports, risk calculator, etc.) are structured around measuring patient outcomes using NQF-endorsed outcomes measures that rely on data reporting and analysis of aggregate data. If cost data were available, we would suggest that it too is only relevant in the context of patient outcomes, in the aggregate. STS is not in favor of piecemeal incentives or penalties at the individual procedure, disease, patient, or physician level for the reasons outlined previously.

4. Is it possible to use physician quality measures to encourage patients to better follow doctor's plan to manage diseases? For example, a newly diagnosed diabetic getting a follow up call by the doctor reminding them to check their blood sugar or reminding them to schedule an appointment with a nutritionist. Should these metrics be limited to what is done inside the physician's office?

We believe that outcomes measures should be given more weight in a pay-for quality scenario, but that process and structural measures are a valid way to begin to measure quality. In fact, this is another area where we feel that specialties can begin to make strides towards Phase II implementation in a ramp-up scenario. We would endorse the development and utilization of process measures, an example of which would be receiving credit for executing a "follow-up" call to a newly diagnosed diabetic to remind him to check his blood sugar, etc. Ultimately, however, the system should move toward measurement of longitudinal outcomes for the diabetic patient, such as Hemoglobin A1C levels, vision loss, limb loss, and ultimately survival. Structure and process measures can be used as a basis for registry reporting and physician feedback while data collection for the development of outcomes measures is underway.

5. Should the quality measures be weighted? If there are 10 things that a doctor can do to increase their performance measure, should they be rated equally for payment bonuses or weighted to account for time or difficulty?

We agree that measures should be weighted and propose the following breakdown, based on Donabedian's Triad of Structure, Process, and Outcome[3]:

- Outcomes: 50%
- Process: 30%
- Structural: 20%

[3] Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1966 Jul;44(3):Suppl:166-206.

Member Requests for the Record

The Honorable John D. Dingell

1. During the hearing, you agreed that Congress should look at the innovations and changes being made in the private sector when considering reforms to SGR. Would you please list some suggestions of what you feel might be useful?

Examples of such innovations include:

1. Global payments for episodes of care such as an operative procedure with single payments being made for all physician and hospital services (Medicare demonstration project, payments by some private payors for congenital heart operations).
2. The Virginia Cardiac Surgery Quality Initiative outlined above, and other regional initiatives including the Michigan-STS collaboration on adult cardiac surgery, and the Northern New England Cardiovascular Study Group.

The Honorable Michael Burgess

1. During the hearing, you mentioned the difficulty of obtaining some of the hospital data that CMS is releasing for developing performance metrics. You mentioned that asking CMS each time you request access to the data has become a bottleneck. Are there any other bottlenecks that you would identify for the committee?

As per above, since survival and resource utilization information is such an important part of the outcomes for cardiothoracic surgery and the associated quality improvement efforts, we urge that steps be taken to insure that clinical registries have access to claims data from CMS (and, hopefully, other payors) and outcomes (death) data from the Social Security Administration or another, accessible source. It is imperative that the committees' bill address this foundational issue. As mentioned earlier, the existence of a national registry that collects enormous amounts of clinical data on every patient without ever knowing the patient's ultimate outcome (e.g., alive or dead) is a critical impediment to the relevancy of the data registry. Similarly, not knowing whether a given outcome can be achieved with far less utilization of medical resources appears to be in direct contradistinction to the intent of the proposed legislation.

The ability to link clinical data with administrative data has opened up important new ways to assess the effectiveness of treatment options and offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as late mortality rate, readmission diagnoses, follow-up procedures, medication use, and total costs. STS has successfully linked its clinical data with CMS MEDPAR information, on a project-by-project basis, to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. Linked data are particularly useful in conducting comparative effectiveness research (CER) and establishing appropriateness of care. However, the value of claims data without the context provided by clinical information can be misconstrued and even dangerous to quality improvement because administrative data lack granularity in the clinical domains of diagnosis and therapy (including data about risk factors and severity of disease).

The longitudinal long-term outcomes information derived from these administrative data sources, along with the Social Security Death Master File (SSDMF), helps physicians to provide information to today's patients and families that can help them with shared decision making. Valid and reliable outcomes data give patients confidence in their medical interventions and demonstrate to patients and their families the durability and long-term benefits of medical procedures. It is important to note that STS, through its contracts with the Duke Clinical Research Institute, maintains the patient identifier data separately from the actual clinical and other demographic data, and the only patient level identified information that ever leaves the database is simply that the patient has a record in the database. When the follow-up information is returned from external entities, such as the SSDMF, it is linked back to the records in the de-identified database, but the flow of information is only in this direction. The externally derived data are used to supplement the data in the individual record, but these clinical, patient level data never leaves the database except in de-identified form.

Unfortunately, in November 2011, the Social Security Administration rescinded its policy of sharing state-reported death data as a part of the SSDMF. There are continuing efforts to further restrict access to the SSDMF so as to protect those listed in the file from identity theft. Balanced against these legitimate privacy concerns are the many advantages that SSDMF data can provide for quality improvement and medical research initiatives in the domains of comparative effectiveness research and outcomes assessment. Alternatively, the National Death Index could be supported with the appropriation of significantly greater resources to both lower the substantial cost of data (that makes is use not practical for most large clinical registries) and speed the availability of data from the current two year lag from death to availability of data documenting the death in the NDI.

However, we caution, again, that publication of claims data, without the clinical context and robust demographic information essential to risk-adjustment could have extremely harmful effects. For that reason we oppose current efforts by the administration to provide general public access to Medicare Claims data and request significant revisions to S. 1180 and/or any similar legislation that is considered in the House.

Additional barriers to implementation include the following:

Healthcare providers are now being required to produce objective evidence of the quality, safety and value of care to a variety of healthcare stakeholders. These quality related efforts necessitate the collection, analysis and reporting of different clinical data for each payor. Meaningful data collection often relies on the ability to use individually identifying patient information (particularly in analyses related to the value or sustainability of treatment interventions) in a careful manner that protects patient privacy. Risk-adjusted data collected in this way reliably results in the generation of new knowledge. The current regulatory structure fails to recognize that data collection for quality improvement purposes (including the retention of Personal Health Information) and the generation of "new knowledge" pose no substantial risk to the patient. In the STS National Database environment, privacy risk is minimized since individual patient records exist in the clinical registry in a rigorously de-identified format. As the HIPAA Privacy

Rule already addresses many of these patient privacy risks by imposing restrictions on how certain identifiable health information is collected by health plans, healthcare clearinghouses, and healthcare providers (''covered entities'' and their "business associates") and how it may be used and disclosed, it would appear superfluous and counterproductive to impose Common Rule consent requirements since compliance with HIPAA patient protections are already in place.

In addition, STS requests that Congress instruct CMS to work with the Department of Health and Human Services Office for Human Research Protections (OHRP) and Office for Civil Rights (OCR) to establish appropriate standards for quality improvement (QI) activities that will adequately protect patients without unnecessarily burdening QI efforts. Until that guidance is made available, it is inevitable that significant variability in interpreting and applying the Privacy and Common Rules will persist. Specifically, we ask that OHRP issue guidance that the Common Rule does not apply to the collection and analysis of identifiable patient information for quality assessment and improvement purposes where the entities collecting and analyzing the data (such as clinicians and a corresponding clinical data registry) are engaged in standard patient care and are in compliance with all applicable HIPAA requirements. Moreover, we ask that definitive language be included in federal guidance to allow for a clear differentiation between "human subjects research" and the processes related to the essential prospective analyses directed at advancing our national quality care objectives. In particular, the generation of new knowledge should be recognized as an expected and desired outcome of healthcare quality improvement projects; the processes related to the generation of such knowledge (through quality improvement initiatives that are part of healthcare operations) should therefore be exempt from a requirement for informed consent (on the basis that all HIPAA related regulations are adhered to in the course of clinical data collection and analysis).

STS believes that the most effective mechanisms to improve practice are the collection of clinical data on every case, the submission to a central registry to allow risk adjustment, and the feedback of these risk-adjusted data to the individual physician and practice. Removal of barriers to this process and provision of incentives to encourage participation in this process is essential, including addressing patient privacy issues. We also feel that the practice of defensive medicine is, perhaps, the biggest challenge physicians face when working with patients to identify the best plan for treatment. Having clinical data that support practice guidelines and clinical decision making gives both providers and patients' confidence that the best care at the right time is being provided and received. Reforming the tort system to rely on these advances can only serve to promote provider buy-in to the provisions outlined above. The issue of overutilization will never be fully addressed without a significant and meaningful level of tort reform.

Thank you again for the opportunity to provide testimony and respond to the Committee's questions If you need additional information, or if STS can be of any assistance, please contact Phil Bongiorno, STS Director of Government Relations, at pbongiorno@sts.org or 202-787-1221.

Sincerely,

Jeffrey B. Rich

Jeffrey B. Rich, MD
Past President

cal improvement of protocols or consent forms.[3] On the contrary, this practice seems to pose a significant risk of diminishing studies' ethical integrity. Fortunately, some ways of changing this system are being explored. Recently, the Office for Human Research Protections put out for public comment a proposal to receive direct authority to take action against IRBs — as distinct from the institutions conducting the research — for noncompliance with regulations.[4] The intent is to encourage greater reliance on outside (and central) IRBs by assuring the individual institutions participating in multisite studies that they would not be blamed if an outside IRB were responsible for violations.

Another approach to reducing the number of IRB reviews would be to have sponsors require the use of a central IRB as a condition for participating in a study. Nothing in the existing U.S. regulations would prevent them from doing so. The Department of Veterans Affairs currently operates exactly such a system for a select group of studies. In an attempt to constrain the duplication of review efforts for international multisite studies, the European Union is taking a different approach: it now restricts each participating country to a "single opinion" representing the ethics review for that country, "notwithstanding the number of Ethics Committees" involved.[5]

Any one or a combination of these approaches may turn out to be satisfactory. But recognizing that the problem with multiple-IRB review relates not merely to wasted time and effort but also to less-than-optimal protection of people who volunteer to participate in research should add urgency to our efforts to solve this problem.

The views expressed in this article are those of the author and are not necessarily those of the U.S. Department of Health and Human Services or its operating division, the Office of the Assistant Secretary for Health.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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This article (10.1056/NEJMp1005101) was published on October 13, 2010, at NEJM.org.

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Public Release of Clinical Outcomes Data — Online CABG Report Cards

Timothy G. Ferris, M.D., M.P.H., and David F. Torchiana, M.D.

On September 7, 2010, Consumers Union (publisher of *Consumer Reports*) reported the results of coronary-artery bypass grafting (CABG) procedures at 221 U.S. cardiac surgery programs.[1] The voluntary reporting of risk-adjusted outcomes in approximately 20% of U.S. cardiac surgery programs is a watershed event in health care accountability.

The reported ratings derive from a registry developed by the Society of Thoracic Surgeons (STS) in 1989. More than 90% of the approximately 1100 U.S. cardiac surgery programs participate in the registry. Registry data are collected from patients' charts and include key outcomes such as complications and death, the severity of preoperative illness, coexisting conditions, surgical technique, and medications. These data are maintained by the Duke Clinical Research Institute and are analyzed with the use of well-tested statistical methods. The data-collection and auditing methods, specifications of the measures, and statistical approaches have evolved over the course of two decades and reflect a substantial commitment by cardiac surgeons and their leadership.[2,3]

For years, participants in the STS registry have been examining these data and using them to make improvements. What does the public now get to see? Each surgical program that has chosen to make its data public is assigned a rating of one, two, or three stars. Stars are assigned on the basis of results on 11 performance measures (see table) that have been endorsed by the National Quality Forum. The rating depends on whether the risk-adjusted outcomes in a program fall be-

Measures of Quality Used by the Society of Thoracic Surgeons in the Ratings of Coronary-Artery Bypass Grafting (CABG) Programs.

Measure	Description
Postoperative renal failure	Percentage of patients (without preexisting renal failure) undergoing isolated CABG in whom postoperative renal failure developed or dialysis was required
Surgical reexploration	Percentage of patients undergoing isolated CABG who required a return to the operating room because of bleeding, tamponade, graft occlusion, or other cardiac reason
Antiplatelet medication at discharge	Percentage of patients undergoing isolated CABG who were receiving aspirin, safety-coated aspirin, or clopidogrel at discharge
Beta-blockade at discharge	Percentage of patients undergoing isolated CABG who were receiving beta-blockers at discharge
Antilipid treatment at discharge	Percentage of patients undergoing isolated CABG who were receiving a statin or other pharmacologic lipid-lowering regimen at discharge
Risk-adjusted operative mortality after CABG	Percentage of patients undergoing isolated CABG who died during the hospitalization in which the CABG was performed or within 30 days after the procedure
Preoperative beta-blockade	Percentage of patients undergoing isolated CABG who received beta-blockers within 24 hours before surgery
Prolonged intubation (ventilation)	Percentage of patients undergoing isolated CABG (without preexisting intubation or tracheostomy) who required intubation for more than 24 hours
Rate of deep sternal-wound infection	Percentage of patients undergoing isolated CABG in whom a deep sternal-wound infection developed within 30 days after the procedure
Stroke or cerebrovascular accident	Percentage of patients (without preexisting neurologic deficit) undergoing isolated CABG in whom a postoperative neurologic deficit developed that persisted for more than 24 hours
CABG using an internal thoracic artery	Percentage of CABG performed using an internal thoracic artery

low, are equal to, or exceed the average performance range. The performance thresholds are designed to ensure a 99% probability that outlier programs — those rated significantly below or above the mean and therefore given one and three stars, respectively — are truly below or above average. With the use of this method, 23 to 27% of the programs have been identified as outliers over the past 3 years. In addition to the star rating for overall performance, consumers see the star rating and actual performance scores (on a scale from 0 to 100) in four subcategories: 30-day survival ("patients have a 98% chance of surviving at least 30 days after the procedure and of being discharged from the hospital"), complications ("patients have an 89% chance of avoiding all five of the major complications"), use of appropriate medications ("patients have a 90% chance of receiving all four of the recommended medications"), and surgical technique ("patients have a 98% chance of receiving at least one optimal surgical graft").

The move on the part of the STS to make results available to the public will certainly trigger a cascade of responses. Advocates of transparency will point to the shortcomings of the ratings — the voluntary and therefore selective participation of programs (50 of the programs that have chosen to report their data have received three stars, whereas only 5 have received one star), the lack of long-term outcomes (e.g., 10-year survival, graft patency, and functional improvement), and the lack of physician-specific ratings. Expect such advocates to push for more. Nonparticipating cardiac surgery programs will come under pressure to allow the outcomes in their programs to be reported. Physicians in other surgical specialties that are amenable to this type of approach, such as orthopedics or vascular surgery, may be expected to follow suit. And this event will fuel the debate regarding the risks and benefits of public reporting, including the question of whether it assists patients in discriminating among sites of care. While these issues play out, several aspects of this release of ratings deserve attention.

First, years of pressure from policymakers, health care purchasers, and patient-advocacy groups to provide greater accountability played a major role in bringing this publication to fruition. Public reporting of outcomes has widespread support, and cardiac surgeons have been among the principal targets of these efforts. The first statewide report card on cardiac surgical performance was mandated in New York in 1989. Early experiences with pub-

lic reporting of the outcomes of cardiac surgery spurred efforts by the STS and others to improve cardiac surgery.[4] Although some consumer advocates pushing for transparency may view this release as a glass four-fifths empty — given the selectivity and number of programs reporting — the external pressure has been critical in stimulating improvement efforts within the medical profession.

Second, the publication of definitive analyses derived from clinical data can be a double-edged sword for providers. When performance reports are based on administrative data, physicians often justifiably argue that the data are flawed and the conclusions suspect. In contrast, with these new ratings, not only have the participants endorsed the methods, but they have volunteered to display performance results that carry the imprimatur of the physicians' specialty society. Experience with performance reporting in Massachusetts has shown that when the data and analyses are as good as possible, a public report of suboptimal performance requires a substantive public response: state Department of Public Health officials suspended a Massachusetts cardiac surgery program to conduct an external review, amidst substantial media attention, when the program was identified as a high-mortality outlier.

Third, the process of moving clinical data from the STS registry into the public domain has been long, complex, and expensive. As a member-supported organization, the STS navigated treacherous waters to bring its members to the point of permitting the publication of their data. Some key decisions facilitated this process: the STS reported group-level rather than physician-level data, rigorously validated its data-collection and risk-adjustment models, and selected a performance-classification system that maximized specificity. Such choices helped to mitigate physicians' biggest fear: the risk of misclassification. Moreover, cardiac surgery programs have been looking at these data for years, so there shouldn't be any surprises. The success that the STS has had in leading a nontrivial fraction of its members to agree to participate suggests that public reporting can be done in a way that doesn't alienate the profession.

There is no question about the need for accountability on the part of health care providers or the central role of measurement in the improvement of health care. Nonetheless, questions remain about the role of public reporting in improving health care. Performance measurements audited by regulators are one alternative, especially in situations in which the information is too complex for patients to use in discriminating among care sites. Insofar as public reporting drives improvement of all outcomes, it benefits everyone; insofar as risk aversion leads to changes in the population receiving an indicated service, the net effect can be nil or even negative.[5] Given the heterogeneity in the delivery of medical services, it should come as no surprise that we have developed multiple methods for assessing performance and encouraging accountability. Regardless of which approach proves most beneficial to patients, public reporting will increasingly be a fact of life for physicians.

By publishing ratings using the best available data, the STS has responded to the public in a way that attempts to both inform patients and mitigate physicians' fears. We hope that the experience of the STS can be applied to other initiatives that are aimed at bringing performance data derived from clinical sources to the public, thereby reducing the time and expense of this process. For example, this experience may contain lessons for the Centers for Medicare and Medicaid Services as it prepares to handle the wave of clinical data it will receive through the Physician Quality Reporting Initiative and the "meaningful use" program for electronic health records. At least some of these data will almost certainly be publicly reported. The STS's success suggests that reporting can be done in a way that physicians will support. Whether the STS approach is an anomaly or a precedent that other specialty groups will emulate remains to be seen.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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This article (10.1056/NEJMp1009423) was published on September 7, 2010, at NEJM.org.

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I. Introduction

The Data Analyses of The Society of Thoracic Surgeons (STS) National Adult Cardiac Surgery Database are published following each quarterly database harvest and the report is provided to each eligible STS database participant. This report is an important quality improvement tool for participants, allowing them to compare their risk-adjusted performance with that of similar participants, participants in their geographic region and the entire body of STS database participants.

This participant-specific report is unique to your organization. The data presented were collected during harvests from 2007, 2008 and 2009 of the STS Adult Cardiac Surgery Database at the Duke Clinical Research Institute (DCRI). The most recent procedure date included in this report is 12/31/2009. Data from previous harvests, when available, were also analyzed for the Executive Summary Section that presents longitudinal 10-year trends. Data in this report were subjected to identical data quality programs to make them consistent with the data specifications of the Adult Cardiac Surgery Database.

This Report Overview is provided as background to help participants understand and interpret the results. Throughout this document, variable short names are used. Detailed information on the STS variables, including variable short names and clinical definitions can be found at the STS website - http://www.sts.org under the STS National Database tab.

II. Report Organization

Beginning in 2008, with the introduction of quarterly harvests, STS Adult Cardiac Surgery Database participants receive harvest reports with alternating content. This change allows distribution of analysis results to database participants in a timelier manner and is consistent with the STS policy to provide NQF Measure and Composite Quality Ratings results based on a full 12 months of data ending each June or December. The table below shows which sections will be provided after each of the four annual harvests:

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Table 1. Quarterly Report Content

	Harvest 1 *data through 12/31*	Harvest 2 *data through 3/31*	Harvest 3 *data through 6/30*	Harvest 4 *data through 9/30*
Report Overview				
General	X	X	X	X
Risk-Adjustment Supplement	X	X	X	X
Composite Quality Ratings/NQF Measures	X		X	
Composite Quality Ratings	X		X	
NQF Measures	X		X	
Executive Summary	X	X	X	X
Major Procedures Mortality	X	X	X	X
Participant-Specific Cardiac Procedures	X	X	X	X
Regional Outcomes Comparison	X		X	
Other Procedures	X	X	X	X
Appendix: Participant-Specific Data Quality Summary	X		X	

Report Overview - General: Important information on the structure and content of the report, including risk-adjusted results.

Report Overview - Risk-adjustment Supplement: Information about how participants can utilize STS risk-adjustment locally including instructions for calculating certain risk-adjustment statistics.

Report Overview - STS Composite Quality Rating and NQF Measures Summary: Information about the calculation and interpretation of the STS Composite Quality Rating and the NQF measure results. (Harvest 1 and 3 only)

STS Composite Quality Rating and NQF Measures: This section contains the participant STS Composite Quality Rating and the participant and STS overall results on the NQF Cardiac Surgery Quality Measures. (Harvest 1 and 3 only)

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Executive Summary: This section displays overall database participant volume and procedure volume along with mortality and length of stay summaries. It displays annual distribution of all database procedures.

Major Procedures Mortality: This section displays unadjusted and risk-adjusted mortality for the combined group of major procedures for which a risk-adjustment model exists: Isolated CAB, Isolated Valve Replacement, and Valve Replacement + CAB procedures.

Participant-Specific Cardiac Procedures: The following sections display data for participant, a like-participant comparison group, and the overall STS for the following procedure classifications.

Isolated Coronary Artery Bypass	**(CAB)**
Isolated Aortic Valve Replacement	**(AV Replace)**
Aortic Valve Replacement + CAB	**(AV Replace + CAB)**
Isolated Mitral Valve Replacement	**(MV Replace)**
Mitral Valve Replacement + CAB	**(MV Replace + CAB)**
Isolated Mitral Valve Repair	**(MV Repair)**
Mitral Valve Repair + CAB	**(MV Repair + CAB)**

CAB data are also stratified into the following subsets: On-Pump, Off-Pump, First Operation, Reoperation.

Regional Outcomes Comparison: This section displays participant data alongside regional comparison data for selected outcomes. (Harvest 1 and 3 only)

Other Procedures: This section displays only overall STS data for other cardiac procedures - includes AVR+MVR, Pulmonic Valve, Tricuspid Valve, LVA, VSD, ASD, SVR, and Aortic Aneurysm procedures, and Ventricular Assist Device.

Appendix: Participant-Specific Data Quality Summary: This section provides a summary of your participating organization's specific data quality issues among CAB cases. (Harvest 1 and 3 only)

III. How to Read this Report

a. Patient Population

Records were included in this report if they met the following criteria:

- Patient age 18 or older
- Valid procedure classification (see Section III.b. below)
- Valid date of surgery

Please note that individual records have been excluded from certain analyses for which they are irrelevant. Footnotes about these exclusions have been provided throughout the report and a summary table of the exclusions has been provided in Section III.d.

The time window of procedures presented in this report varies depending on the section of the report:

STS Composite Quality Rating and NQF Measures (Harvest 1 and 3 only)	CAB: Valve, Valve + CAB:	Last 12 months Last 60 months
Executive Summary	Last 10 calendar years	
Major Procedures Mortality Summary	Last 3 calendar years	
Participant-Specific Cardiac Procedures	Participant: Like Group: STS:	Last 3 calendar years Last calendar year Last calendar year
Regional Outcomes Comparison (Harvest 1 and 3 only)	Participant: Region:	Last calendar year Last calendar year
Other Procedures	Last calendar year	

NOTE:

Not all participants have submitted data for the entire time period presented in this report.

b. Procedure Classification

The majority of this report represents the following seven procedure classifications:

Isolated Coronary Artery Bypass	(CAB)
Isolated Aortic Valve Replacement	(AV Replace)
Aortic Valve Replacement + CAB	(AV Replace + CAB)
Isolated Mitral Valve Replacement	(MV Replace)
Mitral Valve Replacement + CAB	(MV Replace + CAB)
Isolated Mitral Valve Repair	(MV Repair)
Mitral Valve Repair + CAB	(MV Repair + CAB)

Records were classified as one of the above if there were no other cardiac or non-cardiac procedures performed at the same time [exception: OCarACD (arrhythmia correction devices) was not a classification exclusion criterion]. See Table 12 for more details.

Lower volume cardiac procedures are summarized for the STS as a whole in the Other Procedures section. These include:

Aortic Valve + Mitral Valve Replacement
Pulmonic Valve
Tricuspid Valve
Left Ventricular Aneurysm
Ventricular Septal Defect
Atrial Septal Defect
Surgical Ventricular Restoration
Aortic Aneurysm: Ascending Aorta, Aortic Arch, Descending Aorta, and Thoracoabdominal Aorta
Ventricular Assist Device (VAD)

Except for Aortic Valve + Mitral Valve Replacement, these procedures are considered independently. It is possible, for instance, for a record to contain both a Pulmonic Valve procedure and a Tricuspid Valve procedure; that record would be counted in both categories.

c. Reporting Levels

Participant: Your Participant ID is used as the grouping identifier for reporting. The definition of participant varies among data contributors. A participant may be surgeon(s) from a single hospital or across multiple hospitals.

