administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B) [probably should be 1395x(s)(10)(B)]).''

§ 1395w–103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage

(1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) Qualifying plan defined

For purposes of this section, the term ''qualifying plan'' means—

(A) a prescription drug plan; or

(B) an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title.

(b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) in an area—

(1) the Secretary may approve limited risk plans under section 1395w–111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w–111(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–3, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2081.)

§ 1395w–104. Beneficiary protections for qualified prescription drug coverage

(a) Dissemination of information

(1) General information

(A) Application of MA information

A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1395w–22(c)(1) of this title relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and, subject to subparagraph (C), including the information described in subparagraph (B).

(B) Drug specific information

The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

(I) the risks associated with prolonged opioid use; and

(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

(aa) in the case of an MA–PD plan under part C, under such plan; and

(bb) in the case of a prescription drug plan, under such plan and under parts A and B.

(C) Targeted provision of information

A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(2) Disclosure upon request of general coverage, utilization, and grievance information

Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1395w–22(c)(2) of this title to such individual.

(3) Provision of specific information

(A) Response to beneficiary questions

Each PDP sponsor offering a prescription drug plan shall have a mechanism for pro-

viding specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the Internet

A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information

A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1395b–7(a) of this title or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) for a year preceding 2025, the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1395w–102(b)(4)(C) of this title to the extent practicable, as specified by the Secretary.

(b) Access to covered part D drugs

(1) Assuring pharmacy access

(A) Participation of any willing pharmacy

A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies

For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1395w–115 of this title to a plan.

(C) Convenient access for network pharmacies

(i) In general

The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) Application of TRICARE standards

The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) Adequate emergency access

Such rules shall include adequate emergency access for enrollees.

(iv) Convenient access in long-term care facilities

Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25).

(D) Level playing field

Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) Not required to accept insurance risk

The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) Use of standardized technology

(A) In general

The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1395w–102(d) of this title.

(B) Standards

(i) In general

The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of subchapter XI and may be based on standards developed by an appropriate standard setting organization.

(ii) Consultation

In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) Implementation

The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) Requirements on development and application of formularies

If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) Development and revision by a pharmacy and therapeutic (P&T) committee

(i) In general

The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) Inclusion of independent experts

Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) Formulary development

In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) Inclusion of drugs in all therapeutic categories and classes

(i) In general

Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) Model guidelines

The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) Limitation on changes in therapeutic classification

The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) Provider and patient education

The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) Notice before removing drug from formulary or changing preferred or tier status of drug

Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) Periodic evaluation of protocols

In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) Required inclusion of drugs in certain categories and classes

(i) Formulary requirements

(I) In general

Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) Exceptions

The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) Identification of drugs in certain categories and classes

(I) In general

Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

(II) Criteria

The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) Implementation

The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) Requirement for certain categories and classes until criteria established

Until such time as the Secretary establishes the criteria under clause (ii)(II) the

following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.
(II) Antidepressants.
(III) Antineoplastics.
(IV) Antipsychotics.
(V) Antiretrovirals.
(VI) Immunosuppressants for the treatment of transplant rejection.

(H) Use of single, uniform exceptions and appeals process

Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(I) Required inclusion of selected drugs

(i) In general

For 2026 and each subsequent year, the PDP sponsor offering a prescription drug plan shall include each covered part D drug that is a selected drug under section 1320f–1 of this title for which a maximum fair price (as defined in section 1320f(c)(3) of this title) is in effect with respect to the year.

(ii) Clarification

Nothing in clause (i) shall be construed as prohibiting a PDP sponsor from removing such a selected drug from a formulary if such removal would be permitted under section 423.120(b)(5)(iv) of title 42, Code of Federal Regulations (or any successor regulation).

(4) Ensuring access during COVID–19 public health emergency period

(A) In general

During the emergency period described in section 1320b–5(g)(1)(B) of this title, subject to subparagraph (B), a prescription drug plan or MA–PD plan shall, notwithstanding any cost and utilization management, medication therapy management, or other such programs under this part, permit a part D eligible individual enrolled in such plan to obtain in a single fill or refill, at the option of such individual, the total day supply (not to exceed a 90-day supply) prescribed for such individual for a covered part D drug.

