

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS-1531-IFC]

RIN 0938-AO35

**Medicare Program; Medicare Graduate Medical Education
Affiliation Provisions for Teaching Hospitals in Certain
Emergency Situations**

AGENCY: Centers for Medicare & Medicaid Services (CMS),
HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period will modify the current Graduate Medical Education (GME) regulations as they apply to Medicare GME affiliations to provide for greater flexibility during times of disaster. Specifically, this rule will implement the emergency Medicare GME affiliated group provisions that will address issues that may be faced by certain teaching hospitals in the event that residents who would otherwise have trained at a hospital in an emergency area (as that term is defined in section 1135(g) of the Social Security Act (the Act)) are relocated to alternate training sites.

DATES: This interim final rule is effective as of August 29, 2005.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1531-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address

ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1531-IFC,

P.O. Box 8011,

Baltimore, MD 21244-8011.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1531-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your

arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201; or

7500 Security Boulevard,

Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Truong, (410) 786-6005.

Renate Rockwell, (410) 786-4645.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1531-IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

A. Legislative Authority

The stated purpose of section 1135 of the Act is to enable the Secretary to ensure, to the maximum extent feasible, in any emergency area and during an emergency period, that sufficient health care items and services are available to meet the needs of enrollees in Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). Section 1135 of the Act authorizes the Secretary, to the extent necessary to accomplish the statutory

purpose, to temporarily waive or modify the application of certain types of statutory and regulatory provisions (such as conditions of participation or other certification requirements, program participation or similar requirements, or pre-approval requirements) with respect to health care items and services furnished by health care provider(s) in an emergency area during an emergency period.

The Secretary's authority under section 1135 of the Act arises in the event there is an "emergency area" and continues during an "emergency period" as those terms are defined in the statute. Under section 1135(g) of the Act, an emergency area is a geographic area in which there exists an emergency or disaster that is declared by the President according to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and a public health emergency declared by the Secretary according to section 319 of the Public Health Service Act. (Section 319 of the Public Health Service Act authorizes the Secretary to declare a public health emergency and take the appropriate action to respond to the emergency, consistent with existing authorities.)

Throughout the remainder of this discussion, we will refer to such emergency areas and emergency periods as "section 1135" emergency areas and emergency periods.

Section 1871(e)(1)(A) of the Act, as amended by section 903(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), generally prohibits the Secretary from making retroactive substantive changes in policy unless retroactive application of the change is necessary to comply with statutory requirements, or failure to apply the change retroactively would be contrary to the public interest. Due to the infrastructure damage and disruption of operations experienced by medical facilities, and the consequent disruption in residency training, caused by Hurricanes Katrina and Rita in 2005, there is urgent need for the regulation changes provided in this interim final rule with comment period to be applied retroactively. Existing regulations do not adequately address the issues faced by hospitals that are located in the emergency areas addressed in this rule, or hospitals that assisted by training displaced residents from the emergency area. We believe failure to apply the regulatory changes

retroactively would be contrary to the public interest because hospitals affected by Hurricanes Katrina and Rita could otherwise face dramatic financial hardship and impede the recovery of graduate medical education programs in the emergency area.

Specifically, the training programs at many teaching hospitals in New Orleans and surrounding areas were temporarily closed in the aftermath of the hurricanes, and the displaced residents were transferred to other hospitals to continue their training programs in other parts of the country. While many residents will likely be able to return to the hurricane-affected hospitals after some period of time, others may need to remain where they have been transferred for an extended period of time. A regulatory change is required so that Medicare graduate medical education (GME) funding can be maintained while there are displaced residents training at various hospitals outside of the emergency area even as the hurricane-affected hospitals incrementally bring residents back in the process of rebuilding their training programs.