Like Group: The Like Group is a comparison group of STS participants that are most similar to the report participant with respect to annual site case volume and presence or absence of a surgical residency program. Like Groups are determined annually following Harvest 1. For each participant two Like Groups are created. The CAB Like Group is based on the participant's CAB procedure volume, and the Valve Like Group is based on the participant's valve procedure volume. The CAB Like Group is displayed for the Major Procedures Mortality summary and the CAB portion of the Participant-Specific Cardiac Procedures section. The Valve Like Group is displayed for the remainder of the Participant-Specific Cardiac Procedures section. See the Table below for details on Like Group determination. Annualized procedure volume is an average based on the past 3 years of data. The groups are structured such that an adequate number of participants/cases are assigned to each one. The smallest CABG like group (number of cases) contains 13,076 cases. The smallest CABG like group (number of participants) contains 12 participants. The smallest Valve like group (number of cases) contains 2,367 cases. The smallest Valve like group (number of participants) contains 28 participants.

NOTE: Infrequently, risk-adjusted results cannot be calculated for a Like Group due to small sample size and/or zero outcome events. In such instances, a '-' will be presented in place of a statistic.

Table 2. Definition of Like Group

	Annualized Procedure Volume	Surgical Residency*
CAB Like Groups		
	0-199 (low)	No
	0-199 (low)	Yes
	200-399 (moderate)	No
	200-399 (moderate)	Yes
	400+ (high)	No
	400+ (high)	Yes
Valve Like Groups		
	0-49 (low)	No
	0-49 (low)	Yes
	50-119 (moderate)	No
	50-119 (moderate)	Yes
	120+ (high)	No
	120+ (high)	Yes

* A participant is considered to have a surgical residency program if at least one of the hospitals for which data were submitted has a known residency program. Residency programs are identified via annual review of the list of accredited programs specializing in Thoracic Surgery of the American Council for Graduate Medical Education (ACGME), a private, non-profit council that evaluates and accredits medical residency programs in the United States.

Participant's Region: Participant data are compared to regional benchmark data in the Regional Outcomes Comparison section. For most participants the region is the state or province in which they are located. However, for states and provinces that do not contain enough participants to provide a meaningful comparison group, region is defined according to the following table (derived from the Dartmouth Atlas of Health Care).

Please refer to the map in the Regional Outcomes Comparison section (Harvest 1 and 3 only) to identify your region.

Table 3. Regions

Region	States / Provinces
New England	Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont
Middle Atlantic	New Jersey, New York, Pennsylvania
South Atlantic	Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
Great Lakes	Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central	Alabama, Kentucky, Mississippi, Tennessee
Great Plains	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central	Arkansas, Louisiana, Oklahoma, Texas
Mountain	Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific	Alaska, California, Hawaii, Oregon, Washington
Canada	Alberta, British Columbia, Manitoba, Nova Scotia, New Brunswick, Ontario, Quebec

d. Data Handling

Missing data
For dichotomous and categorical variables, percentages are calculated using all records, unless otherwise specified (See Inclusion/Exclusion Criteria below for specific restrictions). For continuous variables, missing data are not calculated into summary results or into mean and median calculations. The Case Count Report provided along with each harvest report indicates the number of cases used for each result in the report.

Zero values
For the analysis of Perfusion Time (PerfusTm) and Cross Clamp Time (XClampTm), zeros are not included in the calculation of means and medians.

Outlier Values
Values that have been determined to be aggregate outliers (see the Participant-Specific Data Quality Summary for more information on outliers – Harvest 1 and 3 only) are **bolded** within this report.

Inclusion/Exclusion Criteria
In nearly all cases, results represent the entire group of cases eligible for that section of the report (e.g. all isolated CAB procedures in the isolated CAB section of the report). However, certain variables must be analyzed using a restricted population. An example of such a variable is Discharge Location (DisLoctn). Analysis of this variable should only include those patients discharged from the hospital alive. Footnotes about such case selection restrictions appear in the report. Table 4 below contains a summary of these restrictions.

Table 4. Analysis Restrictions*

Data element	Inclusion/exclusion criteria
Hemodynamics & Catheterization	
EF < 40	Patients with measured EF
Pulmonary Hypertension	Patients with measured PA mean pressure
Comorbidities	
Previous PCI Stent	Patients with previous PCI
Preoperative and Discharge Medications	
Preop: ADP Inhibitors Discontinuation	Patients on ADP Inhibitors within 5 days
All Medications – eligible	Excludes contraindicated/not indicated
Operative Information	
Vein Harvest Technique	Patients with at least 1 harvested vein
Internal Mammary Artery Used	Excludes patients with prior CAB surgery
Postoperative Information:	
Initial Ventilation <6 Hours	Excludes patients extubated in OR
Additional Ventilation Hours	Patients reintubated
Additional ICU hours	Patients readmitted to the ICU
Complication	
Leg infection	Excludes patients with zero vein grafts
Arm infection	Excludes patients with zero vein grafts
Renal Failure	Excludes patients with preop dialysis
Atrial Fibrillation	Excludes patients with preop AFib
Discharge & Readmission	
Discharge Location	Excludes in-hospital mortalities
Discharge Medications	Excludes in-hospital mortalities
Readmission	Excludes in-hospital mortalities
Smoking Cessation Counseling	Excludes in-hospital mortalities and N/A responses
Cardiac Rehabilitation Referral	Excludes in-hospital mortalities and N/A responses

* See Table 2 of the STS Composite Quality Rating and NQF Measures Report Overview (Harvest 1 and 3 only) for specifics on inclusion/exclusion criteria for the STS Composite Quality Rating and NQF Measures sections of the report.

Data Warehouse Edits

When data arrive at the data warehouse, they are checked carefully for logical inconsistencies and parent/child variable relationship violations. Any inconsistencies or violations are communicated to participants in the detailed Data Quality Report that is generated automatically following each harvest file submission. If the data inconsistencies are not changed by the participant prior to harvest close, the data warehouse performs consistency edits and/or parent/child edits on the data in order for them to be analyzable. Participants are informed of such edits to their data in the Data Quality Report.

A complete list of data edits performed at the data warehouse is available at the STS website - http://www.sts.org - under the STS National Database tab.

NOTE: Commercial software vendors are encouraged, but not required, to incorporate edit checks for such data inconsistencies into their STS-certified software packages to reduce the number of data edits that must take place at the data warehouse.

e. Reported Variables

Because we have found that lengthy clinical outcomes reports are hard to read, this report does not contain every variable collected as part of the STS Adult Cardiac Surgery Database. Members of the STS and the DCRI carefully select the variables for inclusion in the report. Feedback from the participant sites is vital to this decision-making process.

The variables and data definitions used in this report are from Versions 2.35, 2.41, 2.52.1, and 2.61 Adult Cardiac Database Specifications.

PROCEDURE TIME WINDOW	ALLOWABLE DATA VERSION(S)
1/1999 - 12/2001	2.35
1/2002 - 6/2002	2.35, 2.41
7/2002 - 12/2003	2.41
1/2004 - 12/2004	2.41, 2.52.1
1/2005 - 6/2007	2.52.1
7/2007 - 12/2007	2.52.1, 2.61
1/2008 - 9/2009	2.61

Calculated Variables
Several report variables, such as Obesity, and Observed Operative Mortality are calculated using the STS variables and data definitions. Please refer to Table 13 at the back of this section of the Report Overview for a complete list of calculated variables.

f. Data Presentation

The tables and figures in this report primarily show variable means, medians, 25th and 75th percentiles, or percents.

Mean: A measure of central tendency that is computed by adding up all the individual values in the group and dividing by the number of the values in the group.

Median: A measure of central tendency that is the value under and over which 50% of the individual values lie.

25th percentile: The value under which 25% of the individual values lie.

75th percentile: The value under which 75% of the individual values lie.

The risk-adjusted outcomes in this report are presented as O/E ratios, estimated Odds Ratios, and risk-adjusted rates (see Section IV below for details). Each of

these is presented with **95% confidence intervals (CI)** – the range of values in which the analysts are 95% confident that the true value for the underlying population falls.

Indentation
Throughout the report, indentation indicates that indented lines are related to the un-indented lines in a hierarchical manner. Results on indented lines are generally not based upon a smaller denominator than the un-indented lines unless there is an explicit footnote to that effect. For instance for Isolated CABs in the *Participant-Specific Cardiac Procedures* report section, 'Previous PCI' is an un-indented line and the timing of the previous PCI (≤ 6hours prior to surgery, >6 hours prior to surgery) is on subsequent indented line(s). The denominator for both of these items is the same – the total number of isolated CAB procedures.

Dashes
A value of '-' indicates that there were no occurrences of a value for that variable in the data for that time period.

g. Comparisons to Like Group, Region and Overall STS

While we encourage participants to focus on how their results compare with those from their region, their like group, and national STS outcomes, a few words of caution are needed:

- There is a wide range in the volume of procedures submitted among participants. Those participants with low volume must be aware that their measured results are less stable as compared with those from a high volume participant (indicated by the wide confidence intervals surrounding low volume estimates).

- If an individual participant's results in a given region vary considerably from their peers, they can potentially alter that region's results. For example, if a participant erroneously reported their CAB patients all have a post-op stroke, then that region's aggregate stroke rate may be falsely elevated. Because of its size, the more stable benchmark will always be the overall STS results.

- Finally, it must be recalled that the current STS data have not been fully validated. While we believe that participants generally report accurate results, participants may vary in the degree to which they identify certain events (e.g. postoperative complications and 30-day mortality).

IV. Risk-Adjusted Results: Overview

a. What is risk adjustment?

The purpose of risk adjustment is to allow STS database participants to compare their performance with other participants (e.g. overall STS, like participants, region or state). By accounting for and controlling patient risk factors that are present prior to surgery, risk adjustment "levels the playing

field" as best as possible. Unadjusted event rates are not used for such comparisons because they are influenced by patient case-mix and disease severity, which vary from participant to participant. Comparing unadjusted event rates would unfairly penalize participants that perform operations on higher-risk patients. Risk adjustment more accurately represents a participant's performance relative to that of a reference group presented with the same patient population. Importantly, as these are indirectly standardized rates, it is often not appropriate to directly compare the risk-adjusted mortality rates of two specific participants unless their patient populations are relatively similar (Shahian DM, Normand S-LT. Comparison of "risk-adjusted" hospital outcomes. Circulation. 2008 Apr 15;117(15):1955-63).

b. STS risk-adjustment models

In conjunction with the 2.61 data version update, the STS Quality Measurement Taskforce substantially revised all existing risk models and introduced several new ones. The models were developed and tested using all cases from 1/1/2002-12/31/2006. These new models are referred to as the 2008 STS models. The previous STS risk models distributed with data version 2.52.1 are referred to as the 2004 STS models. Work is well underway on a set of manuscripts that will provide the details of model development process and the models themselves.

Beginning with cases performed in 2008 all risk-adjustment analyses for the STS Adult Cardiac Surgery Database report will be performed with the 2008 STS models. With the exception of STS Composite Quality Rating analyses, cases performed prior to 1/1/2008 will be analyzed with the previous set of models. See below for more details about the 2008 risk models.

NOTE:

- **Risk-adjusted results will only be provided for a time period of 6 or more months of data due to concerns for small sample size.**
- **Newly introduced models for valve and valve + CAB combinations will not be added into the report until at least 2009.**

The STS currently has 3 risk models: CAB, Valve, and Valve + CAB. The models apply to 7 specific surgical procedure classifications:

Table 5. Surgical procedure classifications for STS risk models

CAB model	
1. Isolated Coronary Artery Bypass	(CAB Only)
Valve model	
2. Isolated Aortic Valve Replacement	(AV Replace)
3. Isolated Mitral Valve Replacement	(MV Replace)
4. Isolated Mitral Valve Repair	(MV Repair)

Valve+CAB model	
5. Aortic Valve Replacement + CAB	(AV Replace + CAB)
6. Mitral Valve Replacement + CAB	(MV Replace + CAB)
7. Mitral Valve Repair + CAB	(MV Repair + CAB)

See Table 12 below for detailed definitions of these procedure classifications.

c. Model endpoints

Table 6 contains a complete listing and definition of all model outcomes. The STS is pleased to now have mortality and morbidity models for all of the procedure classifications in Table 5 above. Previously, morbidity endpoints were only modeled for the isolated CAB population.

NOTE: Newly introduced models for valve and valve + CAB combinations will not be added into the report until at least 2009.

Table 6. Definition of STS Risk Model Outcomes

Endpoint	Description
Operative Mortality	STS v2.61 Sequence number 3050 (MtOpD): Operative mortality includes both (1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days; and (2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure unless the cause of death is clearly unrelated to the operation.
Permanent Stroke	STS v2.61 Sequence number 2830 (CNStrokP): Postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in cerebral blood supply) that did not resolve within 24 hours.
Renal Failure	STS v2.61 Sequence number 2890 (CRenFail): Acute or worsening renal failure resulting in one or more of the following: 1. Increase of serum creatinine to > 2.0, and 2x most recent preoperative creatinine level. 2. A new requirement for dialysis postoperatively.
Prolonged Ventilation > 24 hours	STS v2.61 Sequence number 2860 (CPVntLng): Prolonged pulmonary ventilator > 24 hours. Include (but not limited to) causes such as ARDS, pulmonary edema, and/or any patient requiring mechanical ventilation > 24 hours postoperatively.

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Endpoint	Description
Deep Sternal Wound Infection	STS v2.61 Sequence number 2780 (CIStDeep): Deep sternal infection, within 30 days postoperatively, involving muscle, bone, and/or mediastinum REQUIRING OPERATIVE INTERVENTION. Must have ALL of the following conditions: 1. Wound opened with excision of tissue (I&D) or re-exploration of mediastinum 2. Positive culture 3. Treatment with antibiotics.
Reoperation For any reason	STS v2.61 Sequence numbers 2720 (COpReBld), 2730 (COpReVlv), 2740 (COpReGft), 2750 (COpReOth), 2760 (COpReNon): Reoperation for bleeding/tamponade, valvular dysfunction, graft occlusion, other cardiac reason, or non-cardiac reason
Major Morbidity or Operative Mortality	A composite endpoint defined as any of the outcomes listed in the first six rows of this table.
Short Stay: PLOS < 6 days *	Discharged alive and within 5 days of surgery
Long Stay: PLOS >14 days	Failure to be discharged within 14 days of surgery

*NOTE: The definition of the short length-of-stay endpoint differs from previous versions of the STS risk model. In the new definition, patients must be discharged alive in order to receive credit for a PLOS < 6 days.

d. Model patient populations

The models can be applied to all adult patients who fall into one of the 7 surgical procedure populations described above in Table 5 above, except as follows:

- The models will only calculate a predicted risk value for adult patients age 18 to 110 years.
- The models will only calculate a predicted risk value for those patients for whom both age and gender are known.
- The models for renal failure will NOT calculate a predicted risk value for any patients who are on dialysis preoperatively.

e. Missing data handling for models

It is important to understand how missing data values are handled when the STS risk-adjustment models are applied to patients with incomplete data. With the exception of age and gender, missing data values are imputed by assigning a likely substitute value. The algorithm used for missing data imputation is described below:

Required variables: Age and gender are required variables for all models. If either is missing, no value for predicted risk will be calculated.

Categorical variables: Missing data are generally assumed to have the lowest risk category. For example, if diabetes was not coded, it would be assumed to be "No"; if procedure priority were not coded, the procedure would be assumed to be "Elective." In most cases, the lowest risk category is also the most frequent.

Continuous variables: Table 7 shows the values assigned to missing data for continuous model variables.

Table 7. Imputation of Missing Continuous Variables

Model Variable	Model Imputation Information
Body Surface Area (BSA)	If gender is "Male" set BSA = 2.00m^2 If gender is "Female" set BSA = 1.75m^2
Ejection Fraction (EF)	CAB Model If CHF is no or missing, set EF = 50% If CHF is yes and gender is Male, set EF = 35% If CHF is yes and gender is Female, set EF = 45% Valve Model Set EF = 50% Valve+CAB Model If CHF is yes and gender is Male, set EF = 40% Otherwise, set EF = 50%
Last Preop Creatinine	Set CreatLst = 1.0

f. Discrimination and calibration of risk-adjustment models

At the time the 2008 STS risk models were developed, each model was tested to ensure there was a close fit between the model and the data. Outcomes may have changed since the time of model development, therefore it is important to assess whether the models continue to perform well on each subsequent harvest. Two important aspects of model performance that are assessed on a continual (per harvest) basis are calibration and discrimination.

Calibration: A model is said to be well calibrated if there is a close match between the observed number of deaths and the number of deaths predicted by the model. Typically, calibration is assessed on the population of interest overall, as well as in several subgroups. For example, it is common to compare observed vs. predicted event rates within 10 subgroups based on deciles of predicted risk.

In the past, we have found that risk-adjustment models that were developed several years ago are not well calibrated when applied to a contemporary data set. In general, older models tend to over-estimate risk relative to contemporary

experience because outcomes have improved over time. **To make the models more accurate, each model is re-calibrated each harvest.** This recalibration ensures that the total number of "events" predicted by the model will exactly match the actual number of events that was observed in the data. After this initial recalibration, calibration is then assessed graphically by plotting and comparing observed vs. predicted event rates within several patient subgroups. Because of the large number of models and subpopulations, these graphs are not provided in the report overview but are available on request.

Discrimination: A model is said to have good discrimination if it is able to distinguish patients who are likely to have an event from those who are not likely to have an event. A commonly used measure of discrimination is the C statistic (also known as the area under the ROC curve). The C statistic represents the probability that a patient who experienced an event (e.g. died) had a higher predicted risk compared to a patient who did not experience the event. The C statistic generally ranges from 0.5 to 1.0 with 0.5 representing no discrimination (i.e. a coin flip) and 1.0 representing perfect discrimination. C statistics for all STS models for the time period included in this report are presented in the Table 8 below.

Table 8. STS Model C Statistics (Discrimination) – 2009 Harvest 3
2004 STS Models – January 1, 2006 – December 31, 2007
2008 STS Models – January 1, 2008 – December 31, 2009

Isolated CAB

Model Endpoint	2004 STS Models	2008 STS Models
Operative Mortality	0.801	0.806
Permanent Stroke	0.701	0.708
Renal Failure	0.748	0.774
Prolonged Ventilation	0.746	0.755
Deep Sternal Wound Infection	0.657	0.686
Reoperation for any reason	0.653	0.659
Major Morbidity or Operative Mortality	0.717	0.725
Short Length of Stay	0.710	0.719
Prolonged Length of Stay	0.760	0.767

Isolated Valve

Model Endpoint	2004 STS Models	2008 STS Models
Operative Mortality	0.764	0.783
Permanent Stroke	NA	0.684
Renal Failure	NA	0.752
Prolonged Ventilation	NA	0.749
Deep Sternal Wound Infection	NA	0.659
Reoperation for any reason	NA	0.646
Major Morbidity or Operative Mortality	NA	0.718
Short Length of Stay	NA	0.744
Prolonged Length of Stay	NA	0.769

Valve + CAB

Model Endpoint	2004 STS Models	2008 STS Models
Operative Mortality	0.737	0.748
Permanent Stroke	NA	0.635
Renal Failure	NA	0.715
Prolonged Ventilation	NA	0.716
Deep Sternal Wound Infection	NA	0.704
Reoperation for any reason	NA	0.627
Major Morbidity or Operative Mortality	NA	0.699
Short Length of Stay	NA	0.729
Prolonged Length of Stay	NA	0.727

g. Predicted risk values

After information has been entered on a given case, the STS risk model (either from your STS software vendor or internal system) will provide a risk percentage for each of the outcomes. The risk percentage is the estimated percent chance of the outcome for a patient with the indicated risk factors. Please note that depending upon your vendor software, a risk percentage for each outcome might be calculated *as each question is answered*; therefore, the most reliable risk percentage will appear only after all available data have been entered.

Note on interpretation of values:
The inherent limitations of statistical risk-adjustment models should be kept in mind when interpreting risk percentage values for an individual patient. Risk adjustment attempts to take into account as many of the patient's risk factors as possible. However, there are some rare or difficult to measure factors that are not included in the STS risk-adjustment models and which may increase or decrease a patient's risk of an adverse outcome.

As with any statistical estimates, the risk percentage values should be supplemented by the professional judgment of the patient's healthcare provider, particularly their cardiac surgeon.

Impact of new models on predicted risk values
The STS is committed to updating its risk models approximately once every 3 years. The risk profiles of cardiothoracic surgery patients have been consistently worsening through time at the same time that outcomes of cardiothoracic surgery have improved through time. Therefore, it is normal and expected that predicted risk values calculated with the new model will be on average lower than those calculated with the old model.

h. Risk-adjusted summary statistics

The STS report uses two types of summary statistics to present risk-adjusted results: i) observed to expected (O/E) Ratios; and ii) model-based Odds Ratio (OR) estimates. Because each of these statistics has advantages, the STS has decided to provide both in the report. As discussed in the interpretation manual (next section of this report overview), the interpretations of the Odds Ratio and O/E Ratio are similar. It is the method of estimating these quantities that differs.

O/E Ratio
The O/E Ratio is the ratio of a participant's number (or percent) of observed outcome events relative to the number (or percent) of outcome events that is expected (predicted) by the STS risk-adjustment model, based on the participant's case mix. See Section IV.d. for information on how to interpret the O/E Ratio.

Estimated Odds Ratio
The other main summary statistic, the estimated Odds Ratio, is obtained by fitting a set of hierarchical logistic regression models to the harvested data. These models are estimated every six months in conjunction with generating the report. They are only used for the current report and are not used subsequently. Unlike the "STS risk-adjustment models" described in Section IV.b., these models cannot be incorporated into your STS certified software.

In a hierarchical logistic regression model, the probability that a patient experiences an adverse event is assumed to depend on both patient characteristics (e.g. patient risk factors) as well as the participant (e.g. performance). The Odds Ratio measures the effect that the participant has on a patient's probability of experiencing an adverse event. The interpretation of the Odds Ratio is similar to that of the O/E Ratio in that smaller Odds Ratios imply better performance. See Section IV.d. for information on how to interpret the Odds Ratio.

Comparison of O/E Ratios and Odds Ratios
Because each of these statistics has its advantages, the STS has decided to provide both in the report. The benefit of O/E Ratios is that they are familiar to many surgeons and are simple to compute using an STS-certified software package. The hierarchical models used to create the estimated Odds Ratios do not provide a formula that can be incorporated into a software package. The main benefit of Odds Ratios obtained from hierarchical models is that they provide a more reliable estimate of performance for hospitals with a small number of patients.

Because hierarchical models borrow information across participants when estimating performance for each individual participant, risk-adjusted statistics are closer to the overall STS average than under the non-hierarchical approach. For example, although a participant might have zero events this year, the best estimate of long-run performance is not 0%, but something higher and closer to the overall STS average. How much higher depends on sample size. If a

participant has a very large sample size, then there is considerable evidence in support of 0% being the true value, and it does not move very much with the hierarchical "shrinkage estimators". However, if the participant has a relatively small sample size, it is a lot more likely that 0 events was simply a chance occurrence rather than a reflection of true performance. In such cases, the overall mean from all participants is given more weight and the observed 0% mortality is "shrunken" toward that mean.

This approach, although intuitively not satisfying to the participant with 0 events, ultimately allows for more accurate risk-adjustment results since it removes some of the instability caused by smaller participants with extreme results. It also protects participants who might have very high observed mortality based on a very small sample size, when in reality that was a reflection of random chance. Their results would similarly be shrunk towards the STS mean.

The following journal article contains more detailed and technical discussion of the hierarchical approach to risk-adjustment: Christiansen CL, Morris CN. Improving the Statistical Approach to Health Care Provider Profiling. *Ann Intern Med.* 1997;127:764-768.

i. Interpretation manual

When the risk-adjustment models are applied for the purposes of this report, several statistics are computed that allow for performance comparison: O/E Ratios, Odds Ratios and Risk-adjusted rates. The following sample page illustrates how these risk-adjusted statistics appear in the report for mortality. **Please note that expected/predicted rates are no longer provided in the report**. Please see item *d. STS Certified Software Package Predicted Risk Scores* in the Report Overview Risk-adjustment Supplement for information on how to calculate expected/predicted rates using results from your STS data software vendor.

