manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the act (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) two shall be representatives of the interests of the general public.

Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the act (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990 provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental agencies, including State or Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor.

Qualifications

Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels shall have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are shown above. The term of office is up to 4 years, depending on the appointment date.

National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise. The particular needs are shown above. The term of office is up to 4 years, depending on the appointment date.

Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a government representative or health professional should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs are shown above. The term of office is up to 4 years, depending on the appointment date.

Technical Electronic Product Radiation Safety Standards Committee

Persons nominated must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs are shown above. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Consumer/General Public Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations that has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vita of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: July 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–18161 Filed 7–19–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education (CHGME) Payment Program: Final Methodology for Determination of FTE Resident Count, Treatment of New Children's Teaching Hospitals, and Calculation of Indirect Medical Education Payment

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: This notice sets forth final methodology for determining full time equivalent (FTE) resident count, treatment of new children's teaching hospitals, and calculation of indirect medical education (IME) payments for the Children's Hospitals Graduate Medical Education (CHGME) Payment program, authorized by section 340E of the Public Health Service Act (42 U.S.C. 256e), amended by Pub. L. 106–310, The Children's Health Act, 2000. In compliance with the Paperwork Reduction Act of 1995, the Department obtained Office of Management and Budget (OMB) approval of the data collections required and imposed on the public (OMB No. 0915–0247).

FOR FURTHER INFORMATION CONTACT: Ayah E. Johnson, Graduate Medical Education Branch, Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–08, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–1058 or e-mail address *ChildrensHospitalGME@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The CHGME program, as authorized by section 340E of the Public Health Service (PHS) Act (the Act) (42 U.S.C. 256e), provides funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that results from Medicare funding for graduate medical education (GME). Pub. L. 106–310 amended the CHGME statute to continue the program until Federal Fiscal Year (FFY) 2005.

On March 1, 2001, the Secretary published a notice in the **Federal Register** (66 FR 12940) establishing final rules for eligibility, funding criteria, payment methodology and performance measures for the CHGME program. That notice also sought public comments on proposals for (1) The criteria for determining full time equivalent (FTE) resident count; (2) the treatment of new children's teaching hospitals with respect to resident count; and (3) the methodology for IME payments. During the comment period, the Department received comments from seventeen interested parties, including hospitals, hospital and professional associations, Medicare consulting companies, and law firms.

The Secretary thanks the respondents for the quality and thoroughness of their comments. As a result of these comments, the Department has made revisions and clarifications in this final notice. The comments and Department's responses to the comments, and the final rules are set forth below.

General Comments

Several respondents recommended that the CHGME program follow Medicare's rules as closely as possible: (1) Because these rules are well defined and are known to those children's hospitals that file Medicare cost reports (MCR); and (2) to conform to Congress' intent to provide funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that results from Medicare funding for graduate medical education. The respondents indicated that the Department should make exceptions to compliance with policy following Medicare principles only in those instances in which the unique characteristics of children's hospitals render the application of Medicare principles impossible or undesirable, and it should explain the specific rationale for each exception.

In the implementation of the CHGME program, the Department has incorporated applicable Medicare rules and regulations. However, it is important to recognize that fundamental differences exist between the Medicare and CHGME programs that make certain Medicare rules and regulations inapplicable to the CHGME program. For instance:

(1) The CHGME program includes children's hospitals that span the spectrum of pediatric patient care, including acute, rehabilitation, oncology, orthopedics, and long term care;

(2) The CHGME program includes resident training that occurs in all areas of the hospital complex for both DME and IME;

(3) The CHGME program is bound to the FFY in which appropriated funds must be distributed without the opportunity to reconcile funding across FFYs;

(4) The Medicare GME payments are associated with treatment of Medicare patients;

(5) The Medicare patient population is primarily non-pediatric; and

(6) The Medicare program monies come from a trust fund.

Determining FTE Resident Counts Beginning in FFY 2001

With the exception of some revisions for clarification, the criteria for determining FTE resident counts beginning in FFY 2001 are unchanged from those proposed in the March **Federal Register** notice. Beginning in FFY 2001, for hospitals, that report residents to Medicare, there will be an order of priority for acceptance of resident counts submitted to the CHGME program:

(1) For the most recent cost report periods ending on or before December 31, 1996, a hospital must report the latest settled FTE resident count or a ''preliminary'' fiscal intermediary (FI) determined resident count. All preliminary FI determined counts must be determined according to HCFA and Medicare criteria. Hospitals may not use the ''preliminary'' numbers that were used for the FFY 2000 CHGME program unless those FTE resident counts have since become finalized or are validated according to HCFA and Medicare standards.

(2) For settled cost reports in other years, the CHGME program will accept the latest settled cost report. If a settled cost report has been reopened, the CHGME program will accept the latest settled count or, if available, the most recent ''preliminary'' FI determined FTE count.

(3) For unsettled cost reports, the CHGME program will accept in order of priority:

(a) The most recent preliminary FI determined FTE resident count prior to the application deadline; if not available, then

(b) The amended filed FTE resident count; if not available then

(c) The as filed FTE resident count.