(B) Safety edit exception

A prescription drug plan or MA–PD plan may not permit a part D eligible individual to obtain a single fill or refill inconsistent with an applicable safety edit.

(c) Cost and utilization management; quality assurance; medication therapy management program

(1) In general

The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1396r–8(k)(7)(A)(i) of this title).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).[1]

(F) With respect to plan years beginning on or after January 1, 2022, a drug management program for at-risk beneficiaries described in paragraph (5).

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) Medication therapy management program

(A) Description

(i) In general

A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) Targeted beneficiaries described

Targeted beneficiaries described in this clause are the following:

(I) Part D eligible individuals who—

(aa) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(bb) are taking multiple covered part D drugs; and

(cc) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).

(B) Elements

Such program—

(i) may include elements that promote—

(I) enhanced enrollee understanding to promote the appropriate use of medica-

[1] So in original. Probably means first par. (6).

tions by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(II) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(III) detection of adverse drug events and patterns of overuse and underuse of prescription drugs; and

(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—

(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under section 1395w–22(n)(2) of this title, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and

(II) cost-effective means by which an enrollee may so safely dispose of such drugs.

(C) Required interventions

For plan years beginning on or after the date that is 2 years after March 23, 2010, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) Assessment

The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E)[2] Automatic enrollment with ability to opt-out

The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E)[2] Development of program in cooperation with licensed pharmacists

Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) Coordination with care management plans

The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1395b–8 of this title.

(G) Considerations in pharmacy fees

The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed under this subparagraph.

(3) Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities

The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

[2] So in original. Two subpars. (E) have been enacted.

(4) Requiring valid prescriber National Provider Identifiers on pharmacy claims

(A) In general

For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) Procedures

(i) Validity of prescriber National Provider Identifiers

The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) Informing beneficiaries of reason for denial

The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) Report

Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

(D) Notification and additional requirements with respect to outlier prescribers of opioids

(i) Notification

Not later than January 1, 2021, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information as specified in accordance with clause (iii).

(ii) Identification of outlier prescribers of opioids

(I) In general

The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA–PD plans under part C and based on the thresholds established under subclause (II), identify prescribers that are outlier opioids prescribers for a period of time specified by the Secretary.

(II) Establishment of thresholds

For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish thresholds, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.

(III) Exclusions

The following shall not be included in the analysis for identifying outlier prescribers of opioids under this clause:

(aa) Claims for covered part D drugs for part D eligible individuals who are receiving hospice care under this subchapter.

(bb) Claims for covered part D drugs for part D eligible individuals who are receiving oncology services under this subchapter.

(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Inspector General of the Department of Health and Human Services.

(iii) Contents of notification

The Secretary shall include the following information in the notifications provided under clause (i):

(I) Information on how such prescriber compares to other prescribers within the same specialty and geographic area.

(II) Information on opioid prescribing guidelines, based on input from stakeholders, that may include the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain and guidelines developed by physician organizations.

(III) Other information determined appropriate by the Secretary.

(iv) Modifications and expansions

(I) Frequency

Beginning 5 years after October 24, 2018, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input and changes in opioid prescribing utilization and trends.

(II) Expansion to other prescriptions

The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.

(v) Additional requirements for persistent outlier prescribers

In the case of a prescriber who the Secretary determines is persistently identified under clause (ii) as an outlier prescriber of opioids, the following shall apply:

(I) Such prescriber may be required to enroll in the program under this sub-

chapter under section 1395cc(j) of this title if such prescriber is not otherwise required to enroll, but only after other appropriate remedies have been provided, such as the provision of education funded through section 6052 of the SUPPORT for Patients and Communities Act, for a period determined by the Secretary as sufficient to correct the prescribing patterns that lead to identification of such prescriber as a persistent outlier prescriber of opioids. The Secretary shall determine the length of the period for which such prescriber is required to maintain such enrollment, which shall be the minimum period necessary to correct such prescribing patterns.

(II) Not less frequently than annually (and in a form and manner determined appropriate by the Secretary), the Secretary, consistent with clause(iv)(I), shall communicate information on such prescribers to sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan.

(vi) Public availability of information

The Secretary shall make aggregate information under this subparagraph available on the internet website of the Centers for Medicare & Medicaid Services. Such information shall be in a form and manner determined appropriate by the Secretary and shall not identify any specific prescriber. In carrying out this clause, the Secretary shall consult with interested stakeholders.