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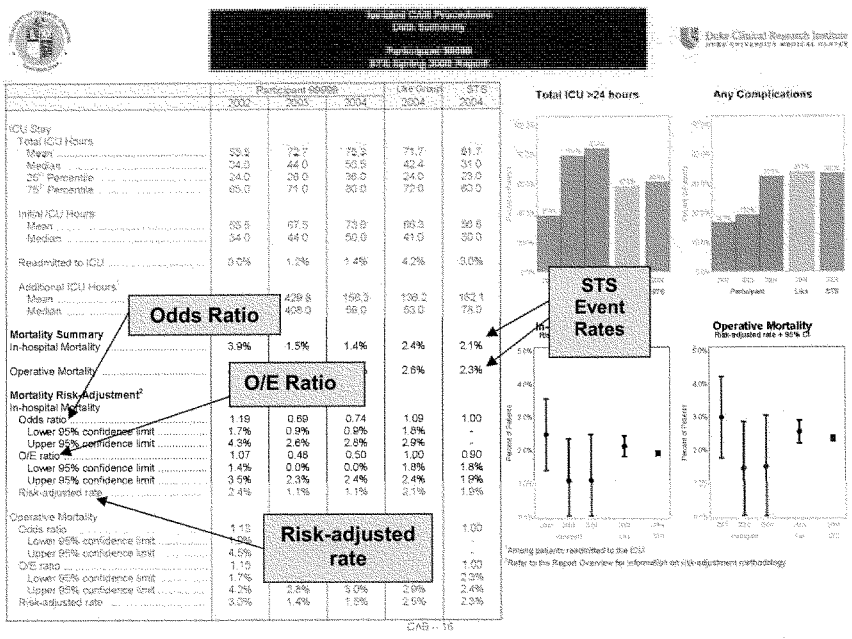

O/E Ratio
The O/E Ratio is a statistic that allows a participant to gauge whether their observed outcomes were better, the same, or worse than what would be expected given the existing underlying risk factors of the patients. Table 9 below contains details for interpreting specific O/E Ratio values. In general, smaller O/E Ratios imply better performance. See Section IV.c and the Report Overview Risk-adjustment Supplement for more details about how the O/E Ratio is calculated.

Starting in 2005, STS risk-adjustment models are re-calibrated each year to make them as up-to-date as possible when assessing performance during a given year. This re-calibration is needed because overall STS performance improves in the interval between development and subsequent updating of the STS risk-adjustment models. While updating the STS Risk-adjustment models more frequently is the alternative to re-calibration, it is currently not a feasible option since vendors currently only update their risk-adjustment models at the time of a data specification upgrade. Because the models are re-calibrated for each year included in the report, the O/E Ratio reflects performance relative to the STS average during that calendar year. This allows participants to benchmark their performance relative to a contemporary standard. Model recalibration was not performed prior to the Spring 2005 report so participants

may have seen a shift in their performance from the last time O/E Ratios were provided in the report without recalibration (Spring 2004).

The following is an example of why the re-calibration is needed and why a participant may have seen a shift in their performance. For a hypothetical participant 99999 the 2003 CAB operative mortality O/E Ratio was 0.90 in the Spring 2004 report. Because the risk-adjustment model was estimated using data from 1997-1999, an appropriate interpretation would be that participant 99999 performed better in 2003 than the average participant performed during1997-1999. Under the same methods and for the same time period, the overall STS mortality O/E Ratio was 0.80. In this light, participant 99999's O/E of 0.90 is actually worse than the STS overall O/E of 0.80. Because of the dynamic of overall improving participant performance through time, a more appropriate comparison group for participants is their current peer groups – the average STS participant during a given year. With the new approach to re-calibrate the models each year, the overall STS O/E is always 1.0 and for the above example, participant 99999's O/E becomes 1.125 (=0.90/0.80).

Because of this calibration, STS certified software cannot directly produce the O/E Ratios in this report. However, we have used a re-calibration method that makes it easy for participants to reproduce our results, if desired. See the Report Overview - Risk Adjustment Supplement for information about how the re-calibrated O/E Ratios can be achieved locally.

Odds Ratio
Similar to the O/E Ratio, the Odds Ratio is a statistic that allows a participant to gauge its performance relative to other participants after adjusting for patient risk factors. More specifically, the Odds Ratio is the ratio of the predicted odds of an outcome for a patient relative to what it would be if the surgery were to be performed by an "average" STS participant. The "odds" of an outcome is closely related to the probability of an outcome and is used in these calculations for technical reasons. See Section IV.c for additional details about the Odds Ratio and how it differs from the O/E Ratio. The interpretation of the estimated Odds Ratio is similar to the interpretation of the O/E Ratio with smaller Odds Ratios implying better performance.

The following table illustrates the possible interpretations of the O/E Ratio.

Table 9. O/E Ratio Interpretations*

Statistic	Interpretation
O/E Ratio > 1	When the O/E Ratio is greater than 1, the participant had an observed outcome level that was greater than expected. The participant performed worse than expected.
O/E Ratio < 1	When the O/E Ratio is less than 1, the participant had an observed outcome level that was less than expected. The participant performed better than expected
O/E Ratio = 1	When the O/E Ratio is 1, the participant had an observed outcome level equal to expected. The participant performed as expected.

* The interpretations in this table can also be roughly extended to Odds Ratios - values less than 1 imply better than average performance, values of 1 imply average performance and values over 1 imply worse than average performance. Note that the Odds Ratio will generally be closer to 1.0 than the O/E Ratio. It is possible that these two measures will be discrepant, but only if they are close to 1.0.

Risk-adjusted rates

Risk-adjusted rates are calculated by multiplying the O/E Ratio by the overall STS unadjusted event rate for that time period (See the Report Overview Risk Adjustment Supplement for more details on calculation of the risk-adjusted rate). Because the risk-adjusted rate is so closely related to the O/E Ratio, the information provided by these two statistics is similar and the choice of which statistic to use is really only a choice of unit of measure. Although one advantage of the O/E Ratio is that it is centered around 1.0 regardless of the outcome being measured, the risk-adjusted rates have the advantage that they can be easily interpreted as a clinically meaningful outcome event percent on a familiar scale.

The following table illustrates the possible interpretations of the risk-adjusted rate.

Table 10. Risk-adjusted Rate Interpretations

Statistic	Interpretation
Risk-adjusted rate > STS event rate	When the risk-adjusted rate for a particular adverse outcome is greater than the STS average rate, then the participant had more of those outcomes than expected given their case-mix.
Risk-adjusted rate < STS event rate	When the risk-adjusted rate for a particular adverse outcome is less than the STS average rate, then the participant had less of those outcomes than expected given their case-mix.
Risk-adjusted rate = STS event rate	When the risk-adjusted rate for a particular adverse outcome is equal to the STS average rate, then the participant had the same number of those outcomes as expected given their case-mix.

95% Confidence Intervals
The estimated Odds Ratios and the O/E Ratios provided in the report are accompanied by upper and lower 95% Confidence Intervals. The 95% Confidence Intervals indicate the range of values within which the analysts are 95% confident that the true value for the underlying population falls. (The true population value is the value that would be observed hypothetically in a very large sample of patients.) If the upper and lower bounds of the 95% Confidence Intervals for a participant contain the overall STS value, then the value for the participant is not statistically different from the STS overall.

Sample risk-adjustment data and interpretation
Table 11a below contains hypothetical data on 3 participants and the overall STS. This information is provided as a tool to aid in the interpretation of report data. The table is followed by text descriptions of how each of the 3 hypothetical participants' results would be interpreted. Table 11b below contains the same sample data with a brief interpretation summary next to each value or set of values.

Table 11a. Sample Data

Example – CAB Mortality				
	Participant A	Participant B	Participant C	STS
# procedures	495	575	1462	345,674
# outcome events	5	13	37	6,913
Observed mortality %	1.0%	2.3%	2.5%	2.0%
Expected mortality %	3.4%	2.1%	2.5%	2.0%
Odds Ratio	0.40	1.02	1.00	1.00
Odds Ratio 95% CI	(0.30, 0.82)	(0.63, 1.64)	(0.73, 1.40)	—
O/E Ratio	0.29	1.10	1.00	1.00
O/E Ratio 95% CI	(0.00, – 0.75)	(0.86 – 1.34)	(0.69 – 1.40)	—
Risk-adjusted rate	0.58% (0.29 x 2.0%)	2.2% (1.10 x 2.0%)	2.0% (1.00 x 2.0%)	—

NOTE: Because the numbers in the table were calculated using nonrounded values, you may not be able to duplicate identical values.

Participant A:
Participant A had a higher than average expected mortality (3.4%) but lower than average observed mortality (1.0%) which combined to produce a highly favorable O/E Ratio (0.29 = 1.0/3.4; well below 1.0). The risk-adjusted rate (0.58%) also points to lower-than-expected mortality in that it is lower than the overall STS mortality rate. The estimated Odds Ratio is 0.40, which is less than 1.0. This means that the predicted odds of mortality for a patient undergoing surgery at participant A is lower than it would be if the same patient were instead having surgery at an "average" STS hospital. The predicted odds of death for any patient treated at participant A is lower compared to an average hospital by a factor of 40% (= 0.40 x 100%). Because the 95% confidence interval on both the Odds Ratio and the O/E Ratio do not include the STS value (1.0) the favorable mortality results are unlikely to be due to chance variation. In other words, the lower-than-expected mortality is statistically significant.

Participant B:
Participant B's observed mortality rate was 2.3% (= 13/575 x 100). The expected mortality rate of 2.1% is obtained from the STS CAB mortality model. It is a function of the participant's patient case-mix and cannot be derived from other numbers in the table. The O/E Ratio is 1.10 (= 2.3/2.1). The fact that the O/E is greater than 1.0 implies that the observed mortality (2.3%) was larger than the expected mortality rate (2.1%). Specifically, the observed mortality exceeded the expected rate by 10% (= 100% x [O/E – 1]). Finally, the estimated Odds Ratio (1.02) is greater than 1.0. This means that the predicted risk of death for a patient having surgery at participant B is larger than the predicted risk if the same patient was instead having surgery at an "average" STS hospital. The confidence interval on the Odds Ratio extends from below 1.0 to above 1.0 (from 0.63 to 1.64). Because both the Odds Ratio and the O/E Ratio confidence intervals

include the STS value (1.0), there is uncertainty about whether the true risk of mortality for a future hypothetical patient is lower or higher than average. The excess mortality observed at participant B may be attributable to chance variation; it is not statistically significant.

Participant C:
Participant C's observed mortality rate (2.5%) is higher than the overall STS average mortality rate (2.0%). However, its expected mortality rate (2.5%) is also higher than average (2.0%), reflecting a riskier than average patient population. By coincidence, the observed mortality rate matches the expected mortality rate exactly. As a result, the O/E is exactly equal to 1.0 and the participant's risk-adjusted mortality rate is equal to the overall STS average (2.0% = 1.0 x 2.0%). This is uncommon. Because the expected number of deaths is usually a fraction, whereas the observed number is a whole number, the observed mortality rate is rarely equal to the expected rate.

Table 11b. Sample Data and Interpretation

Example – CAB Mortality				
	Participant A	Participant B	Participant C	STS
# procedures	495	575	1462	345,674
# outcome events	5	13	37	6,913
Observed mortality %	1.0% **↓ Expected 2.0%**	2.3% **↑ Expected 2.0%**	2.5% **↑ Expected 2.0%**	2.0%
Expected mortality %	3.4% **↑ Expected 2.0%**	2.1% **↑ Expected 2.0%**	2.5% **↑ Expected 2.0%**	2.0%
Odds Ratio	0.40 **<1.0; Odds of death are better than at average STS site**	1.02 **>1.0; Odds of death are worse than at average STS site**	1.00 **=1.0; Odds of death are same as at average STS site**	1.00
Odds Ratio 95% CI	(0.30, 0.82) **Does not include STS 1.0=Statistically Significantly different**	(0.63, 1.64) **Does include STS 1.0=Not Statistically Significantly different**	(0.73, 1.40) **Does include STS 1.0=Not Statistically Significantly different**	—
O/E Ratio	0.29 **<1.0=Better than Expected**	1.10 **>1.0=Worse than Expected**	1.00 **=1.0=As Expected**	1.00
O/E Ratio 95% CI	(0.00 – 0.75) **Does not include STS 1.0=Statistically Significantly different**	(0.86 – 1.34) **Does include STS 1.0=Not Statistically Significantly different**	(0.69 – 1.40) **Does include STS 1.0=Not Statistically Significantly different**	—
Risk-adjusted rate	0.58% (0.29 x 2.0%) **O/E*STS National** **↓ STS**	2.2% (1.10 x 2.0%) **O/E*STS National** **↑ STS**	2.0% (1.00 x 2.0%) **O/E*STS National** **= STS**	—

A note on interpretation
Participants that have results that are statistically different from the STS (the range between participant Confidence Intervals does not contain the STS value) should approach the use of that information with caution. Despite the utility of risk-adjustment to allow for fair comparisons, certain limitations should be kept in mind:

Extreme values are possible due to chance. If a surgeon only operated one time, the surgeon's observed mortality rate would either be 0% (= 0/1 x 100%) or 100% (= 1/1 x 100%). A mortality rate of 0% would be extremely low; 100% would be extremely high. Neither outcome would accurately reflect the surgeon's true ability, which probably lies somewhere between 0% and 100%. Because surgical outcomes have a random component, a large sample of patient operations is required in order to accurately measure a surgeon's performance. Even with one hundred patients, the death of a single patient can cause the mortality rate to jump by 1%. (The risk-adjusted mortality will also be substantially changed by a single patient outcome.) The exact value of a statistic such as the observed mortality rate or the observed to expected ratio must always be considered in conjunction with its confidence Interval, which shows the range of plausible values based on the sample size.

Variations in coding of risk factors could explain extreme values. The validity of the risk-adjusted results relies on consistent and accurate coding of risk factors and surgical outcomes. In reality, there may be some variation in the way risk factors and outcomes are coded by two different participants. If one hospital tends to over-state the risk profiles of its patients while another hospital under-states the risk profiles of its patients, the hospital that over-states the risk profiles will have an unfair advantage. To minimize bias, it is essential to pay close attention to STS data definitions when coding events and risk factors.

Not all risk factors are captured in the model. Risk-adjustment attempts to level the playing field by adjusting for the risk profiles of the participant's patient population. However, there are potentially difficult to measure factors that are not included in the risk adjustment model and which may increase or decrease a patient's risk of an adverse outcome. For this reason, two patients having exactly the same *measured* risk factors prior to surgery might actually have substantially different real risks. If a participant tends to treat patients that are at greater or lower risk than they might appear based on the measured risk factors, this may bias their risk-adjusted results upward or downward.

V. Participant-Specific Data Quality Summary

Information about your participant organization's data quality is provided in the Participant-Specific Data Quality Summary (Harvest 1 and 3 only) to help you interpret and weight your reported results. We encourage you to review this information to help you assess the accuracy and reliability of your report.

Table 12. Procedure Identification Table

Variable Short Name	CAB Only	AV Replace	AV Replace + CAB	MV Replace	MV Replace + CAB	AV Replace + MV Replace	MV Repair	MV Repair + CAB
OpCAB	Yes	No/Missing	Yes	No/Missing	Yes	No/Missing	No/Missing	Yes
OpValve	No/Missing	Yes	Yes	Yes	Yes	Yes	Yes	Yes
VAD	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OpAortic	No/Missing	Replacement	Replacement	No/Missing	No/Missing	Replacement	No/Missing	No/Missing
OpMitral	No/Missing	No/Missing	No/Missing	Replacement	Replacement	Replacement	**	**
OpTricus	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OpPulm	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OpONCard	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OpOCard	Do not use OpOCard for exclusions. Use specific variables below.							
OCarLVA	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarVSD	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarASD	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarBati	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarSVR	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarCong	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarLasr	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarTrma	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarCrTx	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarACD	Do not use OCarACD for exclusions.							
OCarAFib	None/Missing	None/Missing	None/Missing	None/Missing	None/Missing	None/Missing	None/Missing	None/Missing
ONCAoAn	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing
OCarOthr	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing	No/Missing

** Annuloplasty Only or Reconstruction w/ Annuloplasty or Reconstruction w/out Annuloplasty.

Table 13. Calculated Variables

Demographics	Body Mass Index (BMI)	BMI = (**WeightKg**) / (**HeightCm** / 100)^2. Note: BMI categories (underweight, normal, etc.) are those accepted by the National Institutes of Health and represent a departure from previous STS reports.
	Multiple Races	When more than one race is indicated: **RaceCaucasian, RaceBlack, RaceAsian, RaceNativeAm, RacNativePacific, RaceOther.** Multiple Races is only calculated for data version 2.61 records.
Hospitalization	Total Length of Stay	Total length of stay is the number of days from the date of admission (**AdmitDt**) to the date of discharge (**DischDT**).
	Post-procedure Length of Stay	Post-procedure length of stay is the number of days from the date of surgery (**SurgDT**) to the date of discharge (**DischDT**).
	Short Post-procedure Length of Stay	For the time period through 12/31/2007, a "short stay" was when the post-procedure length of stay was less than 6 days. Beginning 1/1/2008 this definition was changed to take into account inhospital mortality - a "short stay" is when the patient was *discharged alive* and the post-procedure length of stay is less than six days.
	Long Post-procedure Length of Stay	A "long stay" is when the post-procedure length of stay is greater than fourteen days.
Previous Interventions	Previous Cardiac Surgery	When the patient has undergone any previous CAB operations, valve operations, or other cardiac operations (with or without cardio-pulmonary bypass). For versions 2.35 and 2.41, the database variables involved in this determination are: **PrCBNum, PrCNNum, PrCAB, PrValve, PrOthCar**. Beginning with data version 2.52.1, the variables involved in this determination are **Incidenc, PrCAB, PrValve, PrOthCar**.

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	First Reoperation/Second+ Reoperation	For those patients with a previous cardiac surgery, indication of the number of previous surgeries. For versions 2.35 and 2.41, the database variables involved in this determination are: **PrCBNum**, **PrCNNum**, **PrCAB**, **PrValve**, **PrOthCar**. Beginning with data version 2.52.1, the variables involved in this determination are **Incidenc**, **PrCAB**, **PrValve**, **PrOthCar**.
	Previous PCI	Whether the patient has undergone any previous PCI. For versions 2.35 and 2.41, the database variables involved in this determination are: **PrNSStnt** and **PrPTCA**. Beginning with data version 2.52.1, the variable involved in this determination is **POCPCI**.
	Timing of Previous PCI	For versions 2.35 and 2.41 if patient had both a **PrNSStnt** and a **PrPTCA**, timing was determined by the first to occur. Beginning with data version 2.52.1, timing is determined with the variable **POCPCIIn**.
Operative Information	Distal Anastomoses – Total	Total number of distal anastomoses is the number with arterial conduits plus the number with vein grafts.
	Internal Mammary Artery Used	Any of the following internal mammary arteries: left, right, both
	Radial Artery Used	Any of the following radial arteries used: left, right, both
	Off-Pump Procedure	For version 2.35 data, a procedure is assumed to be off-pump if cardioplegia is not indicated as used and perfusion time equals zero minutes. For version 2.41 data, the variable **CPBUsed** reflected the pump status of a procedure. For data versions 2.52.1 and 2.61, **CPBUtil** is used.
	Skin Incision Duration	Time interval between incision start date/time (**SIStartT**) and incision stop date/time (**SIStopT**).
	OR Duration	Time interval between OR entry date/time (**OREntryDT**) and OR exit date/time (**ORExitDT**)
	Clotting Agents	Any one of the following intraop medications were indicated: **IMedAprot, IMedEACA, IMedDesmo, IMedTran.** Clotting Agents is only calculated for data version 2.61 records.

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Postoperative Information	Initial Ventilation Hours	Prior to data version 2.61 initial ventilation hours were captured in a single variable, **VentHrsI.** Beginning with data version 2.61 initial ventilation hours is a variable calculated as the number of hours between **ORExitDT** and **ExtubateDT**
	Total Ventilation Hours	Prior to data version 2.61 total postoperative ventilation hours were captured in a single variable, **VentHrs.** Beginning with data version 2.61 total postoperative ventilation hours is a variable calculated as the sum of the calculated initial ventilations hours and the variable additional ventilation hours (**VentHrsA**)
	Total Blood Products	The sums of the individual intraoperative and postoperative blood product units.
Complications	Any Major Complications or Mortality	This is a measure of combined outcomes. It is true if any of the following are indicated: Operative mortality, reoperation for any cause, permanent stroke, prolonged ventilation, deep sternal wound infection, or renal failure.
	Any Neurological Complications	Any of the neurological complications found on the STS data collection form.:
	Any Reoperation Complications	Reoperation for any of the reasons found on the STS data collection form.
	Any Vascular Complications	Any of the vascular complications found on the STS data collection form.
	Any Infection Complications	Any of the infection complications found on the STS data collection form.
	Any Pulmonary Complications	Any of the pulmonary complications found on the STS data collection form.
	Any Other Complications	Any of the other complications found on the STS data collection form.
Mortality	Observed Operative Mortality	Operative Mortality (**MtOpD**) adjusted for between-variable inconsistencies.

NOTE: Variable short names are bolded

Table 14. STS Risk Model Variables – 2008 Models

CAB	Operative Mortality	Stroke	Renal Failure	Prolonged Ventilation	Deep Stern Infx	Reop	Mortality/ Morbidity	Length of Stay>14	Length of Stay<6
B. Demographics									
Patient Age (140)	X	X	X	X	X	X	X	X	X
Gender (150)	X	X	X	X	X	X	X	X	X
RaceBlack (192)		X	X	X	X	X	X	X	X
RaceAsian (193)		X	X	X	X	X	X	X	X
Ethnicity (199)		X	X	X	X	X	X	X	X
D. Risk Factors									
Weight (350)	X	X	X	X	X	X	X	X	X
Height (360)	X	X	X	X	X	X	X	X	X
Diabetes (400)	X	X	X	X	X	X	X	X	X
Diabetes Control (410)	X	X	X	X	X	X	X	X	X
Last Preop Creatinine Level (430)	X	X	X	X	X	X	X	X	X
Renal Failure-Dialysis (450)	X	X	NA	X	X	X	X	X	X
Hypertension (460)		X	X	X			X	X	X
Infectious Endocarditis Type (500)									
Chronic Lung Disease (510)	X		X	X	X	X	X	X	X
Immunosuppressive Treatment (520)	X		X	X		X	X	X	X
Peripheral Arterial Disease (530)	X	X	X	X	X	X	X	X	X
Cerebrovascular Disease (540)	X	X	X	X		X	X	X	X
Cerebrovascular Accident (552)	X	X	X	X		X	X	X	X
E. Previous Interventions									
Previous CAB (600)	X	X	X	X	X	X	X	X	X
Previous Valve (610)	X	X	X	X	X	X	X	X	X
Previous PCI Interval (670)	X		X	X		X	X	X	X
F. Preoperative Cardiac Status									
Previous Myocardial Infarction Timing (760)	X	X	X	X			X	X	X
Heart Failure (770)	X		X	X	X	X	X	X	X
Classification-NYHA (775)	X		X	X	X	X	X	X	X
Cardiac Presentation on Admission (791)	X		X	X					
Cardiogenic Shock (810)	X	X	X	X		X	X	X	X
Resuscitation (830)	X	X	X	X	X	X	X	X	X
Arrhythmia Afib / Aflutter (853)	X	X	X	X		X	X	X	X
G. Preoperative Medications									
Inotropes (970)	X		X	X		X	X	X	X
H. Hemodynamics and Cath									
Number of Diseased Vessels (1050)	X	X	X	X	X	X	X	X	X
Left Main Disease (1060)				X			X		
Ejection Fraction (1080)	X	X	X	X	X	X	X	X	X
Aortic Stenosis (1120)				X			X	X	X
Mitral Stenosis (1140)									
Aortic Insufficiency (1170)									X
Mitral Insufficiency (1180)	X			X		X	X	X	X
Tricuspid Insufficiency (1190)			X	X			X		X
I. Operative									
Incidence (1230)	X	X	X	X	X	X	X	X	X
Status (1240)	X	X	X	X	X	X	X	X	X
IABP-Timing (1440)	X		X	X		X	X	X	X