Under section 1886(h) of the Act, as amended by section 9202 of the Consolidated Omnibus Budget

Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272), the Secretary is authorized to make payments to hospitals for the direct costs of approved GME programs. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for a Medicare discharge to reflect the higher patient care costs of teaching hospitals, that is, the indirect graduate medical education (IME) costs. Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act established limits on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments and the IME adjustment, respectively, thereby establishing hospital-specific direct GME and IME full-time equivalent (FTE) resident caps. However, under the authority granted by section 1886(h)(4)(H)(ii) of the Act, the Secretary may issue rules to allow institutions that are members of the same affiliated group to apply their direct GME and IME FTE resident caps on an aggregate basis through a Medicare GME affiliation agreement. The Secretary's regulations permit hospitals, through a Medicare GME affiliation agreement, to adjust IME and direct GME FTE resident caps to reflect the

rotation of residents among affiliated hospitals. The current regulation at §413.75(b), implementing Medicare GME affiliations, specifies that hospitals may only form a Medicare GME affiliated group with other hospitals if they are in the same or contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program. The existing regulations do not provide for hospitals whose residency programs have been disrupted in an emergency area to enter into valid Medicare GME affiliation agreements with host hospitals where the hospitals may not meet the regulatory requirements for Medicare GME affiliations. Therefore, through this interim final rule with comment period, we are supplementing the regulations at §413.75(b) and §413.79(f) with provisions for emergency Medicare GME affiliated groups to provide relief to hospitals with disrupted residency programs in an emergency area. These provisions are being made effective retroactive to August 29, 2005.

B. Overview of Medicare Direct GME and IME

As we discussed in the previous section, the Medicare program makes payments to teaching hospitals to account for

two types of costs, the direct costs (direct GME) and the indirect costs (IME) of a hospital's graduate medical education program. Direct GME payments represent the direct costs of training residents (for example, resident salaries, fringe benefits, and teaching physician costs associated with an approved GME program) and generally are calculated by determining the product of the Medicare patient load (that is, the percentage of the hospital's Medicare inpatient days), the hospital's per resident payment amount, and the weighted number of FTE residents training at the hospital during the cost reporting period.

The IME adjustment is made to teaching hospitals for the additional indirect patient care costs attributable to teaching activities. For example, teaching hospitals typically offer more technologically advanced treatments to their patients, and therefore, patients who are sicker and need more sophisticated treatment are more likely to go to teaching hospitals. Furthermore, there are additional costs related to the presence of inefficiencies associated with teaching residents resulting from the additional tests or procedures ordered by residents and the demands put on physicians who supervise, and staff who support, the

residents. IME payments are made as a percentage add-on adjustment to the per discharge Hospital Inpatient Prospective Payment System (IPPS) payment, and are calculated based on the hospital's ratio of FTE residents to available beds as defined at §412.105(b). The statutory formula for calculating the IME adjustment is:

$c \times [(1 + r)^{405} - 1]$, where "r" represents the hospital's ratio of FTE residents to beds, and "c" represents an IME multiplier, which is set by the Congress.

The amount of IME payment a hospital receives for a particular discharge is dependent upon the number of FTE residents the hospital trains, the hospital's number of available beds, the current level of the statutory IME multiplier, and the per discharge IPPS payment. Sections 1886(d)(5)(B)(v) and 1886(h)(4)(F) of the Act established hospital specific limits (that is, caps) on the number of allopathic and osteopathic FTE residents that hospitals may count for purposes of calculating indirect and direct GME payments, respectively.

C. Effect of Existing Regulations

As explained above, the Secretary's authority under section 1135 of the Act is prompted by the occurrence of an

emergency or disaster that leads to designation of a section 1135 emergency area, and continues throughout a section 1135 emergency period. For example, when Hurricane Katrina occurred on August 29, 2005, disrupting health care operations and medical residency training programs at teaching hospitals in New Orleans and the surrounding area, the conditions were met for an emergency area and emergency period under section 1135(g) of the Act. Under section 1135 of the Act, the Secretary was then authorized to waive a number of provisions to ensure that sufficient services would be available in the section 1135 emergency area to meet the needs of Medicare, Medicaid, and SCHIP patients. Shortly after Hurricane Katrina occurred, we were informed by hospitals in New Orleans that the training programs at many teaching hospitals in the city were closed as a result of the disaster and that the displaced residents were being transferred to training programs at host hospitals in other parts of the country. For purpose of discussion in this rule, a host hospital is a hospital that trains residents displaced from a training program in a section 1135 emergency area. A home hospital is a hospital that meets all of the following: (1) is located in a section 1135

emergency area (2) had its inpatient bed occupancy decreased by 20 percent or more due to the disaster so that it is unable to train the number of residents it originally intended to train in that academic year, and (3) needs to send the displaced residents to train at a host hospital.