(vii) Opioids defined

For purposes of this subparagraph, the term ''opioids'' has such meaning as specified by the Secretary.

(viii) Other activities

Nothing in this subparagraph shall preclude the Secretary from conducting activities that provide prescribers with information as to how they compare to other prescribers that are in addition to the activities under this subparagraph, including activities that were being conducted as October 24, 2018.

(5) Drug management program for at-risk beneficiaries

(A) Authority to establish

A PDP sponsor may (and for plan years beginning on or after January 1, 2022, a PDP sponsor shall) establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) Requirement for notices

(i) In general

A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) Initial notice

An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals en-

rolled in prescription drug plans under this part).

(iii) Second notice

A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) Timing of notices

(I) In general

Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) Exception

In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) At-risk beneficiary for prescription drug abuse

(i) In general

Except as provided in clause (v), for purposes of this paragraph, the term ''at-risk beneficiary for prescription drug abuse'' means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) Exempted individual described

An exempted individual described in this clause is an individual who—

(I) receives hospice care under this subchapter;

(II) is a resident of a long-term care facility, of a facility described in section 1396d(d) of this title, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(iii) Program size

The Secretary shall establish policies, including the guidelines developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

(iv) Clinical contact

With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

(v) Treatment of enrollees with a history of opioid-related overdose

(I) In general

For plan years beginning not later than January 1, 2021, a part D eligible individual who is not an exempted individual described in clause (ii) and who is identified under this clause as a part D eligible individual with a history of

opioid-related overdose (as defined by the Secretary) shall be included as a potentially at-risk beneficiary for prescription drug abuse under the drug management program under this paragraph.

(II) Identification and notice

For purposes of this clause, the Secretary shall—

(aa) identify part D eligible individuals with a history of opioid-related overdose (as so defined); and

(bb) notify the PDP sponsor of the prescription drug plan in which such an individual is enrolled of such identification.

(D) Selection of prescribers and pharmacies

(i) In general

With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) select—

(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a ''prescriber'') who may write prescriptions for such drugs for such beneficiary; and

(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

(ii) Reasonable access

In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

(iii) Beneficiary preferences

If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(I) review such preferences;

(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(III) inform the beneficiary of such selection or change of selection.

(iv) Exception regarding beneficiary preferences

In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

(I) at least 30 days written notice of the change of selection; and

(II) a rationale for the change.

(v) Confirmation

Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

(E) Terminations and appeals

The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.

(F) Termination of identification

(i) In general

The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk

beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) Rule of construction

Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) Frequently abused drug

For purposes of this subsection, the term ''frequently abused drug'' means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) Data disclosure

(i) Data on decision to impose limitation

In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

(ii) Data to reduce fraud, abuse, and waste

The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

(I) Sharing of information for subsequent plan enrollments

The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

(J) Privacy issues

Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

(K) Education

The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

(i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1395kk–1(h) of this title; and

(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

(L) Application under MA–PD plans

Pursuant to section 1395w–131(c)(1) of this title, the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(M) CMS compliance review

The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.

(6)[3] Utilization management tool to prevent drug abuse

(A) In general

A tool described in this paragraph is any of the following:

(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

(ii) Retrospective utilization review to identify—

(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

(iii) Consultation with the contractor described in subparagraph (B) to verify if an

[3] So in original. Two pars. (6) have been enacted.

individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) Reporting

A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1395ddd of this title with respect to such State a report, on a monthly basis, containing information on—

(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

(ii) the name and prescription records of individuals described in paragraph (5)(C).

(C) CMS compliance review

The Secretary shall ensure that plan sponsor compliance reviews and program audits biennially include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.

(6)[3] Providing prescription drug plans with parts A and B claims data to promote the appropriate use of medications and improve health outcomes

(A) Process

Subject to subparagraph (B), the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor, on a periodic basis and in an electronic format, beginning in plan year 2020, data described in subparagraph (D) with respect to enrollees in such plan. Such data shall be provided without regard to whether such enrollees are described in clause (ii) of paragraph (2)(A).

(B) Purposes

A PDP sponsor may use the data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in clause (i) of paragraph (2)(A).

(ii) To improving care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For any other purpose determined appropriate by the Secretary.