Valve (AVRepl, MV Repl, MVRepr)	Operative Mortality	Stroke	Renal Failure	Prolonged Ventilation	Deep Stern Infx	Reop	Mortality/ Morbidity	Length of Stay>14	Length of Stay<6
B. Demographics									
Patient Age (140)	X	X	X	X	X	X	X	X	X
Gender (150)	X	X	X	X	X	X	X	X	X
RaceBlack (192)		X	X	X		X	X	X	X
RaceAsian (193)									
Ethnicity (199)		X	X	X		X	X	X	X
D. Risk Factors									
Weight (350)	X	X	X	X	X	X	X	X	X
Height (360)	X	X	X	X	X	X	X	X	X
Diabetes (400)	X		X	X	X	X	X	X	X
Diabetes Control (410)	X		X	X	X	X	X	X	X
Last Preop Creatinine Level (430)	X	X	X	X		X	X	X	X
Renal Failure-Dialysis (450)	X	X	NA	X	X	X	X	X	X
Hypertension (460)	X	X	X	X			X		X
Infectious Endocarditis Type (500)	X	X	X	X		X	X	X	X
Chronic Lung Disease (510)	X		X	X	X	X	X	X	X
Immunosuppressive Treatment (520)	X		X				X	X	
Peripheral Arterial Disease (530)	X	X				X	X	X	X
Cerebrovascular Disease (540)		X	X	X		X	X	X	X
Cerebrovascular Accident (552)		X	X	X		X	X	X	X
E. Previous Interventions									
Previous CAB (600)	X	X	X	X	X	X	X	X	X
Previous Valve (610)	X	X	X	X	X	X	X	X	X
Previous PCI Interval (670)									
F. Preoperative Cardiac Status									
Previous Myocardial Infarction Timing (760)	X			X		X	X	X	X
Heart Failure (770)	X		X	X		X	X	X	X
Classification-NYHA (775)	X		X	X		X	X	X	X
Cardiac Presentation on Admission (791)	X								
Cardiogenic Shock (810)	X	X		X		X	X	X	
Resuscitation (830)	X	X	X	X		X	X	X	X
Arrhythmia Afib / Aflutter (853)	X	X		X		X	X	X	X
G. Preoperative Medications									
Inotropes (970)	X		X	X	X	X	X	X	X
H. Hemodynamics and Cath									
Number of Diseased Vessels (1050)		X		X			X	X	X
Left Main Disease (1060)	X		X		X				
Ejection Fraction (1080)	X		X	X	X	X	X	X	X
Aortic Stenosis (1120)				X		X	X	X	X
Mitral Stenosis (1140)	X								
Aortic Insufficiency (1170)									
Mitral Insufficiency (1180)		X							
Tricuspid Insufficiency (1190)			X	X		X	X	X	X
I. Operative									
Incidence (1230)	X	X	X	X	X	X	X	X	X
Status (1240)	X	X	X	X	X	X	X	X	X
IABP-Timing (1440)	X		X	X	X	X	X	X	X
K. Valve Surgery									
Mitral Procedure (1640)	X	X	X	X	X	X	X	X	X

Valve+CAB (AVRepl+CAB, MVRepl+CAB, MVRepr+CAB)	Operative Mortality	Stroke	Renal Failure	Prolonged Ventilation	Deep Stern Infx	Reop	Mortality/ Morbidity	Length of Stay>14	Length of Stay<6
B. Demographics									
Patient Age (140)	X	X	X	X	X	X	X	X	X
Gender (150)	X	X	X	X	X	X	X	X	X
RaceBlack (192)			X	X		X	X	X	X
RaceAsian (193)									
Ethnicity (199)			X	X		X	X	X	X
D. Risk Factors									
Weight (350)	X	X	X	X	X	X	X	X	X
Height (360)	X	X	X	X	X	X	X	X	X
Diabetes (400)	X	X	X	X	X		X	X	X
Diabetes Control (410)	X	X	X	X	X		X	X	X
Last Preop Creatinine Level (430)	X	X	X	X		X	X	X	X
Renal Failure-Dialysis (450)	X	X	NA	X	X	X	X	X	X
Hypertension (460)		X	X	X	X		X	X	X
Infectious Endocarditis Type (500)	X	X	X	X		X	X	X	X
Chronic Lung Disease (510)	X		X	X	X	X	X	X	X
Immunosuppressive Treatment (520)	X		X	X		X	X	X	X
Peripheral Arterial Disease (530)	X	X	X	X		X	X	X	
Cerebrovascular Disease (540)	X	X	X	X	X	X	X	X	X
Cerebrovascular Accident (552)	X	X	X	X	X	X	X	X	X
E. Previous Interventions									
Previous CAB (600)	X	X	X	X	X	X	X	X	X
Previous Valve (610)	X	X	X	X	X	X	X	X	X
Previous PCI Interval (670)									
F. Preoperative Cardiac Status									
Previous Myocardial Infarction Timing (760)	X	X	X	X		X	X	X	
Heart Failure (770)	X	X	X	X		X	X	X	X
Classification-NYHA (775)	X	X	X	X		X	X	X	X
Cardiac Presentation on Admission (791)	X	X	X	X					
Cardiogenic Shock (810)	X	X	X	X		X	X	X	
Resuscitation (830)	X	X	X	X		X	X	X	X
Arrhythmia Afib / Aflutter (853)	X	X	X	X		X	X	X	X
G. Preoperative Medications									
Inotropes (970)	X		X	X		X	X	X	X
H. Hemodynamics and Cath									
Number of Diseased Vessels (1050)	X	X	X	X	X	X	X	X	X
Left Main Disease (1060)	X			X					
Ejection Fraction (1080)	X		X	X		X	X	X	X
Aortic Stenosis (1120)									
Mitral Stenosis (1140)	X							X	
Aortic Insufficiency (1170)									
Mitral Insufficiency (1180)							X		
Tricuspid Insufficiency (1190)	X		X	X			X		X
I. Operative									
Incidence (1230)	X	X	X	X	X	X	X	X	X
Status (1240)	X	X	X	X	X	X	X	X	X
IABP-Timing (1440)	X		X	X		X	X	X	X
K. Valve Surgery									
Mitral Procedure (1640)	X	X	X	X	X	X	X	X	X

The Society of Thoracic Surgeons
Adult Cardiac Surgery Database
Data Collection Form Version 2.73
January 14, 2011

A. Administrative

Participant ID: ParticID (40)	Record ID: (software generated) RecordID (50)	STS Cost Link: CostLink (60)	Patient ID: (software generated) PatID (80)

B. Demographics

Patient Last Name: PatLName (90)	Patient First Name: PatFName (100)	Patient Middle Name: PatMName (120)
Date of Birth: __ __/__ __/__ __ __ __ (mm/dd/yyyy) DOB (130)	Patient Age: _____ Age (140)	Sex: ☐ Male ☐ Female Gender (150)
Social Security Number: __ __ __ - __ __ - __ __ __ __ SSN (160)	Medical Record Number: MedRecN (170)	

Patient's Address:

Street Address: PatAddr (180)	City: PatCity (190)	
Region: PatRegion (200)	ZIP Code: PatZIP (210)	Country: PatCountry (220)

Is This Patient's Permanent Address: ☐ Yes ☐ No
PermAddr (230)

(If No →)

Patient's Permanent Address:

Street Address: PatPermAddr (240)	City: PatPermCity (250)	
Region: PatPermRegion (260)	ZIP Code: PatPermZIP (270)	Country: PatPermCountry (280)

Race (Select all that apply.)

White: RaceCaucasian (290)	☐ Yes	☐ No	Black/African American: RaceBlack (300)	☐ Yes ☐ No
Asian: RaceAsian (310)	☐ Yes	☐ No	Am Indian/Alaskan Nat: RaceNativeAm (320)	☐ Yes ☐ No
Native Hawaiian/Pacific Islander: RacNativePacific (330)	☐ Yes	☐ No	Other: RaceOther (340)	☐ Yes ☐ No

Hispanic, Latino or Spanish Ethnicity: ☐ Yes ☐ No
Ethnicity (350)

Referring Cardiologist: RefCard (360)	Referring Physician: RefPhys (370)

C. Hospitalization

Hospital Name: _____ (If Not Missing →)
HospName (380)

Hospital ZIP Code: HospZIP (390)

Hospital State: HospStat (400)

Hospital National Provider Identifier: _____
HospNPI (410)

Payor - (Select all that apply.)

Government Health Insurance: PayorGov (420) ☐ Yes ☐ No (If Yes, select all that apply.)

- Medicare: ☐ Yes ☐ No (If Yes →) PayorGovMcare (430)
  - Health Insurance Claim Number: _____ HICNumber (440)
  - Medicare Fee For Service: ☐ Yes ☐ No PayorGovMcareFFS (450)
- Medicaid: ☐ Yes ☐ No PayorGovMcaid (460)
- Military Health Care: ☐ Yes ☐ No PayorGovMil(470)
- State-Specific Plan: ☐ Yes ☐ No PayorGovState (480)
- Indian Health Service: ☐ Yes ☐ No PayorGovIHS (490)
- Correctional Facility: ☐ Yes ☐ No PayorGovCor (500)

Commercial Health Insurance: ☐ Yes ☐ No
PayorCom (510)

Health Maintenance Organization: ☐ Yes ☐ No
PayorHMO (520)

Non-U.S. Insurance: PayorNonUS (530) ☐ Yes ☐ No

None / Self: PayorNS (540) ☐ Yes ☐ No

Arrival Date: __/__/____ (mm/dd/yyyy)	Arrival Time: __:__ (hh:mm 24-hour clock)	Admit Date: __/__/____ (mm/dd/yyyy)

ArrivalDt (550)	ArrivalTm (560)	AdmitDt (570)

Admit Source: ☐ Elective Admission
AdmitSrc (580) ☐ Emergency Department
☐ Transfer in from another acute care facility (If Transfer →) Other Hospital Performs Cardiac Surgery ☐ Yes ☐ No
OthHosCS (590)
☐ Other

Surgery Date: __/__/__ (mm/dd/yyyy) SurgDt (610)	Discharge Date: __/__/__ (mm/dd/yyyy) DischDt (620)

D. Risk Factors

Weight (kg): _____ WeightKg (630) | Height (cm): _____ HeightCm (640)

Cigarette Smoker: ☐ Yes ☐ No (If Yes →) Current Cigarette Smoker: ☐ Yes ☐ No
CigSmoker (650) CigSmokerCurr (660)

Other Tobacco Use: ☐ Yes ☐ No OthTobUse (661)

Family History of Premature Coronary Artery Disease: ☐ Yes ☐ No | Last Hematocrit: _____ | Last WBC Count: _____
FHCAD (670) Hct (680) WBC (690)

Platelet Count Prior to Surgery: _____ | International Normalized Ratio prior to Surgery: _____
Platelets (700) INR (710)

HIT Antibodies ☐ Yes ☐ No ☐ Not Applicable | Total Bilirubin Prior to Surgery: _____
HITAnti (711) TotBirbn (720)

Total Albumin Prior to Surgery:_____ | A1c Level prior to surgery: _____ | Last Creatinine Level Prior to Surgery: _____
TotAlbumin (730) A1cLvl (740) CreatLst (750)

Diabetes: ☐ Yes ☐ No (If Yes →) Diabetes-Control: ☐ None ☐ Diet ☐ Oral ☐ Insulin ☐ Other
Diabetes (780) DiabCtrl (790)

Dyslipidemia: ☐ Yes ☐ No | Dialysis: ☐ Yes ☐ No | MELD Score: _____ (System Calculation) | Hypertension: ☐ Yes ☐ No
Dyslip (800) Dialysis (810) MELDScr (815) Hypertn (820)

Infectious Endocarditis: ☐ Yes ☐ No
InfEndo (830)
(If Yes →) Infectious Endocarditis Type: ☐ Treated ☐ Active InfEndTy (840)
Infectious Endocarditis Culture: InfEndCult (850)
☐ Culture negative ☐ Staphylococcus aureus ☐ Streptococcus species
☐ Coagulase negative staphylococcus ☐ Enterococcus species ☐ Fungal ☐ Other

Chronic Lung Disease: ☐ No ☐ Mild ☐ Moderate ☐ Severe ChrLungD (860)

Pulmonary Function Test Done: ☐ Yes ☐ No PFT (880)
(If Yes →) FEV1 % Predicted: _____
FEV1 (890)
DLCO Test Performed: ☐ Yes ☐ No (If Yes →) DLCO % Predicted: _____
DLCO (892) DLCOPred (893)

Arterial Blood Gas Performed: ☐ Yes ☐ No (If Yes →) Oxygen Level : _____ Carbon Dioxide Level: _____
ABG (900) PO2 (910) PCO2 (920)

Home Oxygen: ☐ Yes ☐ No | Inhaled Medication or Oral Bronchodilator Therapy: ☐ Yes ☐ No
HmO2 (930) BDTx (940)

Sleep Apnea: ☐ Yes ☐ No | Liver Disease: ☐ Yes ☐ No
SlpApn (950) LiverDis (960)

Immunocompromise Present: ☐ Yes ☐ No | Peripheral Artery Disease: ☐ Yes ☐ No
ImmSupp (970) PVD (980)

Unresponsive Neurologic State: ☐ Yes ☐ No | Syncope: ☐ Yes ☐ No
UnrespStat (1000) Syncope (1001)

Cerebrovascular Disease: ☐ Yes ☐ No CVD (1010)
(If Yes →) Prior CVA: ☐ Yes ☐ No (If Yes →) Prior CVA-When: ☐ Recent (<=2 wk.) ☐ Remote (>2 wk.)
CVA (1020) CVAWhen (1030)
CVD TIA: ☐ Yes ☐ No CVDTIA (1050)
CVD Carotid stenosis: ☐ None ☐ Right ☐ Left ☐ Both CVDCarSten (1070)
(If "Right" or "Both" →) Severity of stenosis on the right carotid artery: ☐ 80 - 99% ☐ 100% CVDStenRt (1071)
(If "Left" or "Both" →) Severity of stenosis on the left carotid artery: ☐ 80 - 99% ☐ 100% CVDStenLft (1072)
History of previous carotid artery surgery and/or stenting: ☐ Yes ☐ No CVDPCarSurg (1080)

Illicit Drug Use: ☐ Yes ☐ No | Alcohol Use: ☐ <=1 drink/week ☐ 2-7 drinks/week ☐ >=8 drinks/week
IVDrugAb (1130) Alcohol (1131)

Pneumonia: ☐ No ☐ Recent ☐ Remote | Mediastinal Radiation: ☐ Yes ☐ No | Cancer Within 5 Years : ☐ Yes ☐ No
Pneumonia (1140) MediastRad (1150) Cancer (1160)

Five Meter Walk Test Done: ☐ Yes ☐ No FiveMWalkTest (1161)
(If Yes →) Time 1: _____ (secs) Time 2: _____(secs) Time 3 : _____ (secs)
FiveMWalk1 (1170) FiveMWalk2 (1180) FiveMWalk3 (1190)

E. Previous Cardiac Interventions

Previous Cardiac Interventions: ☐ Yes ☐ No (If Yes →)
PrCVInt (1200)

Previous CAB prior to current admission: ☐ Yes ☐ No PrCAB (1215)
Previous Valve: ☐ Yes ☐ No (If Yes ...) PrValve (1216)
Previous Aortic Valve Replacement - Surgical: ☐ Yes ☐ No PrevProcAVReplace (1220)
Previous Aortic Valve Repair - Surgical : ☐ Yes ☐ No PrevProcAVRepair (1230)
Previous Mitral Valve Replacement - Surgical: ☐ Yes ☐ No PrevProcMVReplace (1240)
Previous Mitral Valve Repair - Surgical: ☐ Yes ☐ No PrevProcMVRepair (1250)
Previous Tricuspid Valve Replacement - Surgical: ☐ Yes ☐ No PrevProcTVReplace (1260)
Previous Tricuspid Valve Repair - Surgical: ☐ Yes ☐ No PrevProcTVRepair (1270)
Previous Pulmonic Valve Repair / Replacement - Surgical: ☐ Yes ☐ No PrevProcPV (1280)
Previous Aortic Valve Balloon Valvuloplasty: ☐ Yes ☐ No PrevProcAVBall (1285)
Previous Mitral Valve Balloon Valvuloplasty: ☐ Yes ☐ No PrevProcMVBall (1290)
Previous Transcatheter Valve Replacement: ☐ Yes ☐ No PrevProcTCVRep (1300)
Previous Percutaneous Valve Repair: ☐ Yes ☐ No PrevProcPercVRepair (1310)
Indication for Reoperation: ☐ Structural Prosthetic Valve Deterioration
IndReop (1340) ☐ Non-structural prosthetic valve dysfunction
(If Non-structural prosthetic ...) Primary type: ☐ Paravalvular Leak ☐ Hemolysis
NonStVDys (1350) ☐ Entrapment by pannus, tissue, or suture
☐ Sizing or positioning issue
☐ Other
☐ Prosthetic Valve Endocarditis
☐ Valve Thrombosis
☐ Failed Repair
☐ Repeat valve procedure on a different valve
☐ Other
Exact Date of Previous Valve Procedure Known: ☐ Yes ☐ No PrValDtKnown (1410)
(If Yes ...) Date of Previous Valve Procedure: __ __ /__ __ /__ __ __ __ PrValveDate (1420)
(If No ...) Estimate Number of Months Since Previous Valve Procedure: _____ PrValveMonths (1430)
Previous Other Cardiac: ☐ Yes ☐ No PrOthCar (1440) (If Yes ...) Previous Arrhythmia Surgery: ☐ Yes ☐ No POArr (1445)
Previous Congenital: ☐ Yes ☐ No PrOthCongen (1450)
Previous ICD (Implantable Cadioverter/Defibrillator): ☐ Yes ☐ No PrOCAICD (1460)
Previous Pacemaker: ☐ Yes ☐ No PrOCPace (1470)
Previous PCI (Percutaneous Cardiac Intervention): ☐ Yes ☐ No POCPCI (1480)
(If Yes ...) PCI Performed Within This Episode Of Care: ☐ Yes, at this facility ☐ Yes, at some other acute care facility ☐ No
POCPCIWhen (1481)
(If Yes ...) Indication for Surgery: ☐ PCI Complication
POCPCIndSurg (1490) ☐ PCI Failure without Clinical Deterioration
☐ PCI/CABG Hybrid Procedure
PCI Stent : ☐ Yes ☐ No (If Yes ...) Stent Type: ☐ Bare metal ☐ Drug-eluting ☐ Unknown
POCPCISt (1500) POCPCIStTy (1510)
PCI Interval: ☐ <= 6 Hours ☐ > 6 Hours POCPCIIn (1520)
Other Previous Cardiovascular Intervention: ☐ Yes ☐ No POCO (1530)

F. Preoperative Cardiac Status

Prior Myocardial Infarction: ☐ Yes ☐ No (If Yes ...) PrevMI (1540)
MI When: ☐ <=6 Hrs ☐ >6 Hrs but <24 Hrs ☐ 1 to 7 Days ☐ 8 to 21 Days ☐ >21 Days MIWhen (1550)
Anginal Classification Within 2 weeks: ☐ No Symptoms, No Angina ☐ CCA I ☐ CCA II ☐ CCA III ☐ CCA IV AnginalClass (1570)
Heart Failure Within 2 weeks : ☐ Yes ☐ No (If Yes ...) Classification-NYHA: ☐ Class I ☐ Class II ☐ Class III ☐ Class IV
CHF (1580) ClassNYH (1585)
Prior Heart failure: ☐ Yes ☐ No PriorHF (1590)
Cardiac Presentation on Admission: ☐ No Symptoms,No Angina ☐ Symptoms Unlikely to be Ischemia ☐ Stable Angina
CardPres (1610) ☐ Unstable Angina ☐ Non-ST Elevation MI (Non-STEMI) ☐ ST Elevation MI (STEMI)
Cardiogenic Shock : ☐ Yes ☐ No CarShock (1620)
Resuscitation: ☐ Yes ☐ No Resusc (1630)
Arrhythmia When : ☐ None ☐ Remote ☐ Recent (If Recent ...) ArrhythWhen (1650)
Arrhythmia Type: Vtach/Vfib: ☐ Yes ☐ No — Second Degree Heart Block : ☐ Yes ☐ No
ArrhyVtach (1660) ArrhyVtachHrtBlk (1670)
Sick Sinus Syndrome: ☐ Yes ☐ No — Third Degree Heart Block: ☐ Yes ☐ No
ArrhyVtachSicSinSyn (1680) ArrhyTHB (1690)
Afib/Aflutter : ☐ Yes ☐ No ArrhyAfib (1700)
(If Yes ...) Type: ☐ Paroxysmal ☐ Continuous/Persistent ArrhyAfibTy (1701)

G. Preoperative Medications

Beta Blockers : ☐ Yes ☐ No ☐ Contraindicated MedBeta (1710)
ACE or ARB Inhibitors Within 48 Hours: ☐ Yes ☐ No MedACEI48 (1730)
Nitrates-I.V.: ☐ Yes ☐ No MedNitIV (1740)
Anticoagulants : ☐ Yes ☐ No (If Yes ...) Medication Name : ☐ Heparin (Unfractionated) ☐ Heparin (Low Molecular)
MedACoag (1750) MedACMN (1760) ☐ Thrombin Inhibitors ☐ Other
Preoperative Antiarrhythmics: ☐ Yes ☐ No MedAArrhy (1770)

Coumadin: ☐ Yes ☐ No MedCoum (1780)

Inotropes : ☐ Yes ☐ No MedInotr (1790)

Steroids : ☐ Yes ☐ No MedSter (1800)

Aspirin: ☐ Yes ☐ No MedASA (1820)

Lipid Lowering: ☐ Yes ☐ No (If Yes →) MedLipid (1830) Medication Type : ☐ Statin ☐ Non-statin ☐ Both MedLipMN (1840)

ADP Inhibitors Within Five Days : ☐ Yes ☐ No (If Yes →) MedADP5Days (1850) ADP Inhibitors Discontinuation: _____ (# days prior to surgery) MedADPIDis (1860)

Antiplatelets Within 5 Days : ☐ Yes ☐ No MedAplt5Days (1870)

Glycoprotein IIb/IIIa Inhibitor: ☐ Yes ☐ No (If Yes →) MedGP (1880) Medication Name: ☐ Abciximab (ReoPro) ☐ Eptifibatide (Integrilin) MedGPMN (1890) ☐ Tirofiban (Aggrastat)

Thrombolytics within 48 hours: ☐ Yes ☐ No MedThrom (1900)

H. Hemodynamics/Cath/Echo

Cardiac Catheterization Performed : ☐ Yes ☐ No (If Yes →) CarCathPer (1910) Cardiac Catheterization Date: __ __/__ __/__ __ __ __ CarCathDt (1920)

Number Diseased Vessels: ☐ None ☐ One ☐ Two ☐ Three NumDisV (1930)
Left Main Disease >= 50%: ☐ Yes ☐ No LMainDis (1940)
Proximal LAD >= 70%: ☐ Yes ☐ No ProxLAD (1941)

Ejection Fraction Done: ☐ Yes ☐ No (If Yes →) HDEFD (1950)
HDEF (1960) Ejection Fraction: _____ (%)
HDEFMeth (1970) Ejection Fraction Method: ☐ LV Gram ☐ Radionucleotide ☐ Estimate ☐ ECHO ☐ MRI/CT ☐ Other

LV Systolic Dimension: _____ (mm) LVSD (1980) | LV End-Diastolic Dimension: _____ (mm) LVEDD (1990)

PA Systolic Pressure Measured: ☐ Yes ☐ No (If Yes →) PASYSMeas (2020) PA Systolic Pressure: _____ mmHg(highest prior to surgery) PASYS (2030)

Aortic Valve Disease: ☐ Yes ☐ No (If Yes →) VDAort (2040)

Aortic Etiology: VDAoEt (2090)
- ☐ Degenerative (senile)
- ☐ Endocarditis (If Endocarditis →) Root Abscess: ☐ Yes ☐ No VDEndAB (2110)
- ☐ Congenital (If Congenital →) Type: ☐ Bicuspid ☐ Other VDCongenT (2120)
- ☐ Rheumatic
- ☐ Primary Aortic Disease: (If PAD →) Type: VDPrimAo (2130) ☐ Marfans ☐ Other Connective tissue disorder ☐ Atherosclerotic Aneurysm ☐ Inflammatory ☐ Aortic Dissection ☐ Idiopathic Root Dilation
- ☐ LV Outflow Tract Obstruction: (If LV outflow tract obstruction →) Type: VDLVOutOb (2140) ☐ HOCM ☐ Sub-aortic membrane ☐ Sub-aortic Tunnel
- ☐ Supravalvular Aortic Stenosis
- ☐ Tumor: (If Tumor →) Type: ☐ Myxoma ☐ Papillary fibroelastoma ☐ Carcinoid ☐ Other VDAortTumor (2150)
- ☐ Trauma
- ☐ Other

Aortic Stenosis: ☐ Yes ☐ No (If Yes →) VDStenA (2152)
Smallest Aortic Valve Area: _____ cm^2 VDAoVA (2153)
Highest Mean Gradient : _____ mmHg VDGradA (2154)

Aortic Insufficiency: ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Severe VDInsufA (2155)

Mitral Valve Disease: ☐ Yes ☐ No (If Yes →) VDMit (2160)