Immediately after Hurricane Katrina, home and host hospitals petitioned CMS for a mechanism to allow host hospitals to count the displaced FTE residents they would be training for direct GME and IME payment purposes. In response to the petitions, we immediately issued a Question and Answer (Q&A), which cited provisions in existing regulations at §413.79(h). Section 413.79(h) allows home hospitals that closed, or closed one or more residency training programs, to temporarily transfer FTE residents to host hospitals and allows host hospitals that were already training residents at or above their FTE resident caps to count those displaced residents for direct GME and IME payment (see the CMS Q&A's website: <http://questions.cms.hhs.gov> (the website link is located at ID 5696)).

As specified at §413.79(h), Medicare considers a program at a hospital to be closed if "...the hospital ceases

to offer training for residents in a particular approved medical residency training program." Section 413.79(h) also defines closure of a hospital as when a hospital "...terminates its Medicare agreement under the provisions of §489.52..." The regulations at §413.79(h) allow a host hospital that accepts residents from the closed program to receive a temporary increase in its IME and direct GME resident caps for those residents as long as the home hospital agrees to a corresponding temporary reduction to its own caps. The host hospital under the closed program provisions would receive temporary FTE resident cap adjustments only as long as the specific resident(s) is displaced (and only as long as the home hospital or home hospital's program remains closed). Therefore, once the resident(s) completes training in the program that he or she was training in when the program closed, or he or she returns to train at the home hospital, no additional FTE resident cap adjustments for the host hospital are permitted under §413.79(h). Furthermore, §413.79(h) specifies that a host hospital can receive a temporary increase in its FTE resident caps in order to count displaced FTE residents only if the proper documentation is

submitted to the fiscal intermediaries (FIs) by both the home and host hospital no later than 60 days after the host hospital begins to train the displaced resident(s).

In accordance with the authority granted to the Secretary under section 1135 of the Act, as stated in our Q&A posted on the CMS website, we extended the regulatory 60-day deadline for submitting documentation to CMS as required by §413.79(h) and thus allowed hospitals to submit the documentation by the earlier of the end of the section 1135 emergency period granted for Hurricanes Katrina and Rita or by June 30, 2006. The section 1135 emergency period ended on January 31, 2006. We believe the existing regulation at §413.79(h) addressed the issue of finding host hospitals for residents displaced from home hospitals in the immediate aftermath of Hurricanes Katrina and Rita. However, teaching hospitals in section 1135 emergency areas have since made us aware of several issues that are not addressed (or not addressed adequately) under current regulations. For instance, some of the hurricane-affected programs in New Orleans and elsewhere did not in fact close entirely. In many cases, a reduced number of residents

continued to train in the hospitals' outpatient departments. Therefore, those programs at the home hospitals did not actually close, and neither the home or host hospitals will be able to use the regulatory provisions at §413.79(h) to enable host hospitals that are at or above their FTE resident caps to count displaced residents from home hospitals for Medicare direct GME and IME purposes. We understand that even hospitals that had originally completely closed their programs have been in the process of gradually reopening their programs (that is, residents are being brought back to the home hospitals in stages). Therefore, even where a home hospital temporarily closed a program following the disaster, once it begins training any residents (even a fraction of an FTE resident) in that program again, the program is no longer closed and any adjustments made to the host hospital's cap under the closed program regulation would no longer be allowed. Therefore, we believe that, in order to remove the disincentive faced by hospitals that are at or above their FTE resident caps to continue training displaced residents, some kind of regulatory relief is necessary.

II. Meeting the Needs of Teaching Hospitals Affected By A Disaster

[If you choose to comment on issues in this section, please include the caption "TEACHING HOSPITALS AFFECTED BY A DISASTER" at the beginning of your comments.]

This interim final rule with comment period will amend the Medicare GME affiliation regulations to address the needs and incentives of home and host hospitals in the event of an emergency or disaster. In developing a policy to provide home and host hospitals flexibility in response to a disaster, we address two priorities. First, we believe that in disaster situations, to the extent that the statute permits, the policy should facilitate the continuity of GME, minimizing the disruption of residency training. Second, the policy should take into account that the training programs at home hospitals have been severely disrupted by a disaster and that home hospitals will usually want to rebuild their GME programs as soon as possible.