For hospitals that do not report residents to Medicare (i.e., file low or no utilization cost reports) but have been operating a residency training program and participated in the CHGME program in FFY 2000, the calculation of FTE resident counts remains unchanged from the FFY 2000 application. Unlike the FFY 2000 applications, however, beginning in FFY 2001, the CHGME program requires hospitals to report FTE resident counts based on the hospital cost reporting period rather than on the FFY. In the June 19, 2000, **Federal Register** notice the Department provided examples of how these hospitals could determine FTE resident counts for the 1996 cap year and the 3-year rolling average. The CHGME program will accept this methodology for the 1996, 1998 and 1999 cost reporting periods.

If these hospitals wish to revise their FTE resident counts for these cost reporting periods, they must submit a detailed explanation of the revision with supporting documentation. The supporting documentation must be in compliance with HCFA/Medicare standards used to determine FTE resident counts (e.g., rotation schedules).

Beginning with the cost report period ending in 2000, these hospitals will be required to use the methodology described in 42 CFR 413.86(f)(2) to determine FTE resident counts; that is, to measure the amount of time that a resident works during the cost report period based on the number of days. In addition, these hospitals will continue to be required to apply Medicare standards for documenting the residents to be counted and calculating their FTE time for purposes of determining an FTE resident count.

Hospitals which did not report residents to Medicare and did not participate in the CHGME program in FFY 2000, although they were training residents at that time, are required to use the methodology described in 42 CFR 413.86(f)(2) to determine their FTE resident count for their cap year and 3-year rolling average. Like all hospitals which do not report residents to Medicare, they will be required to apply Medicare standards for documenting the calculating of their FTE resident counts.

Some hospitals have filed a combination of full, low utilization, and no utilization cost reports. For these hospitals, the Department requires that they file the actual FTE resident counts reported for those cost report periods where an E–3, Part IV worksheet has been filed. For those cost report periods where a low or no utilization cost report period was used, the hospitals should recreate their FTE resident count using the methodology referenced above.

Several respondents recommended that resident counts used for distribution of funds after FFY 2002 for all hospitals be based on Medicare cost reporting data. The respondents indicated that such a change should include sufficient time to resolve any technical issues that arise for hospitals that did not report residents in 1996 for determination of their resident cap. They noted that, while in the short term, it is necessary and appropriate to accommodate those hospitals that did not report residents to Medicare, it is important over the longer term for consistency and equity in the resident counting methodology that all eligible hospitals file resident counts on their Medicare cost reports.

The Department does not have the option of requiring resident counts used for distribution of funds to be based on Medicare cost reporting data since section 340E(e)(1) of the CHGME statute requires that:

> * * * interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.

Several respondents requested that HRSA clarify or define a ''preliminary FI determined resident count'' and indicated that some FIs may not provide a ''preliminary FI determined resident count'' prior to the formal resettlement of the revised cost report.

To clarify, a ''preliminary FI determined resident count'' with respect to a settled cost report that has been reopened is any resident count that the FI has determined during the normal course of cost report review (e.g., audit) prior to formal resettlement of the cost report. For example, if the FI and the hospital have negotiated the FTE resident count but not yet completed the paperwork to officially settle the reopened cost report, the hospital can submit the negotiated FTE resident count as a statement written by the FI describing the negotiated FTE resident count as ''preliminary'' to the completion of the resettlement paperwork. The CHGME program will not accept any FTE resident counts from amended reopened cost reports unless the FI submits it to the CHGME program as a valid ''preliminary'' FTE resident count.

For cost reports that have never been settled, a ''preliminary'' FTE resident count issued by an FI would be any resident count the FI has generated during the normal course of cost report review (e.g., desk review) prior to settlement of the cost report.

In some cases during the FFY 2000 CHGME application process, FIs issued ''preliminary'' numbers for FTE resident counts for some of the children's hospitals. Hospitals may not use these ''preliminary'' numbers for the FFY 2001 or future CHGME program application unless those FTE resident counts have since become finalized or are validated according to HCFA and Medicare standards through the normal course of business.

Regarding the use of Medicare standards in issuing ''preliminary'' FTE resident counts, one respondent indicated it was unaware of Medicare standards and that individual intermediary standards are not published.

HCFA provides numerous manuals for FIs and hospitals which outline the standards and definitions used in preparation and review of Medicare cost reports. These manuals are available electronically on the Internet at *http://www.hcfa.gov* and for purchase through the National Technical Information Service (NTIS) Clearinghouse. If hospitals have questions or concerns about their FI's interpretation/application of these standards, they should communicate with their FI or HCFA Regional Offices.

Several respondents raised the issue of applying a written agreement for purposes of training residents between a hospital and a non-hospital site retrospectively in order to count FTE residents rotating through those non-hospital sites.

As stated in the March 1, 2001 **Federal Register** notice, all resident training in non-hospital sites may be included in the FTE resident count as long as the hospital and non-hospital site are in compliance with 42 CFR 413.86(f)(3) and (4).

