value of pursuing such agreements with selected foreign regulatory bodies in its 1992 ''Report of the Task Force on International Harmonization.'' The task force concluded that the development of memoranda of understanding (MOU's) is an effective means of facilitating international harmonization; of ensuring the safety, efficacy, and/or quality of products that are offered for import into the United States; and of efficiently using agency inspectional resources. The task force, however, cautioned that the negotiation of MOU's must be with foreign regulatory agencies that have appropriate authority and expertise to ensure the proper implementation of any MOU that may be agreed upon. A properly conceived and executed agreement with the European Commission would permit the use of EU Member State government inspectional information to assist FDA in its regulatory decisionmaking and could help to set priorities for foreign inspection or import surveillance programs. Early initiatives to pursue an MOU with the European Commission did not receive high priority by either side. Recently the MRA talks have served as a catalyst for reinvigorating these discussions.

The talks have been led by USTR and DOC with the Directorate-General I as their counterpart office in the European Commission. There have been six rounds of talks to date, beginning in April 1994. The most recent round of talks was held in Washington, DC, from November 13 through 15, 1995. FDA has participated in each round of discussions.

To provide an opportunity for public input into the pharmaceutical GMP discussions with the European Commission and the Member States, FDA hosted a public exchange meeting on March 31, 1995. The meeting was attended by approximately 40 persons representing the drug and biologics industries, consultants, and other organizations. Attendees expressed support for, as well as concerns regarding, the proposed agreement.

A delegation of FDA officials attended a pharmaceutical GMP workshop hosted by the European Commission in Brussels from April 3 to 5, 1995. The purpose of the meeting was to exchange information on inspection programs in the United States and the EU, and how each of the EU Member States carries out its role. The Canadian Health Protection Branch also attended the meeting and made a presentation on their pharmaceutical GMP program. At the conclusion of the workshop it was agreed that further cooperative efforts are needed before we could develop an MRA or MOU. Such efforts could include exchange of inspection reports, joint inspections, joint training of inspectors, and development of a joint inventory of facilities requiring inspection.

Also, following the conclusion of the workshop, industry representatives from the EU and the United States were invited to express their views. Both sides expressed support for an agreement. The U.S. pharmaceutical industry generally expressed the desire for a harmonized approach. The EU pharmaceutical industry expressed a desire for an approach that provided for mutual recognition of the current systems.

On May 1, 1995, a delegation of FDA officials also participated in meetings with EU officials and notified body representatives to allow both sides to better understand their respective medical device regulatory regimes. In addition to useful exchange of information and ''confidence building,'' the meetings helped to clarify several technical issues related to an MRA on medical devices.

Through this notice, FDA is establishing a public docket in order to make available at a convenient location certain information concerning its participation in these bilateral MRA talks. Information currently contained in this public docket includes the following:

Minutes of the FDA-sponsored public exchange meeting held on March 31, 1995.

Agenda of FDA-sponsored public exchange meeting held on March 31, 1995.

Statements of participants presented at the FDA-sponsored public exchange meeting held on March 31, 1995.

Summary of the April 3 through 5, 1995, Pharmaceutical GMP Workshop in Brussels.

Summary of the July 10 through 12, 1995, MRA talks in Brussels concerning pharmaceutical GMP's.

FDA summary of November 13 through 15, 1995, round of negotiations.

Presentation of Walter Batts entitled ''Mutual Recognition Agreement Negotiations with EU re: Pharmaceutical GMP's-FDA's Perspective,'' February 13, 1996.

Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11517 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[MB–098–N]

Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the preliminary Federal fiscal year (FFY) 1996 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs. We are publishing this notice in accordance with the provisions of section 1923(f)(1)(C) of the Social Security Act and implementing regulations at 42 CFR 447.297 through 447.299. The preliminary FFY 1996 State disproportionate share hospital (DSH) allotments published in this notice will be superseded by final FFY 1996 DSH allotments to be published in the Federal Register subsequent to the publication of this notice.

EFFECTIVE DATE: The preliminary DSH payment adjustment expenditure limits included in this notice apply to Medicaid DSH payment adjustments that are applicable to FFY 1996.

FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902(a)(13)(A) of the Social Security Act (the Act) requires States to ensure that their Medicaid payment rates include payment adjustments for Medicaid-participating hospitals that serve a large number of Medicaid recipients and other low-income individuals with special needs (referred to as disproportionate share hospitals (DSHs)). The payment adjustments are calculated on the basis of formulas specified in section 1923 of the Act.

Section 1923(f) of the Act and implementing Medicaid regulations at 42 CFR 447.297 through 447.299 require us to estimate and publish in the Federal Register the national target and each State's allotment for DSH payments for each Federal fiscal year (FFY). The implementing regulations provide that the national aggregate DSH limit for a FFY specified in the Act is a target rather than an absolute cap when determining the amount that can be allocated for DSH payments. The national DSH target is 12 percent of the total amount of medical assistance

expenditures (excluding total administrative costs) that are projected to be made under approved Medicaid State plans during the FFY. (Note: Whenever the phrases ''total medical assistance expenditures'' or ''total administrative costs'' are used in this notice, they mean both the State and Federal share of expenditures or costs.)

In addition to the national DSH target, there is a specific State DSH limit for each State for each FFY. The State DSH limit is a specified amount of DSH payment adjustments applicable to a FFY above which FFP will not be available. This is called the ''State DSH allotment''.

Each State's DSH allotment for FFY 1996 is calculated by first determining whether the State is a ''high-DSH State,'' or a ''low-DSH State.'' This is determined by using the State's ''base allotment.'' A State's base allotment is the greater of the following amounts: (1) the total amount of the State's actual and projected DSH payment adjustments made under the State's approved State plan applicable to FFY 1992, as adjusted by HCFA; or (2) $1,000,000.

A State whose base allotment exceeds 12 percent of the State's total medical assistance expenditures (excluding administrative costs) projected to be made in FFY 1996 is referred to as a ''high-DSH State.'' The FFY 1996 State DSH allotment for a high-DSH State is limited to the State's base allotment.

A State whose base allotment is equal to or less than 12 percent of the State's total medical assistance expenditures (excluding administrative costs) projected to be made in FFY 1996 is referred to as a ''low-DSH State.'' The FFY 1996 State DSH allotment for a low-DSH State is equal to the State's DSH allotment for FFY 1995 increased by growth amounts and supplemental amounts, if any. However, the FFY 1996 DSH allotment for a low-DSH State cannot exceed 12 percent of the State's total medical assistance expenditures for FFY 1996 (excluding administrative costs).

A State that is classified as a high-DSH State for one year, because its base allotment exceeds 12 percent of its total medical assistance expenditures for that year, may not continue to meet the high-DSH State definition in other years. That is, if the State's base allotment for another year is equal to or less than 12 percent of its total medical assistance for that year, the State would be classified as a low-DSH State for that year. As a low-DSH State, the State could potentially receive growth for that year.

The growth amount for FFY 1996 is equal to the projected percentage increase (the growth factor) in a low-DSH State's total Medicaid program expenditures between FFY 1995 and FFY 1996 multiplied by the State's final DSH allotment for FFY 1995. Because the national DSH limit is considered a target, low-DSH States whose programs grow from one year to the next can receive a growth amount that would not be permitted if the national limit was viewed as an absolute cap.

There is no growth factor and no growth amount for any low-DSH State whose Medicaid program does not grow (that is, stayed the same or declined) between FFY 1995 and FFY 1996. Furthermore, because a low-DSH State's FFY 1996 DSH allotment cannot exceed 12 percent of the State's total medical assistance expenditures, it is possible for its FFY 1996 DSH allotment to be lower than its FFY 1995 DSH allotment. For example, this occurs when the State experiences a decrease in its program expenditures between FFY 1995 and FFY 1996 and its 1995 FFY DSH allotment is greater than 12 percent of the total projected medical assistance expenditures for the current FFY. This is the case for the State of Rhode Island for FFY 1996.