A. Overview of the Closed Programs Provisions

As we noted in our Q&A (posted on the CMS website), issued in response to inquiries from hospitals affected by

Hurricane Katrina, the regulations at §413.79(h) offer a payment policy option that could be applied in limited situations occurring after a disaster. Thus, a host hospital would be allowed to make temporary adjustments to its IME and direct GME caps (limited by the home hospital's IME and direct GME caps) in order to count displaced residents for direct GME and IME payment purposes. However, due to the complexity of training programs where residents train at multiple hospitals (this is a common training model used throughout the country), there are many potential difficulties that can arise in applying this policy to address disaster situations.

Typically, residents in a program spend time training during the year at multiple hospitals, some of which may have been affected by the disaster, while others may not have been affected. For example, a first year resident in a family practice program may spend one third of the year training at a hospital in New Orleans, and the remaining two-thirds of the year at other hospitals in Baton Rouge. When the New Orleans hospital closed due to the hurricane, this resident may have been training at one of the Baton Rouge hospitals. Therefore, although the resident was not

immediately displaced by the hurricane, since the resident would have rotated to the New Orleans hospital later in the year, the resident will ultimately be affected.

Conversely, a resident that was training in New Orleans at the time of the hurricane was immediately displaced, so even if the resident was transferred to a host hospital in Texas to continue training, that resident may be able to continue to train at the unaffected Baton Rouge hospital after completing a rotation at the host hospital.

Additional complexity can arise through the interaction of the home and host hospital's FTE resident caps. Each one of the home hospitals involved in the previous example could be training residents above their respective IME and direct GME FTE resident caps. Since the closed program provisions are resident-specific, that is, the host hospital's cap adjustment is tied to the specific resident who was displaced, as specified at §413.79(h), documentation would be required to account for each resident's FTE time spent training at each of the home and host hospitals. Additionally, because the policy under §413.79(h) is resident-specific, the host hospital would only receive a temporary cap adjustment for as long as the

specific residents are displaced. Therefore, home and host hospitals would need to provide a very detailed accounting of each resident's training as required at §413.79(h).

Hospitals in New Orleans have notified us that in light of the damage they suffered from the hurricane, documenting the specific residents, their rotations at the various home and host hospitals (and the FTEs associated with each rotation) and where the displaced residents were sent after the hurricane constitutes a major documentation burden. We note that although CMS extended the documentation deadline to January 31, 2006, under the authority of section 1135 of the Act, giving hospitals 5 months from the time of the hurricane to submit this type of documentation, we are aware of no hospitals that complied with all of the documentation requirements listed at §413.79(h) by the due date. Therefore, due to the challenges and complexities mentioned above, we believe that the existing closed program regulations do not adequately address the issues associated with Medicare direct GME and IME payment policies that are faced by residency training programs affected by a disaster.

B. Overview of the Medicare GME affiliation provisions

Accordingly, we are revising §413.75(b) to include definitions of emergency Medicare GME affiliated group, home hospital, host hospital, section 1135 emergency area, and section 1135 emergency period. We are also revising §413.79(f) to set forth the requirements of an emergency Medicare GME affiliation agreement.

The existing definition of Medicare GME affiliated group at §413.75(b) specifies that hospitals may only form a Medicare GME affiliated group with other hospitals if they are in the same or contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program. The existing Medicare GME affiliation provisions at §413.79(f) permit participating teaching hospitals to aggregate and "share" FTE caps during a specified academic year. The Medicare GME affiliation regulations allow hospitals that need to either decrease or increase their FTE resident counts to reflect the normal movement of residents among affiliated hospitals to do so for the agreed-upon training years.

Hospitals that affiliate must submit a Medicare GME

affiliation agreement, as specified at §413.75(b), to their Medicare FIs and to CMS no later than July 1 of the relevant academic year. Each hospital in the Medicare GME affiliated group must have a shared rotational arrangement with at least one other hospital within the Medicare GME affiliated group, and all of the hospitals within the Medicare GME affiliated group must be connected by a series of shared rotational arrangements. The net effect of the adjustments to hospitals' FTE resident caps, whether positive or negative on a hospital-specific basis, in the aggregate must not exceed zero. While additional hospitals may not be added to the Medicare GME affiliated group after July 1 of a year, amendments to the affiliation agreement to adjust the distribution of the number of FTE residents in the original Medicare GME affiliation among the hospitals that are part of the Medicare GME affiliated group can be made through June 30 of the academic year for which they are effective.