Mitral Etiology: VDMitET (2170)
- ☐ Annular or Degenerative Disease (If Annular or Degenerative Disease →) Location: ☐ Posterior Leaflet ☐ Anterior Leaflet ☐ Bileaflet VDMitDegLoc (2180) Type: ☐ Pure Annular Dilation ☐ Mitral Annular Calcification VDMitAnDegDis (2190)
- ☐ Endocarditis
- ☐ Rheumatic
- ☐ Ischemic (If Ischemic →) Type: ☐ Acute (If acute →) Papillary Muscle Rupture: ☐ Yes ☐ No VDMitPMR (2220) ☐ Chronic VDMitIsTy (2210)
- ☐ Congenital
- ☐ Hypertrophic Obstructive Cardiomyopathy (HOCM)
- ☐ Tumor: (If Tumor →) Type: ☐ Myxoma ☐ Papillary fibroelastoma ☐ Carcinoid ☐ Other VDMitTumor (2221)
- ☐ Trauma
- ☐ Non-ischemic cardiomyopathy
- ☐ Other

Mitral Valve Disease Functional Class: ☐ Type I ☐ Type II ☐ Type IIIa ☐ Type IIIb VDMitFC (2230)

Mitral Stenosis: ☐ Yes ☐ No (If Yes →) VDStenM (2240)
Smallest Mitral Valve Area : _____ cm^2 VDMVA (2250)

Highest Mean Gradient: _____ mm Hg VDGradM (2260)
Mitral Insufficiency: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe VDInsufM (2270)

Tricuspid Valve Disease: ☐ Yes ☐ No (If Yes ... VDTr (2280)
Tricuspid Etiology: VDTrEt (2290)
☐ Functional
☐ Endocarditis
☐ Congenital
☐ Tumor
☐ Trauma
☐ Other
Tricuspid Stenosis: ☐ Yes ☐ No VDStenT (2300)
Tricuspid Insufficiency: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe VDInsufT (2320)

Pulmonic Valve Disease: ☐ Yes ☐ No (If Yes ... VDPulm (2321)
Pulmonic Stenosis: ☐ Yes ☐ No VDStenP (2330)
Pulmonic Insufficiency: ☐ None ☐ Trace/trival ☐ Mild ☐ Moderate ☐ Severe VDInsufP (2340)

I. Operative

Surgeon: _____ Surgeon (2350)
Surgeon NPI: _____ SurgNPI (2360)
Taxpayer Identification Number: _____ TIN (2370)

Incidence: Incidenc(2380)
☐ First cardiovascular surgery
☐ First re-op cardiovascular surgery
☐ Second re-op cardiovascular surgery
☐ Third re-op cardiovascular surgery
☐ Fourth or more re-op cardiovascular surgery

Status: Status (2390)
☐ Elective
☐ Urgent (If Urgent ... UrgntRsn (2400)
Reason: ☐ AMI ☐ IABP ☐ Worsening CP ☐ CHF ☐ Anatomy ☐USA ☐ Rest Angina ☐ Valve Dysfunction ☐Aortic Dissection ☐Angiographic Accident ☐Cardiac Trauma ☐ Infected Device ☐ Syncope ☐ PCI/CABG Hybrid ☐ PCI Failure w/out clinical deterioration
☐ Emergent (If Emergent ... EmergRsn (2410)
Reason: ☐ Shock Circ Support ☐ Shock No Circ Support ☐ Pulmonary Edema ☐ AEMI ☐ Ongoing Ischemia ☐ Valve Dysfunction ☐ Aortic Dissection ☐ Angiographic Accident ☐ Cardiac Trauma ☐ Infected Device ☐ Syncope ☐ PCI/CABG Hybrid ☐ Anatomy
☐ Emergent Salvage

Was case previously attempted during this admission, but canceled: ☐ Yes ☐ No PCancCase (2415)
(If Yes ...)
Date of previous case: __ __/__ __/__ __ __ __ (mm/dd/yyyy) PCancCaseDt (2416)
Timing of previous case: PCancCaseTmg (2417)
☐ Prior to induction of anesthesia ☐ After induction, prior to incision
☐ After incision made

Reason previous case was canceled: PCancCaseRsn (2418)
☐ Anesthesiology event ☐ Cardiac arrest ☐ Equipment/supply issue
☐ Unanticipated tumor ☐ Other

Planned previous procedure:
CABG PCancCaseCAB (2419) ☐ Yes ☐ No
Valve PCancCaseVal (2420) ☐ Yes ☐ No
Mechanical Assist Device PCancCaseMech (2421) ☐ Yes ☐ No
Other Cardiac PCancCaseOC (2422) ☐ Yes ☐ No
Other Non-cardiac PCancCaseONC (2423) ☐ Yes ☐ No

Was the current procedure canceled: ☐ Yes ☐ No CCancCase (2424)
(If Yes ...)
Canceled Timing: CCancCaseTmg (2425)
☐ Prior to induction of anesthesia ☐ After induction, prior to incision
☐ After incision made

Canceled Reason: CCancCaseRsn (2426)
☐ Anesthesiology event ☐ Cardiac arrest ☐ Equipment/supply issue
☐ Unanticipated tumor ☐ Other

Planned procedure:
CABG CCancCaseCAB (2427) ☐ Yes ☐ No
Valve CCancCaseVal (2428) ☐ Yes ☐ No
Mechanical Assist Device CCancCaseMech (2429) ☐ Yes ☐ No
Other Cardiac CCancCaseOC (2430) ☐ Yes ☐ No
Other Non-cardiac CCancCaseONC (2431) ☐ Yes ☐ No

Operative Approach: ☐ Full conventional sternotomy ☐ Partial sternotomy ☐ Right or left parasternal incision ☐ Left Thoracotomy ☐ Right Thoracotomy ☐ Transverse sternotomy (includes clamshell)

☐ Minimally invasive OPApp (2435)

Robotic Technology Assisted: ☐ Yes ☐ No Robotic (2436)

Coronary Artery Bypass: ☐ Yes ☐ No OpCAB (2437)
(If "Yes" complete Section J)

Valve Surgery: ☐ Yes ☐ No (If Yes:) (If "Yes" complete Section K) OpValve (2440)

Valve Prosthesis Explant: ☐ Yes ☐ No (If Yes:) ValExp (2450)

Explant Position: ☐ Aortic ☐ Mitral ☐ Tricuspid ☐ Pulmonic
ValExpPos (2451)

Explant Type: ☐ Unknown ☐ Mechanical Valve ☐ Bioprosthetic Valve
ValExpTyp (2460)
☐ Annuloplasty Device ☐ Mitral Clip ☐ Transcatheter Device

Device Manufacturer: ValExpMan(2461)

☐ None (Homograft or Pulmonary Autograft)	☐ Cryolife	☐ Lillehei-Kaster	☐ OmniScience
☐ ATS	☐ Cryolife O'Brien	☐ MCRI	☐ Sorin
☐ Baxter	☐ Edwards	☐ Medtronic	☐ Sorin-Puig
☐ Biocore	☐ Genesee	☐ Medtronic Colvin Galloway	☐ St. Jude Medical
☐ Björk-Shiley	☐ Hancock	☐ Medtronic-Duran	☐ St. Jude Tailor
☐ CarboMedics	☐ Ionescu-Shiley	☐ Medtronic-Hall	☐ Starr-Edwards
☐ Carpentier-Edwards	☐ Labcor	☐ Mitroflow	☐ Ultracor
☐ Cosgrove-Edwards	☐ LifeNet	☐ OmniCarbon	☐ Unknown
			☐ Other

Explant Device: _____ (Refer to Explant Device Key below)ValExpDev (2462)

Second Valve Prosthesis Explant: ☐ Yes ☐ No (If Yes:) ValExp2 (2463)

Explant Position: ☐ Aortic ☐ Mitral ☐ Tricuspid ☐ Pulmonic
ValExpPos2 (2464)

Explant Type: ☐ Unknown ☐ Mechanical Valve ☐ Bioprosthetic Valve
ValExpTyp2 (2465)
☐ Annuloplasty Device ☐ Mitral Clip ☐ Transcatheter Device

Device Manufacturer: ValExpMan2(2466)

☐ None (Homograft or Pulmonary Autograft)	☐ Cryolife	☐ Lillehei-Kaster	☐ OmniScience
☐ ATS	☐ Cryolife O'Brien	☐ MCRI	☐ Sorin
☐ Baxter	☐ Edwards	☐ Medtronic	☐ Sorin-Puig
☐ Biocore	☐ Genesee	☐ Medtronic Colvin Galloway	☐ St. Jude Medical
☐ Björk-Shiley	☐ Hancock	☐ Medtronic-Duran	☐ St. Jude Tailor
☐ CarboMedics	☐ Ionescu-Shiley	☐ Medtronic-Hall	☐ Starr-Edwards
☐ Carpentier-Edwards	☐ Labcor	☐ Mitroflow	☐ Ultracor
☐ Cosgrove-Edwards	☐ LifeNet	☐ OmniCarbon	☐ Unknown
			☐ Other

Explant Device: _____ (Refer to Explant Device Key below)ValExpDev2 (2467)

Explant Device Key (Note this list is different from the incisant list used below)

Mechanical

2 = ATS Mechanical Prosthesis
3 = Björk-Shiley Convex-Concave Mechanical Prosthesis
4 = Björk-Shiley Monostrut Mechanical Prosthesis
6 = CarboMedics Mechanical Prosthesis
57 = CarboMedics Carbo-Seal Ascending Aortic Valved Conduit Prosthesis
58 = CarboMedics Carbo-Seal Valsalva Ascending Aortic Valved Conduit Prosthesis
59 = CarboMedics Reduced Cuff Aortic Valve
60 = CarboMedics Standard Aortic Valve
61 = CarboMedics Top-Hat Supra-annular Aortic Valve
62 = CarboMedics OptiForm Mitral Valve
63 = CarboMedics Standard Mitral Valve
64 = CarboMedics Orbis Universal Valve
65 = CarboMedics Small Adult Aortic and Mitral Valves
53 = Lillehei-Kaster Mechanical Prosthesis
10 = MCRI On-X Mechanical Prosthesis
8 = Medtronic-Hall/Hall Easy-Fit Mechanical Prosthesis
66 = Medtronic ADVANTAGE Mechanical Prosthesis
9 = OmniCarbon Mechanical Prosthesis
54 = OmniScience Mechanical Prosthesis
11 = Sorin Bicarbon (Baxter Mira) Mechanical Prosthesis
12 = Sorin Monoleaflet Allcarbon Mechanical Prosthesis
13 = St. Jude Medical Mechanical Heart Valve
67 = St. Jude Medical Masters Series Mechanical Heart Valve
68 = St. Jude Medical Masters Series Aortic Valve Graft Prosthesis
69 = St. Jude Medical Mechanical Heart Valve Hemodynamic Plus (HP) Series
70 = St. Jude Medical Masters Series Hemodynamic Plus Valve with FlexCuff Sewing Ring
71 = St. Jude Medical Regent Valve
14 = Starr-Edwards Caged-Ball Prosthesis
15 = Ultracor Mechanical Prosthesis
133 = Medtronic Hall Conduit

Bioprosthesis

108 = ATS 3f Aortic Bioprosthesis
72 = Edwards Prima Stentless Porcine Bioprosthesis - Subcoronary
73 = Edwards Prima Stentless Porcine Bioprosthesis - Root
19 = Biocor Porcine Bioprosthesis
74 = Biocor Stentless Porcine Bioprosthesis - Subcoronary
75 = Biocor Stentless Porcine Bioprosthesis - Root
21 = CarboMedics PhotoFix Pericardial Bioprosthesis
76 = Carpentier-Edwards Porcine Bioprosthesis
77 = Edwards Prima Plus Stentless Porcine Bioprosthesis - Subcoronary
78 = Edwards Prima Plus Stentless Porcine Bioprosthesis - Root
22 = Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis
85 = Medtronic Contegra Bovine Jugular Bioprosthesis
37 = Mitroflow Pericardial Bioprosthesis
39 = St. Jude Medical Toronto SPV Stentless Porcine Bioprosthesis
40 = St. Jude Medical-Bioimplant Porcine Bioprosthesis
86 = St. Jude Medical Biocor Stented Tissue Valve
87 = St. Jude Medical Epic Stented Porcine Bioprosthesis
88 = St. Jude Medical Toronto Root Stentless Porcine Bioprosthesis
38 = Sorin Pericarbon Stentless Pericardial Bioprosthesis
111 = Carpentier-Edwards PERIMOUNT MAGNA Pericardial Bioprosthesis with Carpentier-Edwards Thermafix Tissue Process
112 = Carpentier-Edwards PERIMOUNT Theon RSR Pericardial

103 = Carpentier-Edwards PERIMOUNT Pericardial Magna Bioprosthesis
23 = Carpentier-Edwards Standard Porcine Bioprosthesis
25 = Carpentier-Edwards Supra-Annular Aortic Porcine Bioprosthesis
79 = Cryolife O'Brien Stentless Porcine Bioprosthesis - Subcoronary
80 = Cryolife O'Brien Stentless Porcine Bioprosthesis - Root
55 = Hancock Standard Porcine Bioprosthesis
28 = Hancock II Porcine Bioprosthesis
29 = Hancock Modified Orifice Porcine Bioprosthesis
30 = Ionescu-Shiley Pericardial Bioprosthesis
31 = Labcor Stented Porcine Bioprosthesis
81 = Labcor Stentless Porcine Bioprosthesis - Subcoronary
82 = Labcor Stentless Porcine Bioprosthesis - Root
83 = Medtronic Freestyle Stentless Porcine Bioprosthesis - Subcoronary
84 = Medtronic Freestyle Stentless Porcine Bioprosthesis - Root
35 = Medtronic Intact Porcine Bioprosthesis
36 = Medtronic Mosaic Porcine Bioprosthesis
Bioprosthesis
113 = Carpentier-Edwards PERIMOUNT RSR Pericardial Bioprosthesis
114 = Carpentier-Edwards PERIMOUNT Theon Pericardial Bioprosthesis
115 = Carpentier-Edwards S.A.V. Porcine Bioprosthesis
116 = Edwards Prima Plus Stentless Bioprosthesis
117 = Carpentier-Edwards PERIMOUNT Plus Pericardial Bioprosthesis with Tricentrix Holder
118 = Carpentier-Edwards Duraflex Low Pressure Porcine Bioprosthesis
119 = Carpentier-Edwards Duraflex Low Pressure ESR Porcine Bioprosthesis
120 = Carpentier-Edwards PERIMOUNT Theon Pericardial Bioprosthesis with Tricentrix Holder.
121 = St. Jude Medical Biocor Supra Stented Porcine Bioprosthesis
122 = St. Jude Medical Epic Supra Stented Porcine Bioprosthesis.
134 = Carpentier Edwards Physio II
135 = Carpentier Edwards Perimount Magna Mitral Valve

Homograft

89 = CryoLife Aortic Homograft
90 = CryoLife Pulmonary Homograft
91 = CryoLife CryoValve SG(Decellularized)Aortic Homograft
92 = CryoLife CryoValve SG Pulmonary Homograft
41 = Homograft Aortic - Subcoronary
42 = Homograft Aortic - Root
43 = Homograft Mitral
44 = Homograft Pulmonic Root
93 = LifeNet CV Allografts

Autograft

45 = Pulmonary Autograft to aortic root (Ross Procedure)

Ring - Annuloplasty

109 = ATS Simulus Flex-O Ring
94 = CarboMedics AnnuloFlo Ring
95 = CarboMedics AnnuloFlex Ring
96 = CarboMedics CardioFix Bovine Pericardium with PhotoFix Technology
46 = Carpentier-Edwards Classic Annuloplasty Ring
104 = Carpentier-Edwards Geoform Ring
105 = Carpentier-Edwards IMR Ettogix Ring
47 = Carpentier-Edwards Physio Annuloplasty System Ring
48 = Cosgrove-Edwards Annuloplasty System Ring
97 = Edwards MC³ Tricuspid Annuloplasty System
98 = Genesee Sculptor Annuloplasty Ring
49 = Medtronic Sculptor Ring
50 = Medtronic-Duran AnCore Ring
51 = Sorin-Puig-Messana Ring
52 = St. Jude Medical Séguin Annuloplasty Ring.
106 = St. Jude Medical Rigid Saddle Ring
99 = St. Jude Medical Tailor Annuloplasty Ring
123 = ATS Simulus Flexible Annuloplasty ring.
124 = ATS Simulus Semi-Rigid Annuloplasty ring
125 = Carpentier-Edwards Classic Annuloplasty Ring with Duraflo Treatment
126 = Carpentier-Edwards Physio Annuloplasty Ring with Duraflo Treatment
127 = Cosgrove-Edwards Annuloplasty System with Duraflo Treatment
128 = Myxo Ettogix Annuloplasty Ring
131 = Sorin Memo 3D Ring
132 = UNIRING, Universal Annuloplasty System
137 = Medtronic Colvin Galloway Future Ring
138 = Medtronic Profile 3D Ring

Band - Annuloplasty

100 = Medtronic Colvin Galloway Future Band
101 = Medtronic Duran Band
102 = Medtronic Duran - Ancore Band
107 = St. Jude Medical Tailor Annuloplasty Band
110 = ATS Simulus Flex-C Band

Other

777 = Other

VAD Implanted or Removed: ☐ No ☐ Yes, implanted ☐ Yes, explanted ☐ Yes, implanted and explanted (If "Yes" complete Section L)
VADProc (2480)

Other Cardiac Procedure: ☐ Yes ☐ No (If "Yes" complete Section M)
OpOCard (2490)

Other Non-Cardiac Procedure: ☐ Yes ☐ No (If "Yes" complete Section N)
OpONCard (2500)

Unplanned Procedure: UnplProc (2501) (If Yes)
☐ No
☐ Yes, unsuspected patient disease or anatomy
☐ Yes, surgical complication

Unplanned CABG: ☐ Yes ☐ No UnplCABG (2502)
Unplanned Aortic Valve Procedure: ☐ Yes ☐ No UnplAV (2503)
Unplanned Mitral Valve Procedure: ☐ Yes ☐ No UnplMV (2504)
Unplanned Aorta Procedure: ☐ Yes ☐ No UnplAo (2505)
Unplanned VAD Insertion: ☐ Yes ☐ No UnplVAD (2506)
Unplanned Other Procedure: ☐ Yes ☐ No UnplOth (2507)

Enter up to 10 CPT-1 Codes pertaining to the surgery for which the data collection form was initiated:

1. _____	2. _____	3. _____	4. _____	5. _____	6. _____	7. _____	8. _____	9. _____	10. _____
CPT1Code1 (2510)	CPT1Code2 (2520)	CPT1Code3 (2530)	CPT1Code4 (2540)	CPT1Code5 (2550)	CPT1Code6 (2560)	CPT1Code7 (2570)	CPT1Code8 (2580)	CPT1Code9 (2590)	CPT1Code10 (2600)

OR Entry Date And Time: OREntryDT (2610) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)
OR Exit Date And Time: ORExitDT (2620) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)
Initial Intubation Date and Time: IntubateDT (2670) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)
Initial Extubation Date and Time: ExtubateDT (2680) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)
Skin Incision Start Date and Time: SIStartDT (2690) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)
Skin Incision Stop Date and Time: SIStopDT (2700) ___/___/_____ ___:___ (mm/dd/yyyy hh:mm - 24 hr clock)

Appropriate Antibiotic Selection: ☐ Yes ☐ No ☐ Exclusion AbxSelect (2710)	Appropriate Antibiotic Administration Timing: ☐ Yes ☐ No ☐ Exclusion AbxTiming (2720)	Appropriate Antibiotic Discontinuation: ☐ Yes ☐ No ☐ Exclusion AbxDisc (2730)

CPB Utilization: CPBUtil (2740) ☐ None ☐ Combination (If Combination)
Combination Plan: ☐ Planned

CPBCmb (2750) ☐ Unplanned
(If Unplanned:)
Reason: CPBCmbR (2760)
☐ Exposure/visualization
☐ Bleeding
☐ Inadequate size and/or diffuse disease of distal vessel
☐ Hemodynamic instability (hypotension/arrhythmias)
☐ Conduit quality and/or trauma
☐ Other

☐ Full

(If "Combination" or "Full":)
Cardiopulmonary Bypass Time (minutes): _____ PerfusTm (2770)
Lowest Temperature (°C): _____ LwstTemp (2780)
Lowest Hematocrit : _____ LwstHct (2790)
Arterial Cannulation Site:
(Select all that apply :)

Aortic	☐ Yes ☐ No CanArtStAort (2851)	Axillary	☐ Yes ☐ No CanArtStAx (2853)
Femoral	☐ Yes ☐ No CanArtStFem (2852)	Other	☐ Yes ☐ No CanArtStOth (2854)

Venous Cannulation Site:
(Select all that apply :)

Femoral	☐ Yes ☐ No CanVenStFem (2856)	Pulmonary Vein	☐ Yes ☐ No CanVenStPulm (2861)
Jugular	☐ Yes ☐ No CanVenStJug (2857)	Caval/Bicaval	☐ Yes ☐ No CanVenStBi (2862)
Right Atrial	☐ Yes ☐ No CanVenStRtA (2858)	Other	☐ Yes ☐ No CanVenStOth (2863)
Left Atrial	☐ Yes ☐ No CanVenStLfA (2859)		

Circulatory Arrest: ☐ Yes ☐ No (If Yes:) CircArr (2865)
Circulatory Arrest Without Cerebral Perfusion Time: _____ (min) DHCATm (2866)
Circulatory Arrest With Cerebral Perfusion: ☐ Yes ☐ No CPerfUtil (2867)
(If Yes →) Cerebral Perfusion Time: _____ (min) CPerfTime (2868)
Cerebral Perfusion Type: ☐ Antegrade ☐ Retrograde ☐ Both antegrade and retrograde CPerfTyp (2869)

Aortic Occlusion: ☐ None - beating heart
AortOccl (2870) ☐ None - fibrillating heart
☐ Aortic Crossclamp (If "Aortic crossclamp" or "Balloon occlusion" →): Cross Clamp Time: _____ (min)
☐ Balloon Occlusion XClampTm (2880)

Cardioplegia Delivery: CplegiaDeliv (2900) ☐ None ☐ Antegrade ☐ Retrograde ☐Both
(If "Antegrade", "Retrograde" or "Both" →) Type of cardioplegia used: ☐ Blood ☐ Crystalloid ☐ Both ☐ Other CplegiaType (2901)

Cerebral Oximetry Used: ☐ Yes ☐ No (If Yes:) CerOxUsed (2930)

Pre-Induction Baseline Regional Oxygen Saturation:	Left: _____ (%) PreRSO2Lft (2940)	Right: _____ (%) PreRSO2Rt (2950)
Cumulative Saturation Below Threshold:	Left: _____ (min -%) CumulSatLft (2960)	Right: _____ (min -%) CumulSatRt (2970)
Cerebral Oximeter Provided First Indication:	☐ Yes ☐ No COFirstInd (2980)	
Skin Closure Regional Oxygen Saturation:	Left: _____ (%) SCRSO2Lft (2990)	Right: _____ (%) SCRSO2Rt (3000)

Concentric Calcification: ☐ Yes ☐ No ConCalc (3005)
Echo Assessment of Ascending Aorta/Arch: ☐ Yes ☐ No (If Yes:) AsmtAscAA (3010)
Assessment of Aorta Disease: ☐ Normal Aorta ☐ Extensive intimal thickening
AsmtAoDx (3020) ☐ Protruding Atheroma < 5 mm ☐ Protruding Atheroma >= 5 mm
☐ Mobile plaques ☐ Not documented
Assessment Altered Plan: ☐ Yes ☐ No AsmtAPln (3030)

Intraop Blood Products Used: ☐ Yes ☐ No IBldProd (3040)
(If No: →) Intraop Blood Products Refused: ☐ Yes ☐ No IBldProdRef (3050)
(If Yes:) Red Blood Cell Units: _____ IBdRBCU (3060)
Fresh Frozen Plasma Units: _____ IBdFFPU (3070)
Cryoprecipitate Units: _____ IBdCryoU (3080)
Platelet Units: _____ IBdPlatU (3090)
Factor VIIa: _____ IBdFactorVII (3091)

Intraop Antifibrinolytic Medications: Epsilon Amino-Caproic Acid: ☐ Yes ☐ No IMedEACA (3120) Tranexamic Acid: ☐ Yes ☐ No IMedTran (3140)

Intraoperative TEE Performed post procedure: ☐ Yes ☐ No (If Yes:) InOpTEE (3157)
Highest level aortic insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe PRepAR (3158)
Highest level mitral insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe PRepMR (3159)
Highest level tricuspid insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe PRepTR (3161)

J. Coronary Bypass

(If OpCAB = Yes ...)