There is no supplemental amount available for redistribution for FFY 1996. The supplemental amount, if any, is equal to a low-DSH State's proportional share of a pool of funds (the redistribution pool). The redistribution pool is equal to the national 12-percent DSH target reduced by the total of the base allotments for high-DSH States, the total of the State DSH allotments for the previous FFY for low-DSH States, and the total of the low-DSH State growth amounts. Since the sum of these amounts is above the projected FFY 1996 national 12-percent DSH target, there is no redistribution pool and, therefore, no supplemental amounts for FFY 1996.

As prescribed in the law and regulations, no State's DSH allotment will be below a minimum of $1,000,000.

As an exception to the above requirements, under section 1923(f)(1)(A)(I)(II) of the Act and regulations at 42 CFR 447.296(b)(5) and 447.298(f), a State may make DSH payments for a FFY in accordance with the minimum payment adjustments required by Medicare methodology described in section 1923(c)(1) of the Act. The State of Nebraska's preliminary State DSH allotment has been determined in accordance with this exception.

We are publishing in this notice the preliminary FFY 1996 national DSH target and State DSH allotments based on the best available data we received from the States' August 1995 submissions of the Medicaid budget report (Form HCFA–37), as adjusted by HCFA. We intend to publish the final FFY 1996 DSH allotments in the Federal Register subsequent to the publication of this notice.

The final allotments are calculated using actual Medicaid expenditures for FFY 1995 as reported to HCFA on States' quarterly expenditure reports (Form HCFA–64) for FFY 1995 and estimates of Medicaid expenditures for FFY 1996 as reported to HCFA on States' Form HCFA–37 February 1996 submissions.

II. Calculations of the Preliminary FFY 1996 DSH Limits

The total of the preliminary State DSH allotments for FFY 1996 is equal to the sum of the base allotments for all high-DSH States, the FFY 1995 State DSH allotments for all low-DSH States, and the growth amounts for all low-DSH States. A State-by-State breakdown is presented in section III of this notice.

We classified States as high-DSH or low-DSH States. If a State's base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures (excluding administrative costs) projected to be made under the State's approved plan under title XIX of the Act in FFY 1996, we classified that State as a ''high-DSH'' State. If a State's base allotment was 12 percent or less of its total unadjusted medical assistance expenditures projected to be made under the State's approved plan under title XIX of the Act in FFY 1996, we classified that State as a ''low-DSH'' State. Based on this classification, there are 36 low-DSH States and 14 high-DSH States for FFY 1996.

Using the most recent data from the States' August 1995 budget projections (Form HCFA–37), we estimate the States' FFY 1996 national total medical assistance expenditures to be $160,184,881,000. Thus, the overall preliminary national FFY 1996 DSH expenditure target is $19,222,186,000 (12 percent of $160,184,881,000).

In the preliminary FFY 1996 State DSH allotments, we provide a total of $519,764,000 ($310,963,000 Federal share) in growth amounts for the 36 low-DSH States. The growth factor percentage for each of the low-DSH States was determined by calculating the Medicaid program growth percentage for each low-DSH State between FFY 1995 and FFY 1996. To compute this percentage, we first ascertained each low-DSH State's total FFY 1995 medical assistance and

administrative expenditures as reported on the State's August 15, 1995, submission of the Medicaid Budget Report (Form HCFA–37) through the ''cutoff'' date of September 8, 1995. The cutoff date is the date through which the August 1995 Medicaid budget report submission estimates are accepted and applied in preparing the States' Medicaid grant award for the upcoming quarter (October through December 1995). Next, we compared those estimates to each low-DSH State's total estimated unadjusted FFY 1996 medical assistance and administrative expenditures as reported to HCFA on the States' August 1995 Form HCFA–37 submission.

The growth factor percentage was multiplied by the low-DSH States' final FFY 1995 DSH allotment amount to establish the States' preliminary growth amount for FFY 1996.

Since the sum of the total of the base allotments for high-DSH States, the total of the State DSH allotments for the previous FFY for low-DSH States, and the growth for low- DSH States ($19,602,716,000) is greater than the preliminary FFY 1996 national target ($19,222,186,000), there is no preliminary FFY 1996 redistribution pool.