(C) Limitations on data use

A PDP sponsor shall not use data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To inform coverage determinations under this part.

(ii) To conduct retroactive reviews of medically accepted indications determinations.

(iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) To inform marketing of benefits.

(v) For any other purpose that the Secretary determines is necessary to include in order to protect the identity of individuals entitled to, or enrolled for, benefits under this subchapter and to protect the security of personal health information.

(D) Data described

The data described in this clause are standardized extracts (as determined by the Secretary) of claims data under parts A and B for items and services furnished under such parts for time periods specified by the Secretary. Such data shall include data as current as practicable.

(d) Consumer satisfaction surveys

In order to provide for comparative information under section 1395w–101(c)(3)(A)(v) of this title, the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) Electronic prescription program

(1) Application of standards

As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) Program requirements

Consistent with uniform standards established under paragraph (3)—

(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists

An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) Application to medical history information

Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) Limitations

Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) Timing

To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(E) Electronic prior authorization

(i) In general

Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—

(I) a prior authorization request from the prescribing health care professional for coverage of a covered part D drug for a part D eligible individual enrolled in a part D plan (as defined in section 1395w–133(a)(5) of this title) to the PDP sponsor or Medicare Advantage organization offering such plan; and

(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.

(ii) Electronic transmission

(I) Exclusions

For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).

(II) Standards

In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

(III) Application

Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.

(3) Standards

(A) In general

The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) Objectives

Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) Design criteria

Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of subchapter XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) Permitting use of appropriate messaging

Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) Permitting patient designation of dispensing pharmacy

(i) In general

Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) No change in benefits

Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) Development, promulgation, and modification of standards

(A) Initial standards

Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or

modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 242k(k) of this title) under subparagraph (B).

(B) Role of NCVHS

The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1320d(8) of this title)[4]

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) Pilot project to test initial standards

(i) In general

During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) Exception

Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) Voluntary participation of physicians and pharmacies

In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) Evaluation and report

(I) Evaluation

The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) Report to Congress

Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) Final standards

Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) Relation to State laws

The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) Establishment of safe harbor

The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1320a–7b(b) of this title and an exception to the prohibition under subsection (a)(1) of section 1395nn of this title with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1395nn(h)(4) of this title), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(7) Requirement of e-prescribing for controlled substances

(A) In general

Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

(B) Exception for certain circumstances

The Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

(i) a prescription issued when the practitioner and dispensing pharmacy are the same entity;

(ii) a prescription issued that cannot be transmitted electronically under the most

[4] So in original. Probably should be followed by a period.

recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(iii) a prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

(v) a prescription issued by a practitioner prescribing a drug under a research protocol;

(vi) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

(vii) a prescription issued by a practitioner—

(I) for an individual who receives hospice care under this subchapter; and

(II) that is not covered under the hospice benefit under this subchapter; and

(viii) a prescription issued by a practitioner for an individual who is—

(I) a resident of a nursing facility (as defined in section 1396r(a) of this title); and

(II) dually eligible for benefits under this subchapter and subchapter XIX.

(C) Dispensing

(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations.

(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

(D) Enforcement

The Secretary shall, through rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).

(f) Grievance mechanism

Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1395w–22(f) of this title.

(g) Coverage determinations and reconsiderations

(1) Application of coverage determination and reconsideration provisions

A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1395w–22(g) of this title with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) Request for a determination for the treatment of tiered formulary drug

In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) Appeals

(1) In general

Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1395w–22(g) of this title with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D

eligible individual shall be entitled to bring such an appeal.

(2) Limitation in cases on nonformulary determinations

A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) Treatment of nonformulary determinations

If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1395w–102(b)(4)(C)(i) of this title.

(i) Privacy, confidentiality, and accuracy of enrollee records

The provisions of section 1395w–22(h) of this title shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) Treatment of accreditation

Subparagraph (A) of section 1395w–22(e)(4) of this title (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) Public disclosure of pharmaceutical prices for equivalent drugs

(1) In general

A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) Timing of notice

(A) In general

Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) Waiver

The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(*l*) Requirements with respect to sales and marketing activities

The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1395w–21(h)(4)(C) of this title on conducting activities described in section 1395w–21(j)(1) of this title.