Hybrid Procedure CAB and PCI Performed: ☐ Yes ☐ No (If Yes ...) CABHybrPCI (3165)
Status: ☐ Planned - concurrent ☐ Planned - staged ☐ Unplanned HybrStat (3170)
PCI Procedure Performed: ☐ Angioplasty ☐ Stent HybrProc (3180)

Number of Distal Anastomoses with Arterial Conduits: _____ DistArt (3190)

Number of Distal Anastomoses with Venous Conduits: _____ (If >0 ...) DistVein (3200)
Vein Harvest Technique: ☐ Endoscopic ☐ Direct Vision (open) ☐ Both ☐ Cryopreserved DistVeinHTech (3205)
(If "Endoscopic", "Direct Vision (open)" or "Both"...)
Saphenous Vein Harvest Time: _____ (minutes) SaphHrvstT (3206)
Saphenous Vein Preparation Time: _____ (minutes) SaphPrepT (3207)

Internal Mammary Artery used for Grafts: ☐ Left IMA ☐ Right IMA ☐ Both IMAs ☐ No IMA IMAArtUs (3210)

(If No IMA...) Indicate **Primary** Reason: NoIMARsn (3220)
☐ The IMA is not a suitable conduit due to size or flow
☐ Subclavian stenosis
☐ Previous cardiac or thoracic surgery
☐ Previous mediastinal radiation
☐ Emergent or salvage procedure
☐ No LAD disease

(If Left, Right or Both IMAs...) Total # of Distal Anastomoses done using IMA grafts: _____ NumIMADA (3230)
IMA Harvest Technique: IMATechn (3240) ☐ Direct Vision (open) ☐ Thoracoscopy ☐ Combination ☐ Robotic Assist

Number of Radial Arteries Used for Grafts: _____ (If >0 ...) NumRadArtUs (3260)
Number of Radial Artery Distal Anastomoses : _____ NumRadDA (3270)
Radial Distal Anastomoses Harvest Technique: ☐ Endoscopic ☐ Direct Vision (open) ☐ Both RadHTech (3280)
Radial Artery Harvest Time: _____ (minutes) RadHrvstT (3285)
Radial Artery Preparation Time: _____ (minutes) RadPrepT (3286)

Number Other Arterial Distal Anastomoses Used (other than radial or IMA): _____ NumOArtD (3300)

Native Coronary Disease Location Key:

1 = Left Main	4 = Distal LAD	7 = Circumflex	10 = OM 3	13 = PLB
2 = Prox LAD	5 = Diagonal 1	8 = OM 1	11 = RCA	14 = AM branches
3 = Mid LAD	6 = Diagonal 2	9 = OM 2	12 = PDA	15 = Ramus

For each question, check the one choice that applies for each graft:

	CABG NUMBER	1	2	3	4	5	6	7	8	9	10
GRAFT DONE	Yes CAB[02-10]	NA	3440	3530	3620	3710	3800	3890	3980	4070	4160
	No										
NATIVE CORONARY DISEASE LOCATION (See key above) CABDisLoc[01-10]		3355	3445	3535	3625	3715	3805	3895	3985	4075	4165
HIGHEST PERCENT STENOSIS IN NATIVE VESSEL CABPctSten[01-10]		3356	3446	3536	3626	3716	3806	3896	3986	4076	4166
PREVIOUS CONDUIT	Yes - Diseased CABPrevCon[01-10]	3357	3447	3537	3627	3717	3807	3897	3987	4077	4167
	Yes - No disease										
	No previous conduit										
PROXIMAL SITE	In Situ Mammary CABProximalSite[01-10]	3360	3450	3540	3630	3720	3810	3900	3990	4080	4170
	Ascending aorta										
	Descending aorta										
	Subclavian artery										
	Innominate artery										
	T-graft off SVG										
	T-graft off Radial										
	T-graft off LIMA										
	T-graft off RIMA										
PROXIMAL TECHNIQUE	In Situ Mammary CABProxTech[01-10]	3370	3460	3550	3640	3730	3820	3910	4000	4090	4180
	Running										
	Interrupted										
	Anastomotic Device										
	Anastomotic Assist Device										
CONDUIT	Vein graft CABConduit[01-10]	3380	3470	3560	3650	3740	3830	3920	4010	4100	4190
	In Situ LIMA										
	In Situ RIMA										
	Free IMA										
	Radial artery										
	Other arteries, homograft										
DISTAL INSERTION SITE	Right Coronary (RCA) CABDistSite[01-10]	3390	3480	3570	3660	3750	3840	3930	4020	4110	4200
	Acute Marginal (AM)										
	Posterior Descending Artery (PDA)										
	Posterolateral Branch (PLB)										
	Proximal LAD										
	Mid LAD										
	Distal LAD										
	Diagonal 1										
	Diagonal 2										
	Ramus										
	Obtuse Marginal 1										
	Obtuse Marginal 2										
	Obtuse Marginal 3										
	Other										
DISTAL TECHNIQUE	Running CABDistTech[01-10]	3400	3490	3580	3670	3760	3850	3940	4030	4120	4210
	Interrupted										
	Clips										
	Anastomotic device										
DISTAL POSITION	End to Side CABDistPos[01-10]	3410	3500	3590	3680	3770	3860	3950	4040	4130	4220
	Sequential (side to side)										
ENDARTERECTOMY	YesCABEndArt[01-10]	3420	3510	3600	3690	3780	3870	3960	4050	4140	4230
	No										
HYBRID	No CABHyPCI[01-10]	3430	3520	3610	3700	3790	3880	3970	4060	4150	4240
	Angioplasty										

	Stent										

K. Valve Surgery

(If Valve Surgery=Yes ↓)

Aortic Valve Procedure Performed: ☐ Yes ☐ No VSAV (4270)

(If Yes ↓)

Procedure Performed:

VSAVPr (4280):

☐ Replacement

☐ Repair / Reconstruction

(If Repair / Reconstruction ↓)

Primary Repair Type: (Select all that apply)

Commissural Annuloplasty VSAVRComA (4282)	☐ Yes ☐ No	Ring Annuloplasty VSAVRRingA (4283)	☐ Yes ☐ No
Leaflet plication VSAVRLPlic (4284)	☐ Yes ☐ No	Leaflet resection suture VSAVRLResect (4285)	☐ Yes ☐ No
Leaflet free edge reinforcement (PTFE) VSAVRPTFE (4286)	☐ Yes ☐ No	Leaflet pericardial patch VSAVRLPPatch (4287)	☐ Yes ☐ No
Leaflet commissural resuspension suture VSAVRComRS (4288)	☐ Yes ☐ No	Leaflet debridement VSAVRDeb (4289)	☐ Yes ☐ No
Division of fused leaflet raphe VSAVRRaphe (4290)	☐ Yes ☐ No		

☐ Root Reconstruction with valved conduit

☐ Replacement and insertion aortic non-valved conduit

☐ Resuspension AV without replacement of ascending aorta

☐ Resuspension AV with replacement of ascending aorta

☐ Apico-aortic conduit (Aortic valve bypass)

☐ Autograft with pulmonary valve-Ross procedure

☐ Homograft

☐ Valve sparing root reimplantation (David)

☐ Valve sparing root remodeling (Yacoub)

Transcatheter Valve Replacement: ☐ Yes ☐ No VSTCV (4295)

(If Yes →) Replacement approach: ☐ Transapical ☐ Transaxillary ☐ Transfemoral VSTCVR (4300)

Aortic Annular Enlargement: ☐ Yes ☐ No AnlrEnl (4310)

Resection of sub-aortic stenosis: ☐ Yes ☐ No ResectSubA (4311)

Implant Model Number :_____ Size: _____
VSAoIm (4330) VSAoImSz (4340)

Mitral Valve Procedure Performed: ☐ Yes ☐ No VSMV (4351)

(If Yes ↓)

Procedure Performed: VSMVPr (4352)

☐ Repair

(If Repair ↓) Repair Type: (Select all that apply ↓)

Annuloplasty VSMitRAnnulo (4361)	☐ Yes ☐ No	
Leaflet Resection VSMitRLeafRes (4362)	☐ Yes ☐ No	(If Yes ↓) Resection Type: ☐ Triangular ☐ Quadrangular ☐ Other VSLeafResTyp (4380) Location: ☐ Anterior ☐ Posterior ☐ Both Anterior and Posterior VSLeafRepLoc (4390)
Sliding Plasty VSMitRSlidP (4391)	☐ Yes ☐ No	
Annular decalcification VSMitRADecalc (4393)	☐ Yes ☐ No	
Neochords (PTFE) VSMitRPTFE (4394)	☐ Yes ☐ No	(If Yes ↓) Number of neochords inserted: _____ VSNeoChNum (4400)
Chordal /Leaflet transfer VSMitRChord (4401)	☐ Yes ☐ No	
Leaflet extension/replacement/patch VSMitRLeafERP (4402)	☐ Yes ☐ No	
Edge to Edge Repair VSMitREdge (4403)	☐ Yes ☐ No	
Mitral commissurotomy VSMitRMitComm (4404)	☐ Yes ☐ No	

☐ Replacement (If Replacement →) Repair attempted prior to Mitral Valve Replacement: ☐ Yes ☐ No MitralIntent (4410)

Implant Model Number:_____ Size: _____
VSMiIm (4430) VSMiImSz (4440)

Mitral Chords Preserved: ☐ None ☐Anterior ☐ Posterior ☐ Both VSChorPres (4450)

Tricuspid Valve Procedure Performed: OpTricus (4500)
- ☐ No
- ☐ Annuloplasty only
- ☐ Replacement
- ☐ Reconstruction with Annuloplasty
- ☐ Reconstruction without Annuloplasty
- ☐ Valvectomy

(If "Annuloplasty only" OR "Reconstruction with Annuloplasty".)
Type of Annuloplasty: ☐ Pericardium ☐ Suture ☐ Prosthetic Ring
OpTricusAnTy (4510)

Implant Model Number:_____ VSTrIm (4540)
Size: _____ VSTrImSz (4550)

Pulmonic Valve Procedure Performed: OpPulm (4560)
- ☐ No
- ☐ Replacement
- ☐ Reconstruction
- ☐ Valvectomy

Implant Model Number:_____ VSPulm (4580)
Size: _____ VSPulmSz (4590)

L. Mechanical Cardiac Assist Devices

Intra Aortic Balloon Pump (IABP): ☐ Yes ☐ No (If Yes,) IABP (4610)
IABP Insertion: ☐ Preop ☐ Intraop ☐ Postop IABPWhen (4620)
Primary Reason for Insertion: ☐ Hemodyn Instability ☐ PTCA Support ☐ Unstable Angina ☐ CPB Weaning Failure ☐ Prophylactic
IABPInd (4630)
Date IAPB Removed: __ __/__ __/__ __ __ __ (mm/dd/yyyy)
IABPRemDt (4640)

Catheter Based Assist Device Used: ☐ Yes ☐ No (If Yes,) CathBasAssist (4660)
Device: ☐ Impella ☐ Tandem Heart ☐ Other CathBasAssistDev (4670)
When Inserted: ☐ Preop ☐ Intraop ☐ Postop CathBasAssistWhen (4690)
Primary Reason for Insertion: ☐ Hemodynamic instability ☐ CPB weaning failure ☐ PCI failure ☐ Other CathBasAssistInd (4700)
Date Device Removed: __ __/__ __/__ __ __ __ (mm/dd/yyyy)
CathBasAssistRemDt (4710)

Extracorporeal Membrane Oxygenation (ECMO): ☐ Yes ☐ No (If Yes,) ECMO (4730)
ECMO Initiated: ☐ Preop ☐ Intraop ☐ Postop ☐ Non-operative ECMOWhen (4740)
Clinical Indication for ECMO Placement: ☐ Cardiac Failure ☐ Respiratory Failure ☐ Hypothermia ☐ Rescue/salvage
ECMOInd (4750)

Previous VAD: ☐ Yes ☐ No (If Yes,) PrevVAD (4760)
Implanted at another facility: ☐ Yes ☐ No PrevVADF (4770)
Prev VAD Insertion Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy) PrevVADD (4771)
Prev VAD Indication: ☐Bridge to Transplantation ☐ Bridge to Recovery ☐ Destination ☐ Post Cardiotomy Ventricular failure ☐ Device Malfunction ☐ End of Life
PrevVADIn (4772)
Prev VAD Type: ☐ RVAD ☐ LVAD ☐ BiVAD ☐ TAH PrevVADTy (4773)
Prev VAD Device: _____ (refer to current "On-Demand Device Lists" document) PrevVADDevice (4774)

(If VAD Implanted or Removed,)

References to "Initial VAD" refer to the initial VAD for this hospitalization, not a VAD placed during a previous hospitalization.

VAD Implant Type: **Right VAD (RVAD)** **Left VAD (LVAD)** **Biventricular VAD (BiVAD)** **Total Artificial Heart (TAH)**

VAD Device: (refer to current "On-Demand Device Lists" document)

Explant Reason: **1. Cardiac Transplant 2. Recovery 3. Device Transfer 4. Device-Related Infection 5. Device Malfunction 6. End of Life**

Indication for this VAD: ☐ Bridge to Transplantation ☐ Bridge to Recovery ☐ Destination ☐ Postcardiotomy Ventricular Failure ☐ Device Malfunction ☐ End of Life
VADInd (4790)

Initial Implant Data

Implant Type	VAD Device	Implant Date	Explant	Explant Date	Explant Reason	Transplant Date
		___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy		___ / ___ / _____ mm dd yyyy
VImpTy (4850)	VProdTy (4880)	VImpDt (4890)	VExp (4900)	VExpDt (4910)	VExpRsn (4920)	VTxDt (4930)

Additional Implant(s) Data

Second Device Implanted: ☐ Yes ☐ No (If Yes,) VImp2 (4940)

Implant Type#2	VAD Device #2	Implant Date#2	Explant#2	Explant Date#2	Explant Reason#2	Transplant Date#2
		___ / ___ / _____ mm dd yyyy	☐ Yes ☐ No	___ / ___ / _____ mm dd yyyy		___ / ___ / _____ mm dd yyyy
VImpTy2 (4950)	VProdTy2 (4980)	VImpDt2 (4990)	VExp2 (5000)	VExpDt2 (5010)	VExpRsn2 (5020)	VTxDt2 (5030)

Third Device Implanted: ☐ Yes ☐ No (If Yes → VImp3 (5040))

Implant Type#3	VAD Device #3	Implant Date#3	Explant#3	Explant Date#3	Explant Reason#3	Transplant Date#3
		___/___/_____	☐ Yes ☐ No	___/___/_____		___/___/_____
		mm dd yyyy		mm dd yyyy		mm dd yyyy
VImpTy3 (5050)	VProdTy3 (5080)	VImpDt3 (5090)	VExp3 (5100)	VExpDt3 (5110)	VExpRsn3 (5120)	VTxDt3 (5130)

Primary VAD Complications Data:

Intracranial Bleed	PVCmpBld (5140)	☐ Yes ☐ No
Embolic Stroke	PVCmpESt (5150)	☐ Yes ☐ No
Driveline and/or cannula Infection	PVCmpDCI (5160)	☐ Yes ☐ No
Pump Pocket Infection	PVCmpPPI (5170)	☐ Yes ☐ No
Endocarditis	PVCmpEnd (5180)	☐ Yes ☐ No
Device Malfunction	PVCmpMal (5190)	☐ Yes ☐ No
Hemolysis	PVCmpHem (5191)	☐ Yes ☐ No
Bowel Obstruction	PVCmpBO (5200)	☐ Yes ☐ No

Additional Complications (not specific to initial VAD as above) to be collected in Postoperative Events section.

VAD Discharge Status: VADDiscS (5210)
☐ With VAD
☐ Without VAD
☐ Expired in Hospital

M. Other Cardiac Procedure

(If Other Card = Yes ...)

Left Ventricular Aneurysm Repair: ☐ Yes ☐ No OCarLVA (5220)

Ventricular Septal Defect Repair: ☐ Yes ☐ No OCarVSD (5230)

Atrial Septal Defect Repair: ☐ Yes ☐ No OCarASD (5240)
(If Yes →) ASD Type: ☐ Secundum ☐ Sinus Venosus ☐ PFO OCarASDTy (5241)

Surgical Ventricular Restoration: ☐ Yes ☐ No OCarSVR (5290)

Congenital Defect Repair: ☐ Yes ☐ No (If Yes →) OCarCong (5300)

Congenital Diagnoses: Select up to three most significant diagnoses: (refer to "Congenital Diagnoses/Procedures List" document)
Diagnosis 1: _____ OCarCongDiag1 (5310)
Diagnosis 2: _____ OCarCongDiag2 (5320)
Diagnosis 3: _____ OCarCongDiag3 (5330)

Congenital Procedures: Select up to three most significant: (refer to "Congenital Diagnoses/Procedures List" document)
Procedure 1: _____ OCarCongProc1 (5340)
Procedure 2: _____ OCarCongProc2 (5350)
Procedure 3: _____ OCarCongProc3 (5360)

Transmyocardial Laser Re-vascularization (TMR): ☐ Yes ☐ No OCarLasr (5370)

Cardiac Trauma: ☐ Yes ☐ No OCarTrma (5380)

Cardiac Transplant: ☐ Yes ☐ No OCarCrTx (5390)

Arrhythmia Correction Surgery: OCarACD (5400)
☐ None ☐ Permanent Pacemaker
☐ Permanent Pacemaker with Cardiac Resynchronization Technique (CRT)
☐ Implantable Cardioverter Defibrillator (ICD) ☐ ICD with CRT

(If not None →) Arrhythmia Correction Surgery Lead Insertion or Replacement: ☐ Yes ☐ No OCarACDLI (5410)

Arrhythmia Correction Surgery Lead Extraction: ☐ Yes ☐ No OCarACDLE (5430)

Atrial Fibrillation Surgical Procedure: ☐ Yes ☐ No OCarAFibSur (5450)

(If Yes →) Surgical Procedure Location: ☐ Biatrial ☐ Left atrial only ☐ Right atrial only OCarAFibSurLoc (5451)

Left Atrial Appendage Obliterated ☐ Yes ☐ No OCarAFibSurLAA (5452)

Method of Lesion Creation: (Select all that apply.)

Radio frequency	☐ Yes ☐ No OCarAFibMethRad (5455)	Cryo	☐ Yes ☐ No OCarAFibMethCryo (5457)	Laser	☐ Yes ☐ No OCarAFibMethLas (5459)
Ultrasound	☐ Yes ☐ No OCarAFibMethUltra (5456)	Microwave	☐ Yes ☐ No OCarAFibMethMicro (5458)	Cut-and-sew	☐ Yes ☐ No OCarAFibMethCAS (5460)

Atrial Fibrillation Ablation Procedure: OCarAFibAProc (5465)
☐ Primarily epicardial procedure (e.g., pulmonary vein isolation with or without connection to left atrial appendage).
☐ Primarily intracardiac procedure (e.g., Maze procedures; lesions to mitral annulus; etc.)

Aortic Procedure Type: OCAoProcType (5471)

	☐ None	
	☐ Aneurysm	(If Aneurysm ...) Aortic Root: ☐ Yes ☐ No ONCAoRt (5473) (If Yes ...) Dacron graft used: ☐ Yes ☐ No ONCAoGraft (5474) Repair of ascending aortic aneurysm: ☐ Yes ☐ No ONCAsc (5480) Repair of aneurysm in the arch of the aorta: ☐ Yes ☐ No ONCArch (5490) (If Yes ...) Extent of repair: ☐ Hemi-arch ☐ Total arch ONCArchRepExt (5491) Repair of a descending aortic aneurysm: ☐ Yes ☐ No ONCDesc (5500) Repair of a thoracoabdominal aneurysm: ☐ Yes ☐ No ONCThAbd (5510) (If Yes ...) Graft replacement used: ☐ Yes ☐ No ONCThAbdGraft (5511) (If Yes ...) Intercostal vessels re-implanted: ☐ Yes ☐ No ONCThAbdInterVes (5512) CSF drainage utilized: ☐ Yes ☐ No ONCThAbdLumCSF (5513) Extent of descending aorta replacement: ONCThAbdExtent (5514) ☐ Proximal ☐ Mid ☐ Distal ☐ Proximal - Mid ☐ Proximal - Mid - Distal ☐ Mid - Distal
	☐ Dissection (including intramural hematoma) ☐ Trauma ☐ Coarctation ☐ Other	(If Dissection ...) Aortic dissection is acute: ☐ Yes ☐ No AoDisAc (5516) Dissection type: ☐ Stanford Type A ☐ Stanford Type B AoDisTyp (5517) (If Trauma ...) Aortic Trauma type: ☐ Blunt ☐ Penetrating AoTrTyp (5518)
Endovascular Procedure (TEVAR): ☐ Yes ☐ No EndoProc (5520) (If Yes ...) Endovascular Debranching: ☐ Yes ☐ No EndoProcDeb (5521)		
Tumor Resection: ☐ None ☐ Myxoma ☐ Fibroelastoma ☐ Hypernephroma ☐ Sarcoma ☐ Other OCTumor (5530)		
Pulmonary Thromboembolectomy: ☐ None ☐ Yes, Acute ☐ Yes, Chronic OCPulThromDis (5540)		
Other: ☐ Yes ☐ No OCarOthr (5550)		

N. Other Non Cardiac Procedures

(If Other Non-Card = Yes ...)