New Children's Teaching Hospitals

The Department is making final the definition of ''new children's teaching hospitals'' as proposed in the March 1 **Federal Register** notice. For purpose of the CHGME program, a ''new children's teaching hospital'' is a hospital which:

1. Has its own Medicare provider number as a children's hospital described in Sec. 1886(d)(1)(B)(iii) of the Social Security Act but did not train residents until it began training residents from an already existing program, less than three cost report periods prior to the FFY in which CHGME payments are being made; and

2. Has historically participated in a residency training program (e.g., a pediatric department within a larger teaching hospital) and subsequently receives its own Medicare provider number as a children's hospital described in Sec. 1886(d)(1)(B)(iii) of the Social Security Act.

''New children's teaching hospitals'' are distinct from those teaching hospitals that are participating in a new medical residency training program defined under 42 CFR 413.86(g)(12). Medicare regulations at 42 CFR 413.86(g)(6)(i) and (7) set forth criteria for applying the caps and rolling averages in these teaching hospitals with new medical residency training programs.

Establishing the Cap for New Children's Teaching Hospitals

Unlike children's hospitals that can receive adjustments to their caps for new residency training programs according to 42 CFR 413.86(g)(6), ''new children's teaching hospitals'' are treated like all other hospitals that have trained residents for 3 years after the first program began training residents,

as explained in 42 CFR 413.86(g)(6)(i)(C). According to 42 CFR 413.86(g)(4), the hospital's FTE resident cap is based on the unweighted FTE resident count from the most recently completed cost report period ending on or before December 31, 1996. Since ''new children's teaching hospitals'' would not have trained residents during the most recent Medicare cost reporting period ending on or before December 31, 1996, they would have a cap of zero.

To provide an adjustment to the cap of zero, the CHGME program will allow these hospitals to add FTE residents to their cap based on the following-described Medicare regulations:

1. The formation of a new residency program within the first 3 years after the first program begins training residents as described in 42 CFR 413.86(g)(6); or

2. The execution of an affiliation agreement for an aggregate cap, as set forth in 42 CFR 413.86(g)(4) and 63 FR 26338, published in the **Federal Register** on May 12, 1998, with the following exceptions:

a. A ''new children's teaching hospital'' participating in the CHGME program for the first year must establish an effective date of the agreement for the purposes of the CHGME program. For the first year, unless otherwise specified, the Department will use as the effective date of the affiliation agreement for an aggregate cap the date that the hospital becomes eligible for the CHGME program. This effective date will only apply to the CHGME program. A hospital must also have an effective date of July 1 for the Medicare program. Subsequent to the first year of the affiliation agreement, the effective date must comply with the above cited **Federal Register** final rule which specifies an effective date of July 1 for all affiliation agreements. The CHGME program allows this exception because hospitals must meet eligibility criteria and have their caps determined prior to the CHGME application deadline. If the CHGME program application deadline occurs before July 1, some hospitals would have a cap of zero and thus be excluded from receiving funds. By deviating from the prescribed Medicare final rule, the CHGME program will not place some hospitals in this position.

b. Unlike the Medicare program, for the first year, the CHGME program will not prorate the cap based on the effective date of the cap. Instead, the full value of the cap as determined by the affiliation agreement will be used.

Establishing FTE Resident Counts for New Children's Teaching Hospitals

In general, the FTE resident count from each hospital reflects the residents trained during the Medicare cost report period, limited by the cap (the unweighted allopathic and osteopathic FTE resident count from the most recent cost report period ending on or before December 31, 1996). Payments to each hospital are based on the average of the FTE resident count for the most recent Medicare cost report and the prior two cost reports (3-year rolling average), subject to funds available for DME and IME, respectively.

For establishing FTE resident counts, ''new children's teaching hospitals'' are divided into two categories: (1) Those training residents from an existing residency program that received and will continue to receive funds under the CHGME program; and (2) those training residents from an existing residency program that has never received funds under the CHGME program (i.e., residents that have not previously been claimed for payment under the CHGME program).

''New Children's Teaching Hospitals'' Training Residents Previously Claimed For Payment Under the CHGME Program: FTE Resident Count

The Department requires ''new children's teaching hospitals'' training residents who were originally trained in a program that received and will continue to receive funds under the CHGME program to wait until they have completed a medicare cost report period before applying for payments from the CHGME program. The CHGME program would have provided payment to the hospital originally training the residents, prior to the completion of a Medicare cost report period by the new children's teaching hospital, and would not want to pay two hospitals for training the same residents.

These ''new children's teaching hospitals'' must apply the 3-year rolling average according to Medicare regulations at 42 CFR 413.86(g)(5). Over a 3-year period, the ''new children's teaching hospital'' will gradually increase its number of FTE residents that can be claimed on the CHGME application as the children's hospital that originally trained those FTE residents gradually decreases its resident count.

''New Children's Teaching Hospitals'' Training Residents Not Previously Claimed for Payment Under the CHGME Program

Since payments under the CHGME program are based on FTE resident counts from a completed cost report filing period, ''new children's teaching hospitals'' training residents never previously claimed for CHGME payment that have not completed a cost report filing period at the time of the CHGME program application would not have an FTE resident count for a full Medicare cost reporting period to report to the program. These ''new children's teaching hospitals'' must submit a partial-year FTE resident count in their initial applications to the CHGME program according to the following methodology:

a. Divide the number of FTE residents trained during the period from the day the children's hospital becomes eligible for the CHGME program to the CHGME application deadline by the number of days during this period to produce the average number of FTEs per day.

b. Multiply the average number of FTEs per day by the number of days the hospital will train residents during the FFY in which payments are being made.