The low-DSH States' growth amount was then added to the low-DSH States' final FFY 1995 DSH allotment amount to establish the preliminary total low-DSH State DSH allotment for FFY 1996. If a State's growth amount, when added to its final FFY 1995 DSH allotment amount, exceeds 12 percent of its FFY 1996 estimated medical assistance expenditures, the State only receives a partial growth amount that, when added to its final FFY 1995 allotment, limits its total State DSH allotment for FFY 1996 to 12 percent of its estimated FFY 1996 medical assistance expenditures. For this reason, six of the low-DSH States received partial growth amounts.

As explained above, Rhode Island's preliminary FFY 1996 DSH allotment is lower than its final FFY 1995 DSH allotment. Also, in accordance with the minimum payment adjustments required by Medicare methodology, Nebraska's FFY 1996 State DSH allotment is $11,000,000.

In summary, the total of all preliminary State DSH allotments for FFY 1996 is $19,602,716,000 ($11,137,851,000 Federal share). This total is composed of the prior FFY's final State DSH allotments ($19,084,239,000) plus growth amounts for all low-DSH States ($519,764,000), minus the amount of reduction in Rhode Island's FFY 1996 DSH allotment ($1,286,000), plus supplemental amounts for low-DSH States ($0). The total of all preliminary FFY 1996 State DSH allotments is 12.2 percent of the total medical assistance expenditures (excluding administrative costs) projected to be made by these States in FFY 1996. The total of all preliminary DSH allotments for FFY 1996 is $380,531,000 over the FFY 1996 national target amount of $19,222,186,000.

Each State should monitor and make any necessary adjustments to its DSH spending during FFY 1996 to ensure that its actual FFY 1996 DSH payment adjustment expenditures do not exceed its preliminary State DSH allotment for FFY 1996 published in this notice. As the ongoing reconciliation between actual FFY 1996 DSH payment adjustment expenditures and the FFY 1996 DSH allotments takes place, each State should amend its plan as may be necessary to make any adjustments to its FFY 1996 DSH payment adjustment expenditure patterns so that the State will not exceed its FFY 1996 DSH allotment.

The FFY 1996 reconciliation of DSH allotments to actual expenditures will take place on an ongoing basis as States file expenditure reports with HCFA for DSH payment adjustment expenditures applicable to FFY 1996. Additional DSH payment adjustment expenditures made in succeeding FFYs that are applicable to FFY 1996 will continue to be reconciled with each State's FFY 1996 DSH allotment as additional expenditure reports are submitted to ensure that the FFY 1996 DSH allotment is not exceeded. As a result, any DSH payment adjustment expenditures for FFY 1996 in excess of the FFY 1996 DSH allotment will be disallowed; and therefore, subject to the normal Medicaid disallowance procedures.

III. Preliminary FFY 1996 DSH Allotments Under Public Law 102–234

Key to Chart:

Column/Description

Column A = Name of State

Column B = Final FFY 1995 DSH Allotments for All States. For a high-DSH State, this is the State's base allotment, which is the greater of the State's FFY 1992 allowable DSH payment adjustment expenditures applicable to FFY 1992, or $1,000,000. For a low-DSH State, this is equal to the final DSH allotment for FFY 1995, which was published in the Federal Register on September 8, 1995.

Column C = Growth Amounts for Low-DSH States. This is an increase in a low-DSH State's final FFY 1995 DSH allotment to the extent that the State's Medicaid program grew between FFY 1995 and FFY 1996.

Column D = Preliminary FFY 1996 State DSH Allotments. For high-DSH States, this is equal to the base allotment from column B. For low-DSH States, this is equal to the final State DSH allotments for FFY 1995 from column B plus the growth amounts from column C.

Column E = High- or Low- DSH State Designation for FFY 1996. ''High'' indicates the State is a high-DSH State and ''Low'' indicates the State is a low-DSH State.

IV. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (R.A.) (5 U.S.C. 601 through 612), unless we certify that a notice would not have a significant economic impact on a substantial number of small entities. For purposes of an R.A., States and individuals are not considered small entities. However, providers are considered small entities. Additionally, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the R.A. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This notice sets forth no changes in our regulations; rather, it reflects the DSH allotments for each State as determined in accordance with §§ 447.297 through 447.299.