Carotid Endarterectomy: ☐ Yes ☐ No ONCCarEn (5560)

Other Vascular: ☐ Yes ☐ No ONCOVasc (5570)

Other Thoracic: ☐ Yes ☐ No ONCOThor (5580)

Other: ☐ Yes ☐ No ONCOther (5590)

O. Post Operative

Postoperative Creatinine Level: _____ PostCreat (5610)

Blood Products Used Postoperatively: ☐ Yes ☐ No (If Yes ...) BldProd (5620)

Red Blood Cell Units: _____ BdRBCU (5630) Fresh Frozen Plasma Units: _____ BdFFPU (5640) Cryoprecipitate Units: _____ BdCryoU (5650) Platelet Units: _____ BdPlatU (5660)

Extubated in OR: ☐ Yes ☐ No ExtubOR (5670)

Re-intubated During Hospital Stay: ☐ Yes ☐ No (If Yes ...) Additional Hours Ventilated: _____
ReIntub (5680) VentHrsA (5690)

ICU Visit: ☐ Yes ☐ No ICUVisit (5700) (If Yes ...) Initial ICU Hours: _____ ICUInHrs (5710)

Readmission to ICU: ☐ Yes ☐ No ICUReadm (5720) (If Yes ...) Additional ICU Hours: _____ ICUAdHrs (5730)

Post Op Echo Performed: ☐ Yes ☐ No (If Yes ...) POpTTEch (5744)
Highest level aortic insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe POpTTAR (5745)
Highest level mitral insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe POpTTMR (5746)
Highest level tricuspid insufficiency found: ☐ None ☐ Trace/trivial ☐ Mild ☐ Moderate ☐ Severe POpTTTR (5747)

Post Op Ejection Fraction Done: ☐ Yes ☐ No (If Yes ...) POpEFD (5748)
Post Op Ejection Fraction: _____ (%) POpEF (5749)

Cardiac Enzymes (biomarkers) Drawn: ☐ Yes ☐ No (If Yes ...) Peak CKMB: _____ Peak Troponin I _____ Peak Troponin T _____
POpEnzDrawn (5750) POpPkCKMB (5751) POpPkTrI (5752) POpPkTrT (5753)

12-Lead EKG Findings: ☐ Not performed ☐ No significant changes ☐ New Pathological Q-wave or LBBB POpEKG (5754)

Imaging Study Findings: POpImagStdy (5755)
☐ Not performed
☐ Angiographic evidence of new thrombosis or occlusion of graft or native coronary
☐ Imaging evidence of new loss of viable myocardium
☐ No evidence of new myocardial injury

P. Postoperative Events

In Hospital Postoperative Event Occurred: ☐ Yes ☐ No (If Yes ...) Complics (5759)

Operative

ReOp for Bleeding /Tamponade: ☐ Yes ☐ No COpReBld (5760) (If Yes ...) Bleed Timing: ☐ Acute ☐ Late COpReBldTim (5770)

ReOp for Valvular Dysfunction: ☐ Yes ☐ No COpReVlv (5780)

ReOp for Graft Occlusion: ☐ Yes ☐ No COpReGft (5790)
ReOp for Other Cardiac Reasons: ☐ Yes ☐ No COpReOth (5800)
ReOp for Other Non-Cardiac Reasons: ☐ Yes ☐ No COpReNon (5810)
Open chest with planned delayed sternal closure: ☐ Yes ☐ No COpPlndDelay (5811)
Sternotomy Issue: ☐ Yes ☐ No CSternal (5830) (If Yes ...) Sternal instability/dehiscence (sterile): ☐ Yes ☐ No CSternalDehis (5840)

Infection (see CDC definitions in training manual)
Surgical Site Infection: ☐ Yes ☐ No (If Yes ...) SurSInf (5841)
Sternal Superficial Wound Infection: ☐ Yes ☐ No CSternalSupInf (5850)
Deep Sternal Infection: ☐ Yes ☐ No CISt Deep (5860)
Mediastinitis: ☐ Yes ☐ No (If Yes ...) CSternalMedia (5870)
Diagnosis Date: __ __/__ __/__ __ __ __ (mm/dd/yyyy) CSternalMediaDtDiag (5880)
Secondary Procedure Open with Packing/Irrigation: ☐ Yes ☐ No CSternalMediaSPOpen (5890)
Secondary Procedure Wound Vac: ☐ Yes ☐ No CSternalMediaSPWVac (5900)
Secondary Procedure Muscle Flap: ☐ Yes ☐ No CSternalMediaSPMuscle (5910)
Secondary Procedure Omental Flap: ☐ Yes ☐ No CSternalMediaSPOmental (5920)
Thoracotomy: ☐ Yes ☐ No CIThor (5930)
Conduit Harvest or Cannulation Site: ☐ Yes ☐ No CILeg (5940)
Wound Intervention - Open with Packing/Irrigation: ☐ Yes ☐ No WndIntOpen (5960)
Wound Intervention - Wound Vac - ☐ Yes ☐ No WndIntWVac (5970)
Sepsis: ☐ Yes ☐ No CSepsis (6010) (If Yes ...) Positive Blood Cultures: ☐ Yes ☐ No CSepsisPBC (6020)

Neurologic
Postoperative Stroke (Perm>24 hours): ☐ Yes ☐ No CNStrokP (6030)
Transient Ischemic Attack (TIA): ☐ Yes ☐ No CNStrokTTIA (6040)
Encephalopathy: ☐ None ☐ Anoxic ☐ Embolic ☐ Drug ☐ Metabolic ☐ Intracranial Bleeding ☐ Other CNCornaEnceph (6070)
Paralysis: ☐ Yes ☐ No CNParal (6110) (If Yes ...) Paralysis Type: ☐ Transient ☐ Permanent CNParalTy (6120)

Pulmonary
Prolonged Ventilation: ☐ Yes ☐ No CPVntLng (6130)
Pneumonia: ☐ Yes ☐ No CPPneum (6150)
Venous Thromboembolism - VTE: ☐ Yes ☐ No CVTE (6160) (If Yes ...)
Pulmonary Thromboembolism: ☐ Yes ☐ No PulmEmb (6170)
Deep Venous Thrombosis: ☐ Yes ☐ No DVT (6180)
Pleural Effusion Requiring Drainage: ☐ Yes ☐ No CPlEff (6190)

Renal
Renal Failure: ☐ Yes ☐ No CRenFail (6200) (If Yes ...)
Dialysis (Newly Required): ☐ Yes ☐ No (If Yes ...) Required after Hospital Discharge: ☐ Yes ☐ No
CRenDial (6210) DialDur (6220)
Ultra Filtration Required: ☐ Yes ☐ No CUltraFil (6230)

Vascular
Iliac/Femoral Dissection: ☐ Yes ☐ No CVaIlFem (6240)
Acute Limb Ischemia: ☐ Yes ☐ No CVaLbIsc (6250)

Other
Rhythm Disturbance Requiring Permanent Device: ☐ Pacemaker ☐ ICD ☐ Pacemaker/ICD ☐ None CRhythmDis (6270)
Cardiac Arrest: ☐ Yes ☐ No COtArrst (6280)
Anticoagulant Event: ☐ Yes ☐ No COtCoag (6290)
Tamponade (Non-Surgical Intervention): ☐ Yes ☐ No COtTamp (6300)
Gastro-Intestinal Event: ☐ Yes ☐ No COtGI (6310)
Multi-System Failure: ☐ Yes ☐ No COtMSF (6320)
Atrial Fibrillation: ☐ Yes ☐ No COtAFib (6330)
Aortic Dissection: ☐ Yes ☐ No CVaAoDis (6340)
Recurrent Laryngeal Nerve Injury: ☐ Yes ☐ No RecLarynNrvInj (6341)
Phrenic Nerve Injury: ☐ Yes ☐ No PhrenNrvInj (6342)
Other: ☐ Yes ☐ No COtOther (6350)

Q. Mortality

Mortality: ☐ Yes ☐ No Mortalty (6360)	Discharge Status: ☐ Alive ☐ Dead MtDCStat (6370)	Status at 30 days After Surgery: ☐ Alive ☐ Dead ☐ Unknown Mt30Stat (6380)

Primary method used to verify 30-day status: Mt30StatMeth (6381)
☐ Phone call to patient or family ☐ Evidence of life in medical record ☐ Social Security Death Master File
☐ Letter from medical provider ☐ Office visit to surgeon >= 30 days after procedure ☐ Other

(If Mortality = Yes ...)
Operative Death: ☐ Yes ☐ No MtOpD (6390)
Mortality - Date __ __/__ __/__ __ __ __ (mm/dd/yyyy) MtDate (6400)
Location of Death: ☐ OR During Initial Surgery ☐ Hospital (Other than OR) ☐ Home ☐ Extended Care Facility
MtLocatn (6410) ☐ Hospice ☐ Acute Rehabilitation ☐ OR During Reoperation ☐ Unknown ☐ Other
Primary Cause of Death (select only one) MtCause (6420)
☐ Cardiac ☐ Neurologic ☐ Renal ☐ Vascular ☐ Infection ☐ Pulmonary ☐ Valvular ☐ Unknown ☐ Other

R. Discharge	
(If Discharge Status = Alive.)	
ADP Inhibitors:	☐ Yes ☐ No DCADP (6430)
Antiarrhythmics:	☐ Yes ☐ No DCAArhy (6440)
Aspirin:	☐ Yes ☐ No ☐ Contraindicated DCASA (6460)
ACE or ARB Inhibitors:	☐ Yes ☐ No, contraindicated ☐ No, not indicated DCACE (6470)
Beta Blockers:	☐ Yes ☐ No ☐ Contraindicated DCBeta (6480)
Lipid Lowering: DCLipid (6490)	☐ Yes ☐ No ☐ Contraindicated (If Yes:) ☐ Statin ☐ Non Statin ☐ Both ☐ Other DCLipMT (6500)
Coumadin:	☐ Yes ☐ No DCCoum (6510)
Direct Thrombin Inhibitors:	☐ Yes ☐ No DCDirThromIn (6511)
Discharge Location: DisLoctn (6520)	☐ Home ☐ Extended Care/Transitional Care Unit/Rehab ☐ Other Hospital ☐ Nursing Home ☐ Hospice ☐Other
Cardiac Rehabilitation Referral:	☐ Yes ☐ No ☐ Not Applicable CardRef (6530)
Smoking Cessation Counseling:	☐ Yes ☐ No ☐ Not Applicable SmokCoun (6540)

S. Readmission	
(If Discharge Status = Alive.)	
Readmit <=30 Days from Date of Procedure: ☐ Yes ☐ No (If Yes:) Readm30 (6550)	
Readmit Primary Reason: ReadmRsn (6560)	Readmit Primary Procedure: ReadmPro (6570)
☐ Anticoagulation Complication - Valvular ☐ Anticoagulation Complication - Pharmacological ☐ Arrhythmia/Heart Block ☐ Congestive Heart Failure ☐ Myocardial Infarction and/or Recurrent Angina ☐ Pericardial Effusion and/or Tamponade ☐ Pneumonia or other Respiratory Complication ☐ Coronary Artery Dysfunction ☐ Valve Dysfunction ☐ Infection - Deep Sternum / Mediastinitis ☐ Infection - Conduit Harvest Site ☐ Renal Failure ☐ TIA ☐ Permanent CVA ☐ Acute Vascular Complication ☐ Subacute Endocarditis ☐ VAD Complication ☐ Transplant Rejection ☐ PE ☐ DVT ☐ Other - Related Readmission ☐ Other - Nonrelated Readmission	☐ OR for Bleeding ☐ Pacemaker Insertion / AICD ☐ PCI ☐ Pericardiotomy / Pericardiocentesis ☐ OR for Coronary Arteries ☐ OR for Valve ☐ OR for Sternal Debridement / Muscle Flap ☐ Dialysis ☐ OR for Vascular ☐ No Procedure Performed ☐ Other Procedure ☐ Unknown

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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House of Representatives
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June 26, 2013

Dr. Thomas Foels
Chief Medical Officer
Independent Health
511 Farber Lakes Drive
Williamsville, NY 14221

Dear Dr. Foels:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 5, 2013, to testify at the hearing entitled "Reforming SGR: Prioritizing Quality in a Modernized Physician Payment System."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Friday, July 12, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Independent Health. | 511 Farber Lakes Drive, Buffalo, New York 14221 716.631.3001 www.independenthealth.com

July 12, 2013

Sydne Harwick
Legislative Clerk, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Ms. Harwick,

Please find responses to the questions posed by members of the committee on Energy & Commerce as outlined in your June 26, 2013 letter.

Sincerely,

Dr. Thomas Foels
Chief Medical Officer

encl

The Honorable Joseph R. Pitts

1) **From a payer perspective, Independent Health grapples with many of the same issues as CMS does with the Medicare program (albeit on a different scale). From the perspective of someone who has endeavored in such work with providers in New York, do you believe the types of measurement and model programs envisioned under the Committee's legislative framework to be of benefit to the Medicare program?**

Yes, I believe the committee's legislative framework as outlined in the "Discussion Draft: Reform of Sustainable Growth Rate (SGR) and Medicare Payment for Physician Services" contains important, key elements necessary to shift payment toward a pay-for-value program that recognizes and rewards performance and quality.

Specifically, I believe:

- ✓ Quality measures (including functional, process and clinical outcome measures) currently exist and can be further developed that represent and differentiate the ability of primary care physicians and specialty physicians to provide clinical quality.
- ✓ Physicians and professional organizations representing physicians should be involved in metric development, attribution logic, risk adjustment methodologies and scoring systems.
- ✓ That development and implementation of quality measures must precede the broader movement toward alternative payment systems other than fee-for-service (FFS). Bundled payments, case payment, global population-based payments, and/or shared-savings reimbursement each have potential perverse incentives for under-utilization. A robust collection of quality measurements and incentives must be established and operate concurrently with any such alternative payment systems.
- ✓ Public and peer-to-peer transparency of quality measurement is an important element of success for any such program.

I believe additional considerations and discussions are necessary in the following areas:

- ✓ The development of "performance thresholds". Although operationally more challenging, physicians should be rewarded for incremental improvement toward goal. Maximum performance thresholds should be established (ie: at less than 100%) since there are legitimate clinical exceptions to any practice guidelines; performance thresholds should not be established such that they would promote unintended patient harm as the result of inappropriately aggressive medical management nor promote "cherry picking" of patients by practitioners solely for the purpose of improving their performance scores.
- ✓ Clinical quality guidelines should be adopted which specifically address appropriate age/gender and disease co-morbities of the senior patient population. For example, blood glucose (A1C) goals and blood pressure goals for elderly adults may require differing clinical thresholds than these used for middle-aged adults.

- ✓ Physicians must be provided "actionable reporting" of performance in a manner that allows easy interpretation of results, trended reporting to allow providers to understand the impact of their previous interventions to improve care, regional peer comparisons, and educational initiatives (ie: "improvement literacy") to assist them in making necessary improvements in systems of care.
- ✓ Both primary and specialty care physicians should be held mutually responsible for select quality measures. For example, cardiologists should receive reporting and be held responsible for basic quality metrics for diabetic patients under their care, since poorly controlled diabetes constitutes a major risk factor for coronary artery disease progression and stroke.

2) You state in your testimony that one of the guiding principles of IHA are "substantive and sustainable improvement in quality and affordability of the American health care system will require movement away from traditional FFS reimbursement systems. Would you explain why FFS Medicare undercuts quality and affordability in our health care system?

The fee for service system reimburses providers and hospitals solely upon a unit of service being performed.

Here are some examples:

- ✓ An office visit to a primary care physician paid as one unit of service under fee-for-service reimbursement: In one scenario, the primary care physician successfully and effectively provides all clinically relevant, guideline-recommended services, including the coordination of all preventive screening, chronic disease testing for diabetes, smoking cessation recommendations, and other recommended anticipatory needs. Another primary care physician, spending in equal amount of time with the patient, might provide few or none of these services. Currently, in both cases, the physician is reimbursed equally with no recognition of the quality of services provided from that office visit.
- ✓ A specialist seeing a patient referred from a primary care physician does not have immediate access to previous x-rays or results of previous diagnostic tests. A physician taking additional administrative time to coordinate care by obtaining the results of these previous tests currently receives no recognition or financial remuneration for care coordination efforts; as a result, radiologic imaging and diagnostic testing have the potential to be repeated unnecessarily.

In these two simple examples of the current fee-for-service (FFS) Medicare payment system, there's no differentiation of clinical physician services being rendered. In the first example, there is no recognition for the significant difference show in visit quality. In the latter example, there is no recognition or incentive to coordinate care in affordable manner.

3) You state in your testimony that primary care plays a pivotal and foundational role in the transformation to a high quality health care system. I also know that primary care is uniquely positioned in the health care market place to impact cost and quality. With the committee's legislative framework in mind, do you believe it possible to incentivize primary care differently as a way of encouraging even greater quality and affordability in the system? For instance, maybe constructing different types of measures or performance benchmarks could lead to additional benefits in Medicare and patients?

Yes, I believe that primary care is uniquely positioned to play such a pivotal and foundational role. A primary care physician acts as a "comprehensivist"...uniquely and professionally trained to understand and manage a wide spectrum of clinical conditions. Having an established and ongoing relationship with a patient affords a primary care physician the ability to manage the patient longitudinally over time, both diagnostically and therapeutically. This alone provides value in that the primary care physician can manage the patient in a sequential way over time rather than being compelled to bundle services during a simple single episode of care. Also, the primary care physician is in a unique position to understand and manage co-morbid medical and behavioral health conditions. Lastly, the primary care physician's comprehensive understanding of a patient's social needs can be addressed and factored into the patient's therapeutic plan. The inverted ratios of primary care physicians to specialists in the United States contributes to the significant imbalance of demand which exceeds capacity for the primary care physicians, yet allows enhanced capacity and access to specialists. Furthermore, since most Medicare eligible patients have multiple acute and chronic conditions, specialists (acting as "partialists" rather than "comprehensivists") are unable to manage the full array of contributing conditions that might have warranted the referral visit. For example, diabetes is a strong contributor to cardiovascular disease (heart disease and stroke). A cardiologist, managing a diabetic patient with coronary artery disease, would typically not address or feel it their responsibility to co-manage diabetes. Poor access to primary care and easy access to specialty care thus can contribute to missed preventative management opportunities and care disproportionally focused on the sequelae of uncontrolled disease.

The restructuring of primary care in the United States will require a variety of solutions applied simultaneously. First, expanded training programs must be created to increase the number of physicians pursuing a professional career in primary care. Secondly, newly graduated and established primary care physicians should receive ongoing training and education in population management and team-based systems of care. Thirdly, primary care practices must receive enhanced reimbursement to address and balance the existing distortions in professional reimbursement across specialties and to provide sufficient capital for primary care physicians to reinvest in their professional staff, establish high-functioning care teams and acquire the necessary care management tools and technologies to provide population-based care in an effective and efficient manner. Fourth, measurements and incentives should be created to reward achievement of clinical outcomes, completion of critical clinical process measures, and enhanced clinical efficiency. Timely measurement and feedback on performance, combined

with data transparency, meaningful incentives, and ongoing education (improvement literacy) will help drive cycles of continuous quality improvement.

4) The legislative framework envisions a system in which providers might identify themselves for the purposes of measures. Do you think that such a system of quality benchmarks and measurements could also be applied to disease states such as diabetes or cancer?

This is in essence a two-part question. First, providers should be allowed to identify which specialty peer category in which they wish to be measured. For example, many internist physicians are dual-boarded and provide both primary care and specialty care within their practices. Common examples are cardiology and gastroenterology. Depending on the proportion of their professional time spent in each area, they may wish to be categorized under either a primary care or specialty care category. In our experience at Independent Health with pay-for-performance programs, it is important to allow physicians to self-identify their specialty and be placed under the appropriate array of quality metrics.

Secondly, I believe that quality measures and benchmarks can be established for many common disease states. The practical application of such disease- specific measures to physicians will be limited by:

- ✓ The prevalence of the specific disease-state within a physician's Medicare patient population. Conditions with low prevalence will not be able to be measured with statistical validity on an individual physician basis.
- ✓ Measurement should be conducted only when there is significant variation among providers or where median quality performance shows opportunities for improvement. For example, simply because a disease-specific metric can be generated does not mean it should be incentivized; being "easy to measure" differs greatly from "being important to measure".
- ✓ Not all disease states or specialties will lend themselves to measurement in the near term. Efforts should be established to prioritize disease state focus within the Medicare population and develop measurement based upon these priority areas. Not all disease states nor all specialty disciplines require or would benefit from measurement, reporting and incentivization.

5) **You mention in your testimony that no singular payment system is sufficient to simultaneously promote quality, efficiency and effectiveness. Do you believe that entities like Independent Health can help Medicare develop and implement new and innovative payment mechanisms?**

I believe a hybrid approach toward physician payments should be carefully explored. Such hybrid payment systems would incorporate and apply the best attributes of a variety of payment systems accordingly. As presented in my previous written testimony, fee-for-service can be effectively maintained and employed toward potentially under-utilized clinical services. Global population-based prepayment is effective where there are viable, effective alternatives to delivering care other than face-to-face visits. Shared savings opportunities reward providers who work collaboratively with other physicians and institutions to provide effective care coordination. Lastly, quality-based payment serves as an important "check-and-balance" against potential underutilization and creates proper focus on clinical quality opportunities.

Many commercial health plans, including Independent Health and especially those regional not-for-profit health plans affiliated with the Alliance of Community Health Plans (ACHP), have already undertaken innovative approaches toward payment reform. These plans, including Independent Health, have experience and important insight into the design and operational issues associated with alternative payment systems. Existing claims processing systems must be reconfigured to conform to the demands of any alternative payment system. As such, adaptation is challenging. Shared learning among innovative health plans with previous experience would prove of significant benefit to the federal agencies seeking to adopt alternative payment systems.

6) **While primary care and some specialty groups have a long standing history of measure development and performance, others unfortunately lag behind. Do you believe that all provider groups adopting a system of quality measurement will be good for the provision of care in this country, and do you believe that provider specialties that are advanced in these areas might be able to help those who lag behind?**

Please refer to my response to question 4. Medicare should prioritize areas of focus based upon population health needs and opportunities. I do not believe that it is either necessary or wise to work to develop quality performance metrics for each and every specialty. Emphasis should be placed upon where there is demonstrable need for quality improvement.

7) How important is meaningful, timely feedback on performance for such a system to work?

Meaningful, timely feedback is, perhaps, the most critical aspect of driving performance. There is now a long and significant history of physician pay-for-performance in the United States. Although there are many variables among these P4P programs, many have had disappointing long-term impact on improving quality.

Key attributes related to performance feedback of successful programs include:

- ✓ Timely reporting, such that changes in a physician's practice pattern can be demonstrated within the shortest interval possible.
- ✓ Trending data, such that physicians can see their progress toward goal over time.
- ✓ Establishing statistical confidence intervals, such that small sample sizes do not result in large fluctuations in performance over time simply due to statistical variation.
- ✓ Peer norms for comparison, especially among regional providers to whom providers most closely relate professionally.
- ✓ Drill-down reporting (to the patient-specific level) that would allow the provider to both confirm the validity of the performance report and take patient-specific action if cared needs are unmet.

Independent Health has a long history of well-established physician-vetted, actionable reporting and would be available to discuss any such reporting in further detail to any interested party.

The Honorable John Shimkus

1) **Your testimony touches on one such model the "Primary Connections" practice. You state that shared savings models such as Primary Connections "have fostered greater collaborative efforts between primary care and specialty providers." Would you tell me what types of benefits providers, patients, and taxpayers might enjoy should this committee be successful and encourage broad adoption of shared savings and other alternative payment models in Medicare?**

Fundamentally, any individual patient's health care is delivered by a "team" of providers, a by-product of a system of care composed of multiple individuals. Some clinical teams are easily apparent, an example being a doctor, nurse practitioner and nurse within a solo practice. Other "teams" are less obvious and exist in a virtual sense yet they are collaborative team's none-the-less. For example, a primary care office, endocrinology office, cardiology office, and ophthalmology office is all part of a "virtual team" caring for a patient with diabetes.

Optimal health care is the by-product of an optimal health care team. Unfortunately, "team performance" is neither regularly measured nor reported and, even less frequently reimbursed or incentivized or on team basis.

The current fee-for-service (FFS) payment methodology unfortunately recognizes the efforts of individual team-members (not teams) and does so only based upon volume (activities), not upon the success or outcomes those activities.

Shared savings programs have the ability to measure, report, and reward the efficient and effective performance of collaborative and coordinated care teams. Examples of shared savings opportunities include:

- ✓ Primary care provider offices selecting specialty referral sources based upon their efficiency, effectiveness and service attributes (referrals based upon performance transparency vs. based upon anecdotal relationships).
- ✓ Rewards for improved communication and care coordination among providers in an effort to reduce non-value-added duplicate testing and procedures.
- ✓ Encourages development of new and innovative care systems that are focused on measureable outcomes of efficiency and effectiveness (ex: home care programs as an alternative to an avoidable hospitalization).
- ✓ Holistic care that addresses a patients' full spectrum of health care needs related to their condition in an effort to maximize clinical outcomes. [ex: clinical, behavioral, nutritional, social].

2) **Page 21 of the legislative framework released last week calls for the development of a "process by which physicians, medical societies, health care provider organizations, and other entities may propose" Alternative Payment Models for adoption and use in the Medicare program. Do you believe that model development from private payers and providers like those at Independent Health can lead to reforms that could benefit patients, providers, and taxpayers?**

Many commercial health plans have implemented alternative payment models in recent years. This is especially true among regional not-for-profit health plans, who traditionally work closely and collaboratively with providers within their networks to develop payment systems that are built upon transparency, mutual trust, principles of fairness (win-win) and designed to maximize operational ease for all parties. The Alliance of Community Health Plans (ACHP) is one such organization that represents health plans with alternative payment programs of proven success and sustainability. As there are many "lessons learned" already understood and cataloged by these early-innovator health plans, I would strongly encourage collaboration of CMS and the federal government with such organizations in an effort to speed development and deployment of alternative payment on a national level.

The Honorable Gus Bilirakis

1) **How much of these quality measures should be developed for the physician in general or should we have measures for specific diseases? How do we develop quality measures for rare diseases? These are hard to diagnose diseases with small populations. If we do develop metrics for specific conditions, how do we responsibly develop measurements for these conditions when research may be more limited?**

This is in essence a two-part question. First, providers should be allowed to identify which specialty peer category in which they wish to be measured. For example, many internist physicians are dual-boarded and provide both primary care and specialty care within their practices. Common examples are cardiology and gastroenterology. Depending on the proportion of their professional time spent in each area, they may wish to be categorized under either a primary care or specialty care category. In our experience at Independent Health with pay-for-performance programs, it is important to allow physicians to self-identify their specialty and be placed under the appropriate array of quality metrics.

Secondly, I believe that quality measures and benchmarks can be established for many common disease states. The practical application of such disease- specific measures to physicians will be limited by:

- ✓ The prevalence of the specific disease-state within a physician's Medicare patient population. Conditions with low prevalence will not be able to be measured with statistical validity on an individual physician basis.
- ✓ Measurement should be conducted only when there is significant variation among providers or where median quality performance shows opportunities for improvement. For example, simply because a disease-specific metric can be generated does not mean it should be incentivized; being "easy to measure" differs greatly from "being important to measure".
- ✓ Not all disease states or specialties will lend themselves to measurement in the near term. Efforts should be established to prioritize disease states focus within the Medicare population and develop measurement based upon these priority areas. Not all disease states nor all specialty disciplines require or would benefit from measurement, reporting and incentivization.

As a general rule, it is important to "measure what is important to measure" and to resist the urge to measure something simply because it is easy or based upon a perceived need to have a measure for all conditions(both common and rare) or all specialty disciplines. I would strongly encourage the adoption of quality measured based upon a prioritization process based upon:

- ✓ Highest disease prevalence.

- ✓ Greatest performance improvement opportunity (ie: wide existing variation in outcomes among providers or among regions).
- ✓ Clinical areas not receiving sufficient focus or incentivization currently.
- ✓ Favorable return on investment (ROI).
- ✓ Focus may vary by community; attempts should be made to recognize regional variation and the need to measure and incent proportionately (i.e.: create "community report cards" and incent community improvement).