The concept of converting a partial period into a full cost report period is found in the Medicare regulations at 42 CFR 413.86(g)(4) and (e)(5)(ii). Since the CHGME program is paying hospitals for training residents during the FFY for which payments are being made, the Department will convert a partial training period to reflect the amount of time the hospital will train residents during the FFY for which payments are being made. Although this methodology delineates the method by which partial-year residents are counted, it is important to note that all counts are subjected to the cap set by the affiliation agreement.

After the initial application year, payments to ''new children's teaching hospitals'' training residents never previously claimed for CHGME payment will be based on the actual FTE resident count from the most recently completed Medicare cost report period. Once these hospitals have completed three Medicare cost report periods, the 3-year rolling average will apply.

Under Medicare, hospitals training residents that are not in a new residency program, as defined in 42 CFR 413.86(g)(12), are subjected to the 3-year rolling average. For example, under Medicare, in the first year these hospitals would calculate the 3-year rolling average as follows: [FTE resident count for current year + 0 (FTE residents for prior cost report period) + 0 (FTE residents per penultimate cost report period)] divided by three (3).

One purpose of this Medicare policy is to avoid paying two hospitals for the same residents. Over the course of 3 years the hospital which was originally training the residents ''rolls down'' its FTE resident count and the hospital which is assuming training ''rolls up'' its FTE resident count.

The rationale adopted by the CHGME program in deviating from this Medicare policy is that, for the ''new children's teaching hospitals'' training residents that were never previously claimed for CHGME payment, the issue of double payment for residents is not relevant since the program is not currently paying for them. Therefore, to treat all hospitals participating in the CHGME program equitably, the Department will not impose a 3-year rolling average on the FTE residents counts until these ''new children's teaching hospitals'' have completed three cost reporting periods.

Determining Indirect Medical Education (IME) Payments to Hospitals

The March **Federal Register** notice invited comments on the proposed methodology for calculating IME payments organized by: (1) The purpose and use of payments under the program, (2) case mix, (3) number of FTE residents, (4) teaching intensity factor, (5) patient volume, (6) outpatient services, and (7) determination of payments. A discussion of the comments received and the Department's responses follows.

Purpose and Use of IME Payments

The CHGME statute requires the Secretary to make payments to children's hospitals for IME associated with operating approved graduate medical residency training programs for each of fiscal years 2000 through 2005. Section 340E(b)(1)(B) describes IME payments as covering ''expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.'' Section 340E(d)(2) of the Act requires the Secretary to determine IME payments by considering:

1. Variations in case mix among children's hospitals; and
2. The hospitals' number of FTE residents in approved training programs.

The Department utilized the broadest interpretation of this legislative mandate to determine that IME payments determined for purposes of the CHGME program should reflect the indirect costs of GME as defined by statute throughout the entire hospital complex, similar to the allowances for the calculation of DME payments unlike Medicare which limits IME payment adjustments to certain areas of the hospital.

Determination of Case Mix

The determination of case mix is unchanged from that set forth in the March notice. Beginning in FFY 2001, all applicant hospitals must submit a case mix index (CMI), based on the discharges from the most recently completed cost reporting period, using HCFA–DRG Version 17 with the appropriate HCFA Version 17 weights reported to the ten-thousandth decimal place. All DRGs must be included in the calculation of this CMI. In subsequent years, the version of the HCFA–DRG, to be used by hospitals, will be updated annually. To determine which version of the HCFA–DRG grouper and weights hospitals will use in completing an application to the CHGME program, the following methodology will be used:

1. Based on the application deadline, the year end of the most recently completed cost reporting period will be determined for the majority of applicant hospitals.

2. The version of the HCFA–DRG grouper and weights used to calculate the CMI for the FFY corresponding to the year end of the most recently completed cost reporting period for the majority of applicant hospitals will be used to calculate the CMI.

If a children's hospital eligible to participate in the CHGME program has not completed a Medicare cost reporting period prior to submission of an application to the CHGME program, it would base its CMI on discharges from the day it became eligible fo the CHGME program until the CHGME application deadline.

Several respondents requested that DRG 391 be excluded from the calculation of CMI beginning in FFY 2000. These respondents argued that, as only a few hospitals participating in the CHGME program would actually use this DRG code, related to treatment of normal or healthy newborns, the exclusion of this DRG would assist in creating equity among the hospitals in the program.

The Department will include all DRGs in the calculation of its CMI because the activity of all areas of the hospital complex and the severity of illness among the inpatient population that the hospital serves need to be reflected in the hospital's CMI in order to treat all hospitals equitably. The IME payment is meant to reflect the resources used to treat the more severely ill patients in children's hospitals.

Several respondents suggested alterntive methodologies for calculating CMI, including the Resource-Based Relative Value Scale (RBRVS) or the All Patient Refined (APR)–DRGs and APR–DRG relative weights. In addition, several respondents supported the Department's exploration of developing a CMI methodology that is more reflective of the resource intensity of pediatric care.