We have discussed the method of calculating the preliminary FFY 1996 national aggregate DSH target and the preliminary FFY 1996 individual State DSH allotments in the previous sections of this notice. These calculations should have a positive impact on payments to DSHs. Allotments will not be reduced for high-DSH States since we interpret the 12-percent limit as a target. Low-DSH States will get their prior FFY DSH allotments plus their growth amounts.

In accordance with the provisions of Executive Order 12886, this notice was reviewed by the Office of Management and Budget.

(No. 93.778, Medical Assistance Program)

Dated: February 21, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: April 5, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–11627 Filed 5–8–96; 8:45 am]

BILLING CODE 4120–01–P

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

Organ Procurement and Transplantation Network (OPTN) Data System

(OMB No. 0915–0157)—Extension and Revision—The data collection system of the OPTN and Scientific Registry provides for collection of data on organ transplantation, including heart, kidney, liver, heart-lung, pancreas and small intestine transplants. The OPTN data collection is required under Section 372 of the Public Health Service Act and includes data on pre-transplant activities. This includes cadaveric and live donor characteristics, and histocompatibility testing that is used in the matching of donor organs with recipients. Section 373 of the Public Health Service Act requires the Scientific Registry to collect, analyze and report on clinical and scientific data of importance to post-transplant graft and patient function. This involves a routine, periodic, submission of data for each organ transplant patient at the time of transplant, one-year (or six months for heart transplant patients), and annually post-transplant until graft failure or patient death.

Information and data collected by the OPTN and Scientific Registry are used primarily to analyze policies for the allocation of donor organs, and to assess the clinical outcomes of transplantation. The data are also used by the committees and Board of Directors of the OPTN for developing and reviewing policies related to allocation, patient listing criteria, optimal organ preservation times, and infectious disease screening.

Respondents include organ procurement organizations (for cadaveric donor data), histocompatibility laboratories (for tissue typing data), and transplant hospitals (for pre- and post-transplant data on recipients). The data are used to issue two key reports—the Annual Data Report and the Report of Patient and Graft Survival Rates (issued biennially).

HRSA proposes to make only minor changes to the data elements to obtain more detailed information on transplant patients and their post-clinical course. For example, additional categories will be added to several items on the forms. HRSA invites comments on these and other possible changes to the OPTN and Scientific Registry datasets.

The estimated annual response burden is as follows:

Form Type	Number of respondents	No. of responses per respondent	Total responses	Hours per response	Total burden hours
1. Cadaver Donor Registration/Referral	69	217	15,000	[1] 0.2	3,000
2. Living Donor Registration	69	54	3,700	0.2	740
3. Donor Histocompatibility	51	196	10,000	0.1	1,000
4. Potential Recipient Form	69	275	19,000	0.1	1,900
5. Recipient Histocompatibility	51	392	20,000	0.1	2,000
6. Transplant Candidate Registration	69	638	44,000	0.1	4,400
7. Thoracic Registration	166	21	3,500	0.3	1,050
8. Thoracic Follow-Up	166	101	16,800	0.3	5,040
9. Kidney Registration	248	49	12,200	0.3	3,660
10. Kidney Follow-Up	248	399	111,000	[2] 0.2	22,200
11. Liver Registration	119	34	4,000	0.4	1,600
12. Liver Follow-Up	119	176	21,000	0.4	8,400
13. Pancreas Registration	120	8	1,000	0.2	200
14. Pancreas Follow-Up	120	34	4,100	0.2	820
15. Intestine Registration	26	4	100	0.2	20
16. Intestine Follow-Up	26	8	200	0.2	40
Total	799	357	285,600	20	56,070

[1] It is estimated that 15,000 of these forms will be completed each year but approximately 9,500 will be referrals only. For those patients, only the first page of the form and one question on the second page will be completed. The average completion time for all 14,000 forms is 0.2 hours.

[2] Includes an estimated 20,000 kidney transplant patients, transplanted prior to the initiation of the data system, October 1, 1987.