(2) The requirement under section 1395w–21(h)(4)(D) of this title to conduct activities described in section 1395w–21(j)(2) of this title in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1395w–21(h)(6) of this title.

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1395w–21(h)(7) of this title.

(m) Prohibition on limiting certain information on drug prices

A PDP sponsor and a Medicare Advantage organization shall ensure that each prescription drug plan or MA–PD plan offered by the sponsor or organization does not restrict a pharmacy that dispenses a prescription drug or biological from informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug or biological to the enrollee under the plan and a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage.

(n) Program integrity transparency measures

For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1395w–28(i) of this title.

(*o*) Real-time benefit information

(1) In general

After the Secretary has adopted a standard under paragraph (3) for electronic real-time benefit tools, and at a time determined appropriate by the Secretary, a PDP sponsor of a prescription drug plan shall implement one or more of such tools that meet the requirements described in paragraph (2).

(2) Requirements

For purposes of paragraph (1), the requirements described in this paragraph, with respect to an electronic real-time benefit tool, are that the tool is capable of—

(A) integrating with electronic prescribing and electronic health record systems of prescribing health care professionals for the transmission of formulary and benefit infor-

mation in real time to such professionals; and

(B) with respect to a covered part D drug, transmitting such information specific to an individual enrolled in a prescription drug plan, including the following:

(i) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

(ii) Cost-sharing information and the negotiated price for such drug and such alternatives at multiple pharmacy options, including the individual's preferred pharmacy and, as applicable, other retail pharmacies and a mail order pharmacy.

(iii) The formulary status of such drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alternatives included in the formulary of such plan.

(3) Standards

In order to be treated (for purposes of this subsection) as an electronic real-time benefit tool described in paragraph (1), such tool shall comply with technical standards adopted by the Secretary in consultation with the National Coordinator for Health Information Technology through notice and comment rulemaking. Such technical standards adopted by the Secretary shall be developed by a standards development organization, such as the National Council for Prescription Drug Programs, that consults with stakeholders such as PDP sponsors, Medicare Advantage organizations, beneficiary advocates, health care professionals, and health information technology software vendors.

(4) Rules of construction

Nothing in this subsection shall be construed—

(A) to prohibit the application of paragraph (b)(7) of section 423.160 of title 42, Code of Federal Regulations, as is to be added to such section pursuant to the final rule published in the Federal Register on May 23, 2019, and titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses'' (84 Fed. Reg. 23832 through 23884); or

(B) to allow a PDP sponsor to use a real-time benefit tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy type over their preferred pharmacy or pharmacy type nor prohibit the designation of an individual's preferred pharmacy under such tool.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–4, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2082; amended Pub. L. 110–275, title I, §§103(a)(2), (b)(2), (c)(2), (d)(2), 176, July 15, 2008, 122 Stat. 2499–2501, 2581; Pub. L. 111–148, title III, §§3307(a), 3310(a), 3312(a), title X, §10328(a), Mar. 23, 2010, 124 Stat. 471, 475, 476, 964; Pub. L. 114–10, title V, §507, Apr. 16, 2015, 129 Stat. 168; Pub. L. 114–198, title VII, §704(a)(1), (2), (b), July 22, 2016, 130 Stat. 742–748; Pub. L. 115–123, div. E, title III, §50354, Feb. 9, 2018, 132 Stat. 213; Pub. L. 115–262, §2(a), Oct. 10, 2018, 132 Stat. 3670; Pub. L. 115–271, title II, §§2003(a), 2004, 2006, 2007(a), title VI, §§6062, 6063(c)–6065, 6102, 6103(b), Oct. 24, 2018, 132 Stat. 3926, 3928, 3930, 3986, 3989, 4004, 4005; Pub. L. 116–136, div. A, title III, §3714(a), Mar. 27, 2020, 134 Stat. 424; Pub. L. 116–260, div. CC, title I, §119(a), Dec. 27, 2020, 134 Stat. 2951; Pub. L. 117–169, title I, §§11001(b)(1)(E), 11201(e)(2), Aug. 16, 2022, 136 Stat. 1852, 1891.)