The Department continues to recognize that the current CMI may not be reflective of the relative resource utilization in children's hospitals, particularly those providing specialized services, such as rehabilitation and will continue to investigate the feasibility of developing a CMI that is more reflective of the relative resource utilization experienced by children's hospitals. The Department anticipates that this effort will be multi-year. Any analyses and resulting recommendations would be published in subsequent **Federal Register** publications.

Determining the Number of FTE Residents for IME Payments

The criteria for determining FTE residents for IME payments is different from those proposed. In the March 1, 2001 **Federal Register** notice, the Secretary proposed to determine FTE resident counts for IME payment calculation using the ''caps and rolling averages'' consistent with Medicare regulation 42 CFR 412.105(f) with the exception of 42 CFR 412.105(f)(1)(ii)(A). The Department's final criteria for determining the FTE resident count for IME payments include all areas of the hospital complex as specified in 42 CFR 413.86(f)(1), the regulations used to determine FTE resident counts for DME. Time spent by residents on required research is also included if it is part of the resiency program and the resident carries out the research in either: (1) The children's hospital (clinical or bench research); or (2) in a nonhospital site where the research involves direct patient care and the salaries of both the resident and supervising faculty are paid by the children's hospital. Since the FTE resident count used to calculate both DME and IME payments will reflect residents rotating through all areas of the hospital complex, the unweighted FTE resident count is the same for the DME and IME (MCR worksheet E–3, Part IV, line 3.05).

The criteria used by the Department for hospitals reporting FTE resident counts will be the same for IME as they are for DME (see description in previous section). ''New children's teaching hospitals'' that have not completed a cost report period would use a partial-year FTE resident count methodology similar to the methodology used to determine FTE resident counts for DME payments (see previous section).

The calculation of FTE resident counts remains unchanged from the FFY 2000 application for hospitals that do not report residents to Medicare, have been operating a residency training

program and participated in the CHGME program in FFY 2000. Unlike the FFY 2000 applications, however, beginning in FFY 2001, the CHGME program requires hospitals to report FTE resident counts based on hospital cost reporting period rather than on FFY. In the June 19, 2000 **Federal Register** notice the Department provided examples of how these hospitals could determine FTE resident counts for the 1996 cap year and the 3-year rolling average. The CHGME program will accept this methodology for the 1996, 1998 and 1999 cost reporting periods.

If these hospitals wish to revise their FTE resident counts for these cost reporting periods, they must submit a detailed explanation of the revision with supporting documentation that is in compliance with HCFA/Medicare standards used to determine FTE resident counts (*e.g.*, rotation schedules).

Beginning with the cost report period ending in 2000, these hospitals will be required to use the methodology described in 42 CFR 413.86(f)(2), without application of the weighting factors described in 42 CFR 413.86(g)(1), (2), and (3), to determine total unweighted FTE resident counts. Medicare measures the amount of time based on the number of days during the cost reporting period that a resident works. In addition these hospitals will be required to apply Medicare standards for documenting the counting of residents and calculation of their FTE time for purposes of determining an FTE resident count.

Hospitals which did not report residents to Medicare and did not participate in the CHGME program in FFY 2000 although they were training residents at that time are required to use the methodology described in 42 CFR 413.86(f)(2), without application of the weighting factors described in 42 CFR 413.86(g)(1), (2), and (3), to determine their FTE resident count for their cap and 3-year rolling average. Like all hospitals not reporting residents to Medicare, they will be required to apply Medicare standards for documenting the calculating of their FTE resident counts.

Some hospitals file a combination of full, low utilization, and no utilization cost reports. For these hospitals, the Department requires that they file the actual FTE resident counts reported for those cost report periods where an E–3, Part IV worksheet has been filed. For those cost report periods where a low or no utilization cost report period was used, the hospitals should recreate their FTE resident count using the methodology described above.

Caps and Rolling Average

Beginning with FY 2001, the Secretary will apply the ''caps and rolling averages'', consistent with the Medicare regulatory section 42 CFR 412.105(f), with the exception of 42 CFR 412.105(f)(1)(ii). In place of this subsection, the Department will use the criteria of 42 CFR 413.86(f)(1), which define FTE counts for DME.

The Department received a variety of comments on application of the cap and rolling averages to calculating IME payments. Several respondents recommended that the Department postpone the application of the cap and rolling averages to the FTE resident count for calculating IME payments until after the FFY 2002 application deadline so hospitals which reported residents to Medicare for the cap year (most recently completed cost reporting period ending on or before December 31, 1996) would have adequate time to resolve any outstanding issues with their FIs related to this cost reporting period. Other respondents suggested that the Department not apply the caps and rolling average to the IME at all, as the CHGME statute does not require it.

The Department will apply the cap and rolling average to the calculation of IME payments beginning with FFY 2001 in order to comply as closely as possible with Medicare rules and regulations. The Secretary maintains that hospitals which report residents on Medicare cost reports have been aware of an FTE cap as early as their 1998-cost report and assumes that these hospitals are reporting an accurate FTE cap number.