2) **How much input should patient groups have and what type of input into the process should they have when determining these measures?**

I believe patient group might have their greatest impact in helping to delineate community-specific and needs. A patient-centered approach toward metric development contributes to the sense of shared accountability among both patients and providers. A patient centered approach would also facilitate the development of publically transparent provider performance data reporting in a clear, concise and actionable format.

3) **Should the system evolve to allow a direct feedback loop to the doctor? For example, the physician would know that they were paid X because they did or did not do Y to patient Z. Do we want the granular a system, or should the information and payment be done on a more aggregate level?**

Actionable reporting is critical to performance improvement by providers over time.

Physicians must be provided "actionable reporting" of performance in a manner that allows easy interpretation of results, trended reporting to allow providers to understand the impact of their previous interventions to improve care, regional peer comparisons, and educational initiatives (ie: "improvement literacy") to assist them in making necessary practice management improvements to establish improved systems of care.

Meaningful, timely feedback is, perhaps, the most critical aspect of driving performance. There is now a long and significant history of physician pay-for-performance in the United States. Although there are many variables among these P4P programs, many have had disappointing long-term impact in improving quality.

Key attributes of impactful, actionable reporting include:

- ✓ Timely reporting, such that changes in a physician's practice pattern can be demonstrated within the shortest time possible.
- ✓ Trending data, such that physicians can see progress toward goal over time.

- ✓ Establishing statistical confidence intervals, such that small sample sizes do not result in huge fluctuations in performance over time simply due to statistical variation.
- ✓ Peer norms for comparison, especially regional providers to whom providers most closely relate professionally.
- ✓ Patient-specific "Exception reports" so that providers can determine the validity of their performance reports and so that they can act upon unmet clinical needs on a patient specific basis.

Independent Health has a long history of well-established physician-vetted, actionable reporting and would be happy to discuss this in further detail to any interested party.

For example, recent quality improvement efforts at Independent Health involved the application of common diabetic quality metrics to both primary care physicians and to cardiologists who were co-managing these same diabetic patient populations. An important clinical perspective worthy of emphasis is that a patient's underlying diabetic state places them at significantly higher risk for coronary vascular disease. The mere fact that this patient is under the care of a cardiologist may well be an indication that diabetes is a strong contributing causative factor to their current heart disease. Collaborating cardiologists in our program were, at first, reluctant to be held mutually accountable for diabetic quality metrics involving patients under their care, declaring "it is the primary care physician's responsibility to manage diabetes, not mine". Yet, when confronted with performance data demonstrating poor diabetes control and management of patients under their care, cardiologists began to recognize the important role they play in co-monitoring a patient's compliance with needed care.

4) **Is it possible to use physician quality measures to encourage patients to better follow doctor's plan to manage diseases? For example, a newly diagnose diabetic getting a follow up call by the doctor reminding them to check their blood sugar or reminding them to schedule an appointment with a nutritionist. Should these metrics be limited to what is done inside the physician's office?**

Two issues are raised in this question: patient engagement and making primary care physicians and specialists mutually accountable for quality outcomes and performance.

The regard to the former, it would be intriguing to consider establishing an individual "patient report card" that would list out for the patient the services they should be receiving, with an accompanying report of whether these needed services have been met or unmet. For example, although physicians are asked to adopt a best practice clinical guideline for diabetic care management and have various quality measures based upon the tenants of such a clinical practice guidelines, it would be ideal for patients to receive a similar best practice guideline outlining the care they should also follow. If such a document were to be created, patients

would have a much clearer expectation of their disease-specific and health maintenance needs and could themselves, become more fully engaged in conversations with their physicians regarding mutually acceptable disease management goals.

As to the latter issue of holding multiple physicians mutually accountable for quality performance along with primary care physicians, it is important to recognize that fundamentally, any individual patient's health care is delivered by a "team" of providers, a by-product of a system of care composed of multiple individuals. Some clinical teams are easily apparent, an example being a doctor, nurse practitioner and nurse within a solo practice. Other "teams" are less obvious and exist in a virtual sense yet they are collaborative team none-the-less. For example, a primary care office, endocrinology office, cardiology office, and ophthalmology office are all part of a "virtual team" carrying for a patient with diabetes.

Optimal health care is the by-product of an optimal health care team. Unfortunately "team performance" is neither regularly measured nor reported and, even less frequently reimbursed or incentivized as a team.

The current fee-for-service (FFS) payment methodology unfortunately recognizes the efforts of individual team-members (not teams) and does so only based upon volume (activities), not upon the success or shortcomings those activities (outcomes).

5) **Should the quality measure be weighted? If there are 10 things that a doctor can do to increase their performance measure, should they be rated equally for payment bonuses or weighted to account for time or difficulty?**

In regard to the relative weighting of quality measures, there are various important considerations. The most commonly used weighting methodology is to allocate more weight to outcome measures than to process measures. To site a common example, performance would be more heavily weighted to achieving blood sugar control in a diabetic patient (A1C within control; an outcome measure) than to simply obtaining the screening test within the appropriate time period (A1C test complete; a process measure).

Alternatively, one might weight measures based upon some other criteria, for example, placing more heavy weight upon metrics where there exists the lowest current performance level (i.e. largest improvement opportunity) or on individual metrics that might provide the greatest return on investment. It might also be appropriate to vary weighting based upon specific community or regional needs and priority areas. A uniform or standardized national weighting methodology might place too much emphasis on a quality metric needing little additional improvement within an individual community, yet place too little emphasis on a community quality metric truly deserving of additional focus.

One additional methodology for weighting is the creation of a "quality composite index". A quality composite index is the sum of all numerators divided by the sum of all denominators across a spectrum of different and often unrelated quality metrics. An example would be:

Quality Composite Index = $\frac{\text{Q1 numerator}}{\text{Q1 denominator}} + \frac{\text{Q2 numerator}}{\text{Q2 denominator}} + \frac{\text{Q3 numerator}}{\text{Q3 denominator}} = \frac{(Q1n + Q2n + Q3n)}{(Q1d + Q2d + Q3d)}$

Q1, Q2, Q3 = represent three district and unrelated quality metrics

N = numerator or number of patients meeting quality metric goal
D = denominator or number of patients eligible for measurement under that individual metric

Q1 = diabetic patients receiving A1C test annually
$= \frac{230 \text{ received test}}{300 \text{ eligible}} = 76\%$

Q2 = post myocardial infraction patients receiving aspirin therapy
$= \frac{22 \text{ received aspirin}}{25 \text{ eligible}} = 88\%$

Q3 = colorectal cancer screening
$= \frac{49 \text{ received screening}}{75 \text{ eligible for screening}} = 65\%$

Quality Composite Index = $\frac{(230 + 22 + 49)}{(300 + 25 + 75)} = \frac{301}{400} = 75\%$

In this example of a composite index, each individual metric is automatically weighted upon the proportion of a physician's patient panel which meets eligibility criteria for that measure. Thus, diabetes (300 eligible) is inherently weighted more heavily than post myocardial infraction patients (only 25 eligible). In doing so, the differences which inherently exist in patient mix and disease-state composition between one physician vs. another physician are taken into consideration. A physician practice with very few post myocardial infarction patients but many diabetic patients would be weighted differently than a practice with the diverse mix of patients and disease states. In each case, measurement automatically adjusts to reflect the composite "best practice score" based upon multiple clinical parameters across each physician practice.

The composite index also eliminates the need to establish a minimum patient threshold for each quality metric. A physician practice with a small Medicare membership may have no single quality metric denominator reaching statistical significance; yet summing all clinical quality opportunities into a single composite index would be respectful of that practice's aggregate clinical quality opportunity.

Weighting for "time and difficulty" is yet another methodology for consideration. Although it might be challenging to quantitate professional resource investment attribute for any individual quality metric, it would seem possible to achieve consensus from a qualitative perspective (i.e. obtaining an A1C test is relatively more easy and less resource intense than managing a patient A1C blood sugar to goal, which might require multiple office visits and medication changes over time).

The Honorable John D. Dingell

1) **During the hearing, you agreed that Congress should look at the innovations and changes being made in the private sector when considering reforms to SGR. Would you please list some suggestions of what you feel might be useful?**

Attached is a paper that describes payment models implemented by Independent Health and several other members of the Alliance of Community Health Plans (ACHP). There are a number of themes that emerge from our and others' experience with payment models that reduce reliance on fee-for-service. These include:

- Payment models should be structured to put primary care at the center of the system. Payment should recognize the care coordination and integrative functions of the primary care clinician. Primary care physicians need information about which specialists and hospitals are more effective (quality) and more efficient (cost). Especially when combined with innovative benefit designs that encourage patients to choose high value care, these payment models provide strong incentives for primary care physicians to take responsibility for the quality of care and the cost associated with a defined patient population.

- Payment models should be phased in over time, starting with "upside risk" (shared savings, but not shared loss). This fosters trust and confidence among physician practices and allows time for physicians to improve their ability to manage a population before moving to a shared risk arrangement.

- Meaningful and transparent quality and cost measures are a key element. Payment models must be connected to measures that are meaningful to patients and physicians, reflecting both outcomes and the overall cost of care. The attached paper lists a number of measures that often are used to reward physician performance, including preventive health and disease management measures as well as measures of total cost that use risk-adjusted ratios to compare physicians to peer groups.

- Building relationships with physicians is critical. Getting provider buy-in to new payment arrangements that are aligned with outcomes and efficiency measures is an essential component of payment reform. Such buy-in includes work with physicians to explain and benchmark performance, soliciting their professional judgment on the best measures, and including other community stakeholders to ensure broad support for the use of transparent metrics and incentives tied to those metrics.

Please see the attached document ("ACHP Approach to Payment Reform)- which includes additional details of various innovative alternative reimbursement programs among several regional not-for-profit health insurers.

ACHP Approach to Payment Reform - Response to October 3, 2012 Meeting

ACHP member organizations have been leaders in restructuring physician payment and moving away from fee-for-service for many years. Our health plans have adopted these payment reforms in order to align the goals of payers and physicians in keeping people healthy and providing care that is of the highest quality and value. As innovators in different areas of the country, our member organizations have developed physician incentive programs that meet the needs of practices in their communities—whether physicians are delivering care as sole proprietors, multi-specialty clinics or integrated health systems. One unifying characteristic is the simultaneous focus on quality, efficiency, and patient satisfaction.

ACHP health plans support practices financially through one or more of the following mechanisms:

- stipends or transformation "seed money";
- bundled payments;
- pay-for-performance;
- enhanced fee-for-service payments;
- shared savings/gain sharing, and or shared risk;
- care coordination/care management fees

One area of particular innovation, for both integrated systems and health plans that contract with providers (as well as mixed-model health plans), is the Patient-Centered Medical Home. ACHP members see the medical home as a way of transforming primary care and placing it at the center of their care system. They have moved beyond structure (i.e., payment for simply reaching a certain level of Medical Home status) to payment arrangements that combine FFS payments with incentives for quality, efficiency/utilization, outcomes, and patient satisfaction and access. Several ACHP members have started out with smaller quality incentives (e.g., 5%) and moved to arrangements over time in which a primary care physician's reimbursement can be increased significantly by delivering high-quality, efficient care. These payments are still in the context of more limited thoughtful and appropriate risk exposure than traditional capitation payment models. Under these arrangements, payment can be a combination of fee-for-service, capitation, quality incentives, and rewards for efficiency. Specific examples of these arrangements can be found at the end of this document. The variations in the models reflect the significant variation in the degree of medical system integration and capability but all drive toward accountability for triple aim performance and set up dynamics that reward top performers.

What We're Learning - Key Themes

New models for payment are necessary, but by no means sufficient to truly reform care delivery and incent physicians. Payment reform must be integrally linked to efforts to create a higher degree of integration and collaboration between payers and providers, and requires some degree of flexibility for regional customization. It is also critical to acknowledge that payment models aligned with Triple Aim objectives are also necessary but not sufficient. New models for physician payment must also have a clear connection to the ideal of professionalism that drives much physician behavior. An example of this is the impact of public reporting of clinical quality results that, in some markets, has led to steady, year over year performance improvement.

The following pages represent a summary of these key themes, with examples underneath each, in response to the request for further detail on ACHP plans' experience with alternative payment models.

1825 Eye Street, NW, Suite 401 | Washington, DC 20006 | p: 202.785.2247 | f: 202.785.4060 | www.achp.org

Require Reporting of Meaningful and Transparent Quality Measures

Models must be connected to measures that are meaningful to patients, physicians and have an impact on lowering the overall cost of delivering care.

We reviewed the measures that the six health plans that participated in the October 3 meeting (Capital District Physicians' Health Plan, HealthPartners, Independent Health, Priority Health, Tufts Health Plan and UPMC) used for commonalities, and found that the performance on the following HEDIS® treatment and screening measures are often used as a "threshold" for physicians to earn additional bonus payments for cost and patient experience performance.

Health Care Outcomes: Preventive Health

- Cervical cancer screening
- Mammogram screening
- Chlamydia screening
- Glaucoma screening
- lead testing in children
- child/adolescent well care visits
- childhood immunizations

Health Care Outcomes: Disease Management

- Diabetes Care (HbA1c testing and control, LDL testing, nephropathy monitoring, complete lipid profile, eye exam)
- Asthma care management
- Appropriate testing for children with pharyngitis
- Appropriate treatment for children with URI

For Cost/Utilization Measures, the following represents commonalities we found in a high-level analysis:

CDPHP, Health Partners and Independent Health: These plans use risk-adjusted ratios to determine their efficiency index. They compare the total cost relative to peers in the same network/peer group. Health Partners measures total cost and utilization separately using two calculations, whereas CDPHP and Independent use one formula.

- Health Partners formulas:
    - Total Cost Index = Risk Adjusted Per Member/Per Month PMPM / Peer Group Risk Adjusted PMPM
    - Resource Use Index = Risk Adjusted Resource Use PMPM / Peer Group Average Risk Adjusted Resource Use PMPM
- CDPHP formula:
    - Total cost of care Index relative to peers in network including ED, Hospital, Lab, Radiology, Rx, Specialists (Risk adjusted and expressed as a ratio: observed/expected)
- Independent Health formula:
    - Total Cost Index = Risk Adjusted PMPM / Peer Group Risk Adjusted PMPM

Phase in Provider Risk-Sharing: Start with Shared Savings

The ACHP plans have found it productive to start with purely "upside risk" (sharing savings, but not sharing loss), as part of building trust and confidence in physician practices. Physician practices are not used to managing risk, so health plans have achieved buy-in to payment restructuring by sharing savings with providers but, initially absorbing losses themselves. As provider organizations gain skill and confidence in their ability to manage a population, they are in a better position to take accountability for downside risk. It also assures that both plans and providers are selecting categories of risk that providers can control. Many of the ACHP plans with innovative payment models are in transition stages, moving from pay-for-performance to gain sharing that is purely upside, to gain sharing that carries some downside risk.

Even within a single ACHP member plan, there are often multiple versions of an incentive program -- meeting the provider practice where it is in structural and technological capabilities. The goal of these arrangements is to drive physicians to greater innovation, more responsibility for total costs of care, and properly aligned incentives around patient-centered care over time.

Example:

Tufts Health Plan's (THP) value-based global payment strategy is based on a systematic approach that engages both providers and consumers in health care decisions. The Coordinated Care Model is a three-pronged approach that focuses on the alignment of behavior through provider engagement, product design and care management. Provider engagement creates a collaborative alignment around an appropriate level of financial risk - shared vs. full - based on a group's readiness to assume risk. THP assesses each group's readiness to assume risk along several attributes. Groups must possess ***appropriate levels of physician leadership, system integration and cultural alignment and internal provider incentive structures***. The plan also looks at organizational infrastructure related to primary care access, referral management approaches, care management capabilities and data and analytic capacities. Appropriate risk motivation and alignment along these attributes are used as determinants of likely success under a risk based contract. This construct informs the plan's decision on the appropriate level of initial risk and the progressive increases in risk shared by the provider.

Structure Payment and Relationships to Put Primary Care at the Center of the Care System

ACHP's health plans' focus on primary care reflects our belief that the primary care physician should be at the center of a system that is responsible for the health of a defined total population. ACHP member plans provide primary care physicians with information about which specialists and hospitals are more efficient (cost) and more effective (quality). Especially when combined with innovative benefit designs that encourage patients to choose high value care, the plan puts the primary care physician in a position to coordinate care with specialists and other providers and supports them with both the necessary analytical information and the financial incentives to do so. It is clear, however, that to realize the full potential of payment reform, one must extend accountability and transparency to specialty categories of care as well as hospital care.

Example:

Independent Health has spent a great deal of time building a coalition of respected, well recognized high-performing primary care physicians who work collaboratively with each other, specialty physicians, and other providers to improve the health of the population. This coalition and its approach to health care delivery is known as Primary Connections. It is a physician-led, physician-driven initiative, with the health plan as facilitator and collaborator, that includes:

- Innovative hybrid reimbursement model; pay for value with opportunity to share savings
- Enhanced access to analytical data and information
- Deep collaboration between primary care providers and specialists
- Access to dedicated resources: case managers, behavioral therapists, pharmacists, nutritionists

Building trust

The importance of building relationships with physicians over time cannot be overstated. Getting provider buy-in to new payment arrangements that are aligned with outcomes measures is an essential component of payment reform. Such buy-in includes on-the-ground work with physicians to explain and benchmark performance, along with participation with other community stakeholders to ensure broad support and buy-in to the metrics used for incentives. Absent the hard work of developing those relationships, providing the information needed to promote success and aligning incentives between payer and provider, payment reform is not likely to be successful. These connections have been a successful means of drawing a credible connection between aligned payment models, measures of clinical quality, and patient experience and the ideal of professionalism held by the great majority of providers.

One way to engender trust is to acknowledge and solicit the leadership of physicians in identifying clinical needs for the community and developing the programs to address the need. Economic alignment should follow (quickly) upon clinical alignment.

Example:

Through ongoing financial support and engagement with regional quality collaboratives such as the Institute for Clinical System Improvement and Minnesota Community Measurement, HealthPartners has helped establish forums for grappling with some of the most difficult issues arising from attention to the Triple Aim. These forums involve providers from all types of practices as well as the majority of payers in great Minneapolis region and have helped the community move along the path to delivering on the Triple Aim where other communities may have stalled. HealthPartners has used work results from these collaboratives, combined with its own supporting analytics, pay for performance and recognition programs, tiering, patient information, and product design to create consistent market signals tailored to the capabilities of its care delivery partners. This provides a visible path to success on all Triple Aim objectives while pushing continued transformation.

Summary

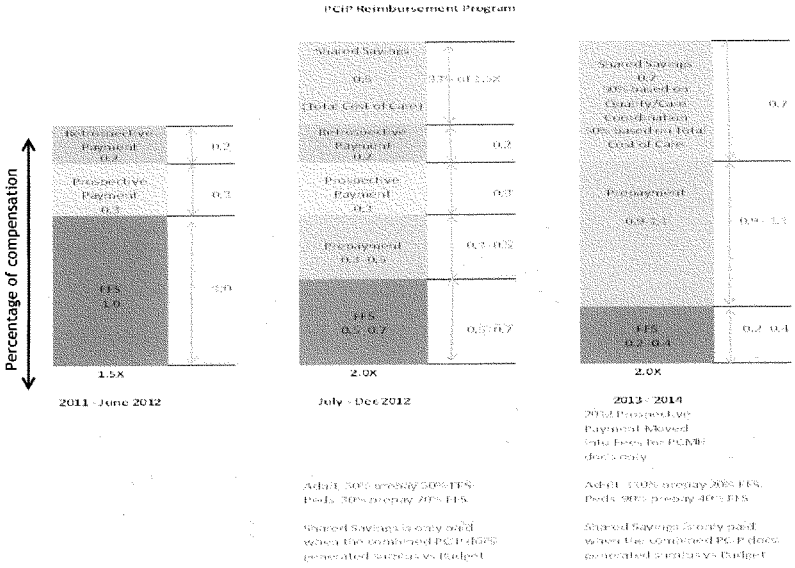
These models are reflective of six ACHP member organizations. Many other ACHP members are also implementing alternative models to fee-for-service for both primary care and specialty physicians. All of our members recognize the importance of linking payment to meaningful measures, involving physicians in the design of new models, and ensuring quality patient care is a key driver behind all payment innovation. We are happy to provide more information about the models from the plans featured in this brief document, as well as other ACHP organizations' approaches to payment.

Examples of Models:

Independent Health

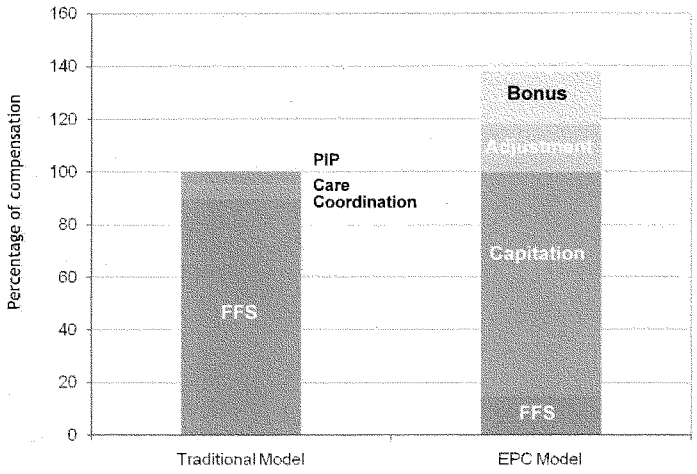
Hybrid reimbursement model:

(1) FFS for preventive services, immunizations, in-office procedures and labs
(2) Prepaid ,risk-adjusted monthly care coordination fee (includes previous FFS services other than preventive services with enhancement to help capitalize practices investment in the development of new care systems and skilled ancillary staffing).
(3) Shared Savings: potential to share in total cost of care savings for their attributed patient population; must meet quality thresholds to access shared savings.

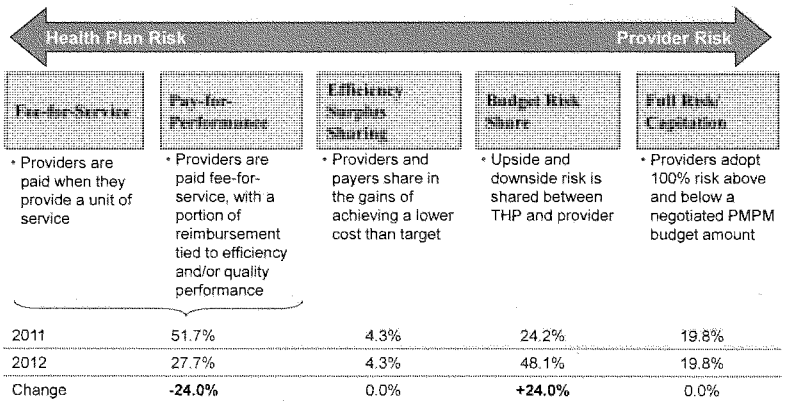


1.5x and 2.0x refers to the opportunity for physicians to make up to one and a half times their current reimbursement.

Capital District Physician's Health Plan - Enhanced Primary Care

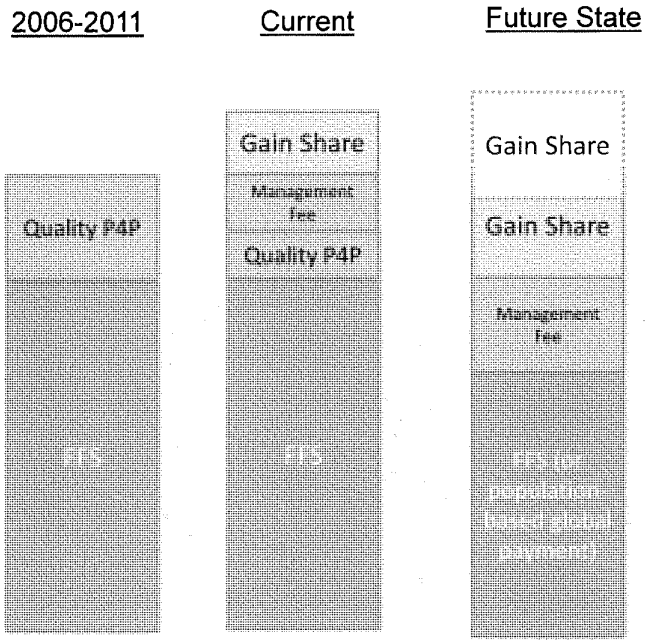


Tufts Health Plan



2011	51.7%	4.3%	24.2%	19.8%
2012	27.7%	4.3%	48.1%	19.8%
Change	**-24.0%**	0.0%	**+24.0%**	0.0%

UPMC Model (PCMH)



Gain is derived from improved coordination and management of services; decreased admits/ER visits/diagnostic services