C. Overview of the Emergency Medicare GME Affiliated Group Provision

[If you choose to comment on issues in this section, please include the caption "OVERVIEW OF THE EMERGENCY MEDICARE GME

AFFILIATED GROUP PROVISION" at the beginning of your comments.]

Based on what we have learned about the impact of a disaster on teaching hospitals, we believe it is necessary to provide hospitals with greater flexibility to distribute FTE resident caps within a group of home and host hospitals if there is an emergency at a home hospital that has resulted in the designation of a section 1135 emergency area. We believe that a modified Medicare GME affiliation policy would allow affected hospitals the maximum degree of flexibility following the disaster so that residents displaced by the disaster can continue their residency training at other hospitals, while the home hospitals can remain committed to reopening their programs.

While there may be hospitals in the section 1135 emergency area that do not experience a disruption in residency training due to the disaster, the provisions in this rule are only intended to help home hospitals, that is, hospitals that have been directly affected by the disaster to the extent that their inpatient bed occupancy is diminished, limiting the hospital's ability to train residents. In determining whether a hospital in a section

1135 emergency area qualifies as a home hospital, we believe it is appropriate to compare the inpatient bed occupancy of the hospital one week before the earlier of the date the section 1135 emergency period begins, or the date on which the hospital began any evacuation efforts in anticipation of an event that results in the declaration of a section 1135 emergency area, to the inpatient bed occupancy of the hospital one week after the section 1135 emergency period begins. If the inpatient bed occupancy decreases by 20 percent or more between these two comparison timeframes, we believe that the significant drop in occupancy can be assumed to be the result of the event that led to the declaration of a section 1135 emergency period. We believe a hospital that experiences such a drop in occupancy may not have enough patients to continue to provide for adequate residency training, and therefore, may need to send residents to host hospitals. The emergency Medicare GME regulations are applicable to these home hospitals. These emergency Medicare GME affiliated group provisions in §413.79(f)(6) are effective as of the date of the first day of a section 1135 emergency period (for example, in the case of Hurricane Katrina, they are

effective on August 29, 2005). The duration of these emergency Medicare GME affiliation agreements is limited to the remainder of the academic year during which the section 1135 emergency period began, plus two additional academic years. Thus, an emergency Medicare GME affiliation agreement is permitted to remain in effect for no more than 3 training years, beginning with the first day of the section 1135 emergency period. (An emergency Medicare GME affiliation agreement could remain in effect for three full academic years only if the first day of a section 1135 emergency period occurred on July 1.)

For example, in the case of Hurricane Katrina, an emergency Medicare GME affiliation could be effective from August 29, 2005, to June 30, 2006 (we refer to this as the first effective year); the affiliation could also be effective for two subsequent academic years: the second effective year of the emergency Medicare GME affiliation would be from July 1, 2006 to June 30, 2007, and the third effective year would be from July 1, 2007 to June 30, 2008. At the conclusion of the allowable effective period for an emergency Medicare GME affiliated group, the emergency provisions at §413.79(f)(6) cease to apply, and the

existing provisions for Medicare GME affiliation agreements at §413.79(f)(1) through (5) would apply.

We believe that the limits on the allowable effective period for emergency Medicare GME affiliated group serve to maintain GME funding over a sufficient period to allow home hospitals to rebuild their GME programs, while also supporting the continuity of residency training. We welcome public comments on whether the allowable effective period is sufficient time to accommodate rebuilding of residency programs at home hospitals.

D. Emergency Medicare GME Affiliated Group Provisions

1. Affiliation Agreement

To provide home hospitals with more flexibility to train displaced residents at various sites, and to allow host hospitals to count displaced residents for IME and direct GME, home hospitals may enter into emergency Medicare GME affiliation agreements effective retroactive to the date of the first day of the section 1135 emergency period.

The emergency Medicare GME affiliated group may include hospitals that would not meet the requirements for a Medicare GME affiliated group as specified as §413.75(b).