In addition to the above comments, two respondents argued that if the Department were to implement the cap and rolling averages on the FTE resident count used in the IME payments, then the cap should be based on the unweighted FTE resident count from the most recently completed cost reporting period ending on or before December 31, 2000, to correspond with the initial year of the CHGME program, FFY 2000. The basis for their argument was that previously, children's hospitals did not receive IME payments and that, in some cases, the hospitals may have added residency programs after the cap year that could not be counted toward the cap on residents. In addition, there was a misunderstanding that hospitals that did not report residents on Medicare cost reports could base their unweighted FTE resident cap on a year other than the most recently completed cost reporting period ending on or before December 31, 1996.

To clarify the policy regarding the year upon which the unweighted FTE resident count is based, all hospitals must use the most recently completed cost report period ending on or before December 31, 1996, to determine the unweighted FTE resident count that would be used as the cap for calculating of IME payments. This standard definition applies to all hospitals participating in the CHGME program regardless of whether or not they report residents on their Medicare cost reports. If a hospital certifies in its application that it has based its cap on the most recent cost reporting period ending on or before December 31, 1996, and subsequent to a CHGME program review/audit, it is discovered that a more recent cost reporting period was used to determine the cap, that hospital would be subject to prosecution by the Federal Government as it would have committed fraud.

Teaching Intensity Factor

In the March notice, the Department invited comments on:

1. The proposed continuation of the use of the Medicare residents-to-bed ratio (IRB)-based teaching intensity factor in the calculation of IME payments. The CHGME program would use the most current PPS IRB in its calculation of IME payments;

2. Application of a cap on the IRB ratio, similar to the cap applied by the Medicare program, 42 CFR 412.105(a)(1), whereby the ratio may not exceed the ratio for the hospital's most recent prior cost reporting period. Application of this cap will not be initiated until FFY 2002 due to the proposed change in the definition of bed count;

3. Suggestions on alternative teaching intensity factors, such as the Medicare resident-to-average daily census (RADC)-based teaching intensity factor (2.8 percent per 0.1 percent increase in RADC ratio) or any other analytically justified teaching intensity factor; and

4. The proposed definition of ''bed count'' to be used in calculating the Medicare IRB teaching intensity factor—the sum of all available beds per day in the most recently completed cost report filing period, including beds and bassinets in the healthy newborn nursery, divided by the number of days in that period. If a children's hospital eligible to participate in the CHGME program has not completed a Medicare cost report period prior to submission of an application to CHGME program, it would base its ''bed count'' on the sum of all available beds per day, including beds and bassinets in the healthy newborn nursery, in the period from the day it became eligible for the CHGME program until the CHGME application

deadline, divided by the number of days in that period.

Teaching Intensity Factor

Beginning in FFY 2001, the Department will use the IRB ratio to determine IME payments. The Department will use the same teaching intensity factor that is used by the Medicare Inpatient PPS in calculating its operating IME adjustment for the FFY in which payments are being made.

One respondent encouraged the use of the resident-to-average daily census (RADC) ratio in factoring in teaching intensity, because the RADC ratio measures actual utilization that occurs in the inpatient unit and thus provides a more realistic measure of intensity. Three respondents supported using the Medicare methodology of computing the number of residents per available bed, as consistency with Medicare is desirable without a compelling reason to depart from the Medicare formula.

The Department intends to continue to assess various teaching intensity factors and formulas designed to capture the IME costs associated with caring for more severely ill patients in a children's hospital.

A Cap on the IRB Ratio

To comply as closely as possible with Medicare rules and regulations, beginning in FFY 2002, the Department will apply a cap on the IRB ratio, similar to the cap applied by the Medicare program pursuant to regulations at 42 CFR 412.105(a)(1), whereby the ratio may not exceed the ratio for the hospital's most recent prior cost reporting period. For those hospitals whose IRB ratio changes, there will be a one-year delay in the implementation of the revised IRB.

Beds To Be Included in Calculation of Bed Count

Beginning in FFY 2001, a bed is defined, for the purposes of the CHGME program, as an adult or pediatric bed, including beds or bassinets assigned to healthy newborns, available for lodging inpatients, including beds in intensive care units, coronary care units, neonatal intensive care units, short stay units, and other special care inpatient hospital units. Beds in the following locations are excluded from the definition: Labor rooms, post-anesthesia or post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments, nurses' and other staff residences, and other such areas as are regularly maintained and utilized for purposes other than inpatient lodging.

Beginning in FFY 2001, children's hospitals will calculate bed count to be used in calculation of the teaching intensity factor used to determine IME payments using the following methodology: The sum of all available inpatient beds per day within the hospital complex in the most recently completed cost report filing period divided by the number of days in that period. If a children's hospital, eligible to participate in the CHGME program, has not completed a Medicare cost reporting period prior to submission of an application to the CHGME program, it calculates its ''bed count'' using a prorated number. The prorated number is based on the sum of all available inpatient beds per day within the hospital complex in the period from the day it became eligible for the CHGME program until the CHGME application deadline, divided by the number of days during that period.

To be considered an available bed, a bed must be permanently maintained for lodging inpatients. It must be available for use and housed in patient rooms or wards (i.e., not in corridors or temporary beds). Thus, beds in a completely or partially closed wing of the facility are considered available only if the hospital put the beds into use when they are needed. The term ''available beds'' as used for the purpose of counting beds is not intended to capture the day-to-day fluctuations in patient rooms and wards being used. Rather, the count is intended to capture changes in the size of a facility as beds are added to or taken out of service.