Editorial Notes

REFERENCES IN TEXT

Section 6052 of the SUPPORT for Patients and Communities Act, referred to in subsec. (c)(4)(D)(v)(I), is section 6052 of title VI of Pub. L. 115–271, which is set out as a note under this section.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsecs. (c)(5)(J) and (e)(2)(C), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

Section 119 of the Medicare Improvements for Patients and Providers Act of 2008, referred to in subsec. (c)(5)(K)(ii), is section 119 of Pub. L. 110–275, which is set out as a note under section 1395b–3 of this title.

AMENDMENTS

2022—Subsec. (a)(4)(B)(i). Pub. L. 117–169, §11201(e)(2), substituted ''for a year preceding 2025, the initial'' for ''the initial''.

Subsec. (b)(3)(I). Pub. L. 117–169, §11001(b)(1)(E), added subpar. (I).

2020—Subsec. (b)(4). Pub. L. 116–136 added par. (4).

Subsecs. (m), (n). Pub. L. 116–260, §119(a)(1), redesignated subsec. (m), relating to program integrity transparency measures, as (n).

Subsec. (*o*). Pub. L. 116–260, §119(a)(2), added subsec. (*o*).

2018—Subsec. (a)(1)(A). Pub. L. 115–271, §6102(1), inserted '', subject to subparagraph (C),'' before ''including''.

Subsec. (a)(1)(B)(vi). Pub. L. 115–271, §6102(2), added cl. (vi).

Subsec. (a)(1)(C). Pub. L. 115–271, §6102(3), added subpar. (C).

Subsec. (c)(1)(F). Pub. L. 115–271, §2004(1), added subpar. (F).

Subsec. (c)(2)(A)(ii). Pub. L. 115–271, §6064, substituted ''are the following:'' for ''are part D eligible individuals who—'' in introductory provisions, added subcls. (I) and (II), redesignated former subcls. (I) to (III) as items (aa) to (cc), respectively, of subcl. (I), and realigned margins.

Subsec. (c)(2)(B). Pub. L. 115–271, §6103(b), struck out ''may include elements that promote'' after ''program'' in introductory provisions, added cls. (i) and (ii), redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (i), and realigned margins.

Subsec. (c)(4)(D). Pub. L. 115–271, §6065, added subpar. (D).

Subsec. (c)(5)(A). Pub. L. 115–271, §2004(2), inserted ''(and for plan years beginning on or after January 1, 2022, a PDP sponsor shall)'' after ''A PDP sponsor may''.

Subsec. (c)(5)(B)(ii)(III), (iii)(IV). Pub. L. 115–271, §2007(a)(1), substituted '', including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution'' for ''and the option of an automatic escalation to external review''.

Subsec. (c)(5)(C)(i). Pub. L. 115–271, §2006(1), substituted ''Except as provided in clause (v), for purposes'' for ''For purposes''.

Subsec. (c)(5)(C)(v). Pub. L. 115–271, §2006(2), added cl. (v).

Subsec. (c)(5)(E). Pub. L. 115–271, §2007(a)(2), substituted ''and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.'' for ''and the option of an automatic escalation to external review to the extent provided by the Secretary.''

Subsec. (c)(6). Pub. L. 115–123 added par. (6) relating to providing prescription drug plans with parts A and B claims data to promote the appropriate use of medications and improve health outcomes.

Subsec. (e)(2)(E). Pub. L. 115–271, §6062, added subpar. (E).

Subsec. (e)(7). Pub. L. 115–271, §2003(a), added par. (7).

Subsec. (m). Pub. L. 115–271, §6063(c), added subsec. (m) relating to program integrity transparency measures.

Pub. L. 115–262 added subsec. (m) relating to prohibition on limiting certain information on drug prices.

2016—Subsec. (a)(1)(B)(v). Pub. L. 114–198, §704(a)(2), added cl. (v).

Subsec. (c)(1)(E). Pub. L. 114–198, §704(b)(1), added subpar. (E).

Subsec. (c)(5). Pub. L. 114–198, §704(a)(1), added par. (5).

Subsec. (c)(6). Pub. L. 114–198, §704(b)(2), added par. (6).

2015—Subsec. (c)(4). Pub. L. 114–10 added par. (4).

2010—Subsec. (b)(3)(G). Pub. L. 111–148, §3307(a), amended subpar. (G) generally. Prior to amendment, subpar. (G) related to required inclusion of drugs in certain categories and classes.

Subsec. (b)(3)(H). Pub. L. 111–148, §3312(a), added subpar. (H).

Subsec. (c)(2)(C) to (G). Pub. L. 111–148, §10328(a), added subpars. (C) to (E) and redesignated former subpars. (C) to(E) as (E) to (G), respectively.

Subsec. (c)(3). Pub. L. 111–148, §3310(a), added par. (3).

2008—Subsec. (b)(3)(C)(i). Pub. L. 110–275, §176(1), substituted ''Subject to subparagraph (G), the formulary'' for ''The formulary''.

Subsec. (b)(3)(G). Pub. L. 110–275, §176(2), added subpar. (G).

Subsec. (*l*). Pub. L. 110–275, §103(a)(2), added subsec. (*l*).

Subsec. (*l*)(2). Pub. L. 110–275, §103(b)(2), added par. (2).

Subsec. (*l*)(3). Pub. L. 110–275, §103(c)(2), added par. (3).

Subsec. (*l*)(4). Pub. L. 110–275, §103(d)(2), added par. (4).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–271, title II, §2003(b), Oct. 24, 2018, 132 Stat. 3928, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to coverage of drugs prescribed on or after January 1, 2021.''

Pub. L. 115–271, title II, §2007(b), Oct. 24, 2018, 132 Stat. 3931, provided that: ''The amendments made by subsection (a) [amending this section] shall apply beginning not later [than] January 1, 2021.''

Pub. L. 115–262, §2(b), Oct. 10, 2018, 132 Stat. 3671, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to plan years beginning on or after January 1, 2020.''

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114–198 applicable to prescription drug plans (and MA–PD plans) for plan years beginning on or after Jan. 1, 2019, see section 704(g)(1) of Pub. L. 114–198, set out as a note under section 1395w–101 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3307(b), Mar. 23, 2010, 124 Stat. 472, provided that: ''The amendments made by this section [amending this section] shall apply to plan year 2011 and subsequent plan years.''

Pub. L. 111–148, title III, §3310(b), Mar. 23, 2010, 124 Stat. 475, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to plan years beginning on or after January 1, 2012.''

Pub. L. 111–148, title III, §3312(b), Mar. 23, 2010, 124 Stat. 476, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to exceptions and appeals on or after January 1, 2012.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 103(a)(2) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 103(a)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

Amendment by section 103(b)(2) of Pub. L. 110–275 effective on a date specified by the Secretary (but in no case later than Nov. 15, 2008), see section 103(b)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

Amendment by section 103(d)(2) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 103(d)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

RULE OF CONSTRUCTION

Pub. L. 111–148, title X, §10328(b), Mar. 23, 2010, 124 Stat. 965, provided that: ''Nothing in this section [amending this section] shall limit the authority of the Secretary of Health and Human Services to modify or broaden requirements for a medication therapy management program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] or to study new models for medication therapy management through the Center for Medicare and Medicaid Innovation under section 1115A of such Act [42 U.S.C. 1315a], as added by section 3021 [of Pub. L. 111–148].''

IMPLEMENTATION OF 2020 AMENDMENT

Pub. L. 116–136, div. A, title III, §3714(b), Mar. 27, 2020, 134 Stat. 424, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendment made by this section [amending this section] by program instruction or otherwise.''

UPDATE OF BIOMETRIC COMPONENT OF MULTIFACTOR AUTHENTICATION

Pub. L. 115–271, title II, §2003(c), Oct. 24, 2018, 132 Stat. 3928, provided that: ''Not later than 1 year after the date of enactment of this Act [Oct. 24, 2018], the Attorney General shall update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances.''

GRANTS TO PROVIDE TECHNICAL ASSISTANCE TO OUTLIER PRESCRIBERS OF OPIOIDS

Pub. L. 115–271, title VI, §6052, Oct. 24, 2018, 132 Stat. 3985, provided that:

''(a) GRANTS AUTHORIZED.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall, through the Centers for Medicare & Medicaid Services, award grants, contracts, or cooperative agreements to eligible entities for the purposes described in subsection (b).

''(b) USE OF FUNDS.—Grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to support eligible entities through technical assistance—

''(1) to educate and provide outreach to outlier prescribers of opioids about best practices for prescribing opioids;

''(2) to educate and provide outreach to outlier prescribers of opioids about non-opioid pain management therapies; and

''(3) to reduce the amount of opioid prescriptions prescribed by outlier prescribers of opioids.