Several respondents recommended that the count of available beds used in the intensity factor exclude beds/bassinets used in the ''well-baby'' nursery as this would be consistent with the Medicare policy. In addition, other respondents indicated that the exclusion or inclusion of short stay or observation beds should not be each individual hospital's determination—it should be program-wide policy consistent with Medicare policy.

The Medicare definition and regulations on counting beds are inapplicable to the CHGME program due to the fundamental differences between the two programs. Therefore, the Department has defined ''bed'' to best carry out the purpose of the CHGME program.

Although, traditionally, Medicare has excluded beds and bassinets used in the ''well-baby'' nursery, it is the understanding of the CHGME program that this is primarily due to the fact that beds and discharges from the ''well-baby'' nursery have not been factored into the calculation of Medicare payments because there is no Medicare utilization attributable to this part of the hospital. As all areas of the hospital complex are included in the determination of IME payments for the CHGME program, the Department feels that this includes all relevant available inpatient beds that are utilized within the hospital as defined above.

In addition, if the Department were to follow Medicare policy, as stated in Medicare program manual HCFA Pub. 15–1 S. 2405.3.G, on the definition of beds to be included in the bed count, beds in hospital-based skilled nursing facilities or in any inpatient area(s) of the facility not certified as an acute care hospital (e.g., long term care beds) or beds in excluded units (e.g., rehabilitation, psychiatric) would need to be excluded from the definition of beds used by the CHGME program in addition to the exclusion of beds/bassinets in the ''well-baby'' nursery. Because the hospitals participating in the CHGME program are not limited to acute care hospitals and the Medicare definition of bed count refers only to acute care beds, the Department believes that the inclusion of all of these beds would be an equitable treatment of all hospitals participating in the CHGME program.

The Department has followed the Medicare policy as closely as possible (see definition above) regarding the inclusion or exclusion of short stay or observation beds. Hospitals participating in the CHGME program must certify the accuracy of the numbers reported on their applications. Hospitals reporting bed counts that include other than inpatient beds are subject to prosecution for fraud by the Federal Government.

Patient Volume

As set forth in the March notice, the Department will use inpatient discharges for the hospital's most recently completed Medicare cost report filing period as the measure of patient volume for IME payments. The hospital should include all inpatient discharges from all parts of the hospital complex.

If a children's hospital eligible to participate in the CHGME program has not completed a Medicare cost report period prior to submission of an application to the CHGME program, its patient volume will be calculated by the following methodology:

a. Divide the number of inpatient discharges from the date the hospital became eligible to the CHGME application deadline by the number of days during this period to produce the average number of discharges per day.

b. Multiply the average number of discharges per day by the number of days the hospital will provide inpatient

care as a hospital eligible to participate in the CHGME program during the FFY in which payments are being made.

One respondent comment that accounting for discharges in the IME payment formula is unnecessary, since it is not a factor for Medicare, and that volume would be reflected by the number of residents in the interns and residents to bed (IRB) ratio.

The Department disagrees with this comment. Since the Medicare IME adjustment is an increase in the PPS payment based on a single discharge, the number of discharges is a critical factor in determining how much IME adjustment a hospital receives from HCFA upon settlement of the cost report by Medicare. For the CHGME program, volume, as determined by the number of discharges, is one of the measures of resource utilization in the children's hospitals.

The FTE resident count in the IRB ratio reflects teaching intensity, not patient volume. The Department assumes that the respondent believes that a hospital with more residents would see a larger volume of inpatients; however, since residents rotating through the outpatient parts of the hospital are included in the FTE resident count, a hospital could have few discharges and a large number of residents.

Outpatient Services

Several respondents were in support of the Department's proposed development of a factor to indicate the resources associated with training in outpatient settings. They suggested that this factor include the development of a case mix index that is more reflective of the relative resource utilization experienced by children's hospitals in both an inpatient and outpatient setting. Other respondents were not in favor of the Department pursuing this avenue of investigation and encouraged the Department to rely on the work being done by HCFA in this area.

Currently HCFA does not have an IME adjustment factor for the outpatient PPS; however, it is collecting data to determine if there is a need for such an adjustment. The CHGME program will consider HCFA's research in addition to pursuing the issue independently.

Determination of IME Payments

Beginning in FFY 2001, the Department will use the following formula for calculating IME payments:

$$\text{IME Pay}_i = Z_{ime} * \frac{NoD_i * CMI_i * (WI_i * .711 + .289) * IME}{\sum_{i=1}^{m} NoD_i * CMI_i * (WI_i * .711 + .289) * IME}$$

The following variables will be used in the formula to determine IME payments:

NoD = number of discharges for hospital

CMI = average case mix index for hospital

WI = area wage index for hospital

IME = IME adjustment/teaching intensity factor for hospital. Currently, the teaching intensity factor is: $1.6((1+\text{residents}_i\text{-to-beds}_i \text{ ratio})^{.405} - 1)$

Z_{ime} = total dollars available for CHGME program IME payments

IME Pay = total IME payments to hospital

i = individual hospital

m = total number of hospitals participating in the CHGME program

residents = average number of unweighted FTE residents in the most recently completed cost reporting period and the prior two cost reporting periods with application of the cap.

beds = sum of all available beds, including beds and bassinets in the healthy newborn nursery, in the most recently completed cost report filing period, divided by the number of days in that period.