''(c) APPLICATION.—Each eligible entity seeking to receive a grant, contract, or cooperative agreement under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

''(d) GEOGRAPHIC DISTRIBUTION.—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall prioritize establishing technical assistance resources in each State.

''(e) DEFINITIONS.—In this section:

''(1) ELIGIBLE ENTITY.—The term 'eligible entity' means—

''(A) an organization—

''(i) that has demonstrated experience providing technical assistance to health care professionals on a State or regional basis; and

''(ii) that has at least—

''(I) one individual who is a representative of consumers on its governing body; and

''(II) one individual who is a representative of health care providers on its governing body; or

''(B) an entity that is a quality improvement entity with a contract under part B of title XI of the Social Security Act (42 U.S.C. 1320c et seq.).

''(2) OUTLIER PRESCRIBER OF OPIOIDS.—The term 'outlier prescriber of opioids' means, with respect to a period, a prescriber identified by the Secretary under subparagraph (D)(ii) of section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–104(c)(4)), as added by section 6065 of this Act, to be an outlier prescriber of opioids for such period.

''(3) PRESCRIBERS.—The term 'prescriber' means any health care professional, including a nurse practitioner or physician assistant, who is licensed to prescribe opioids by the State or territory in which such professional practices.

''(f) FUNDING.—For purposes of implementing this section, $75,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to remain available until expended.''

GRANTS TO PHYSICIANS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS

Pub. L. 108–173, title I, § 108, Dec. 8, 2003, 117 Stat. 2172, provided that:

''(a) IN GENERAL.—The Secretary [of Health and Human Services] is authorized to make grants to physicians for the purpose of assisting such physicians to implement electronic prescription drug programs that comply with the standards promulgated or modified under section 1860D–4(e) of the Social Security Act [42 U.S.C. 1395w–104(e)], as inserted by section 101(a).

''(b) AWARDING OF GRANTS.—

''(1) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted and approved in a time, manner, and form specified by the Secretary.

''(2) CONSIDERATIONS AND PREFERENCES.—In awarding grants under this section, the Secretary shall—

''(A) give special consideration to physicians who serve a disproportionate number of medicare patients; and

''(B) give preference to physicians who serve a rural or underserved area.

''(3) LIMITATION ON GRANTS.—Only 1 grant may be awarded under this section with respect to any physician or group practice of physicians.

''(c) TERMS AND CONDITIONS.—

''(1) IN GENERAL.—Grants under this section shall be made under such terms and conditions as the Secretary specifies consistent with this section.

''(2) USE OF GRANT FUNDS.—Funds provided under grants under this section may be used for any of the following:

''(A) For purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

''(B) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

''(C) Providing education and training to eligible physician staff on the use of technology to implement the electronic transmission of prescription and patient information.

''(3) PROVISION OF INFORMATION.—As a condition for the awarding of a grant under this section, an applicant shall provide to the Secretary such information as the Secretary may require in order to—

''(A) evaluate the project for which the grant is made; and

''(B) ensure that funding provided under the grant is expended only for the purposes for which it is made.

''(4) AUDIT.—The Secretary shall conduct appropriate audits of grants under this section.

''(5) MATCHING REQUIREMENT.—The applicant for a grant under this section shall agree, with respect to the costs to be incurred by the applicant in implementing an electronic prescription drug program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs. Non-Federal contributions under the previous sentence may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009.''

SUBPART 2—PRESCRIPTION DRUG PLANS; PDP SPONSORS; FINANCING

§ 1395w–111. PDP regions; submission of bids; plan approval

(a) Establishment of PDP regions; service areas

(1) Coverage of entire PDP region

The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

(2) Establishment of PDP regions

(A) In general

The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1395w–27a(a)(2) of this title.

(B) Relation to MA regions

To the extent practicable, PDP regions shall be the same as MA regions under section 1395w–27a(a)(2) of this title. The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

(C) Authority for territories

The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

(3) National plan

Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

(b) Submission of bids, premiums, and related information

(1) In general

A PDP sponsor shall submit to the Secretary information described in paragraph (2) with re-