This formula differs from that published in the March notice in that it omits the adjustment factor for hospitals with average lengths of stay greater than 30 days.

Hospitals With Average Length of Stay Greater Than 30 Days

In the March notice, the Department proposed to apply an adjustment factor in the calculation of IME payments for children's hospitals with average lengths of stay greater than or equal to 30 days. These hospitals provide a variety of services, including rehabilitative services, that requires their patients to remain as inpatients for a prolonged period of time. The Department found that the FFY 2000 formula for determining CHGME IME payments may have disadvantaged these hospitals.

Since the length of stay is a major factor in determining the relative costliness of an inpatient stay, the Department proposed an adjustment factor based on the average length of stay (ALOS) to more adequately reflect the relative costliness of patients treated by the children's hospitals with significantly long lengths of stay. For hospitals with ALOS greater than or equal to 30 days, the adjustment factor proposed was the ALOS for the individual hospital divided by the average ALOS for all hospitals with ALOS less than 30 days.

Several respondents supported the principle of adjusting the IME payments for those children's hospitals with average lengths of stay greater than or equal to 30 days as these hospitals are demonstrably different from all other children's hospitals. They noted that it is important that hospitals providing the types of services that require prolonged inpatient lengths of stay (e.g., rehabilitation) not be penalized for providing such services, as length of stay is a major factor in the relative costliness of an inpatient stay. However, the respondents indicated that the aggregate impact of an adjustment would be minimal, since it would involve only a very few small hospitals, and among them, they collectively train only a very few residents. These respondents recommended that HRSA make available the analysis underlying this particular adjustment and seek further comment before making the adjustment final and implementing it.

The Department will postpone the implementation of an adjustment factor based on ALOS to the IME payment formula until it conducts additional analyses. These analyses and subsequent proposed recommendations related to the IME payment formula will be published in a future **Federal Register** notice.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act (RFA of 1980), if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives of costs, of benefits, of

incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Department has determined that the only burden this action will impose on children's hospitals is the resources required to submit an application to the CHGME program. Therefore, in accordance with the RFA and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this action will have a significant impact on a substantial number of small entities in that this action will provide significant funding to eligible children's hospitals. However, since this action will not impose a significant burden on a substantial number of small entities, we have not examined any alternatives for reducing the burden on children's hospitals. The Secretary has also determined that this action does not meet criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy of Federal expenditures.

We have determined that the proposed rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, the proposed rule will not have effects on State, local and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Further, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this action under the threshold criteria of Executive Order 13132, Federalism, and, therefore, have determined that this action would not have substantial direct effects on the rights, roles, and responsibilities of States.

Paperwork Reduction Act of 1995

In accordance with section 3507(a) of the Paperwork Reduction Act (PRA) of 1995, the Department is required to solicit public comments, and receive final Office of Management and Budget (OMB) approval, on collections of information. As indicated, in order to implement the Children's Hospital Graduate Medical Education Payment Program (CHGME), certain information is required as set forth in this notice in order to determine eligibility for payment and amount of payment. In accordance with the PRA, we have received final OMB approval on our proposed collection of information (OMB No. 0915–0247).

Collection of information: The Children's Hospitals Graduate Medical Education Payment Program.

Description: Data is collected on the number of full-time equivalent residents in applicant children's hospital training programs to determine the amount of direct and indirect medical education payments to participating children's hospitals. Indirect medical education payments will also be derived from a formula that requires the reporting of case mix index information from participating children's hospitals. Hospitals will be requested to submit such information in an annual application.

Description of Respondents: Children's hospitals operating approved graduate medical residency training programs.

Estimated Annual Reporting: The estimated average annual reporting for this data collection is approximately 150 hours per hospital. The estimated annual burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
HRSA–99–1					
(Annual)	54	1	54	99.9	5,395
(Reconciliation)	54	1	54	8	432
HRSA–99–2 (IME)	54	1	54	14	756
HRSA–99–4					
(Required GPRA tables)	54	1	54	28	1,512
Total	54	1	54	.....	8,095

National Health Objectives for the Year 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, and its successor, Healthy People 2010. These are Department-led efforts to set priorities for national attention. The CHGME program is related to the priority area 1 (Access to Quality Health Services) in Healthy People 2010, which is available online at *http://www.health.gov/healthypeople.*

Education and Service Linkage

As part of its long-range planning, HRSA will be targeting its efforts to strengthening linkages between Department education programs and programs which provide comprehensive primary care services to the underserved.

Smoke-Free Workplace

The Depaertment strongly encourages all award recipients to provide a smoke-free workplace and promote abstinence from all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

This program is not subject to the Public Health Systems Reporting Requirements.

Dated: June 7, 2001.

Elizabeth M. Duke,

Acting Administrator.

Dated: July 17, 2001.

Tommy G. Thompson,

Secretary.

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