Specifically, for these emergency Medicare GME affiliated groups, home hospitals may affiliate with host hospitals anywhere in the country because we recognize that immediately following a disaster, home hospitals need flexibility to assign displaced residents to any available program. As home hospitals recover the ability to train residents after a disaster, the emergency Medicare GME affiliated group provisions allow home hospitals to return residents to their training sites, thereby giving home hospitals the opportunity to rebuild their programs incrementally.

For the year during which the section 1135 emergency was declared, each hospital participating in the emergency affiliation must submit a copy of the emergency Medicare GME affiliation agreement, as specified under §413.79(f)(6), to CMS and the CMS FI servicing each hospital in the agreement by the later of 180 days after the section 1135 emergency period begins or by June 30 of the relevant training year. Emergency Medicare GME affiliation agreements for the subsequent 2 academic years must be submitted by the later of 180 days after the section 1135 emergency period begins or by July 1 of each

of the years. Amendments to the emergency Medicare GME affiliation agreement to adjust the distribution of the number of FTE residents in the original emergency Medicare GME affiliation among the hospitals that are part of the emergency Medicare GME affiliated group can be made through June 30 of the academic year for which they are effective. The emergency Medicare GME affiliation agreement must be written, signed, and dated by responsible representatives of each participating hospital and must: (1) list each participating hospital and its provider number, and specify whether the hospital is a home or host hospital; (2) specify the effective period of the emergency Medicare GME affiliation agreement; (3) list each participating hospital's IME and direct GME FTE caps in effect for the current academic year before the emergency Medicare GME affiliation (that is, if the hospital was already a member of a regular Medicare GME affiliated group before entering into the emergency Medicare GME affiliation, the emergency Medicare GME affiliation must be premised on the FTE caps of the hospital as adjusted per the regular Medicare GME affiliation agreement, and not include any slots gained under section 422 of the MMA); and (4) specify the total

adjustment to each hospital's FTE caps in each year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to the host hospital's direct and indirect FTE caps that is offset by a negative adjustment to the home hospital's (or hospitals') direct and indirect FTE caps of at least the same amount. The sum total of adjustments to all the participating hospitals' FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted caps of the hospitals participating in the emergency Medicare GME affiliated group. A home hospital's IME and direct GME FTE cap reductions under an emergency Medicare GME affiliation agreement are limited to the home hospital's IME and direct GME FTE resident caps in effect for the academic year in accordance with regulations at §413.79(c)(1) through (c)(3) or §413.75(b), that is, the hospital's base year FTE resident caps as adjusted by any and all existing affiliation agreements.

In addition to meeting the requirements for an emergency Medicare GME affiliation agreement, a host hospital will be required to document that any FTE

residents counted pursuant to the emergency Medicare GME affiliation agreement are, in fact, displaced residents from a program located in the emergency area. That is, the host hospital will need to provide the FI with a list of resident names and social security numbers, and the name of the original sponsor of the program located at the home hospital in the emergency area for each displaced resident. We note that the hospital is already required, as specified at §413.75(d), to provide much of this information in order to include any resident in its FTE count for a particular cost reporting period. We are adding the requirement that a host hospital document the original program sponsor of each displaced resident it is training in order to document that any additional FTE residents counted pursuant to the emergency Medicare GME affiliation agreement are indeed due to training of displaced residents. Providing appropriate and sufficient documentation permits the FI to properly reconcile the correct FTE resident count for each hospital.

2. Multiple Affiliations

In many cases, home hospitals will already have Medicare GME affiliation agreements in effect before the section 1135 emergency period, and may be entering into

emergency Medicare GME affiliation agreements with host hospitals that will already have regular Medicare GME affiliation agreements in effect. Therefore, such situations will lead to multiple layers of Medicare GME affiliations. It is critical that the emergency Medicare GME affiliation agreements accurately state the appropriate caps for each hospital in the affiliated group in order for the FIs to pay the hospitals correctly. The hospitals must attach copies of all existing Medicare GME affiliation agreements (that is, a hospital's regular or other emergency Medicare GME affiliations already in place for the year) when submitting the emergency Medicare GME affiliation agreement to the FI so that the FI can verify and reconcile the cap adjustments. For example, if a home hospital has a direct GME cap of 100 but has an existing affiliation agreement before the disaster in which it reduced its cap by 40 FTEs, then, for purposes of entering into the emergency Medicare GME affiliation agreement, it has an adjusted direct GME cap of 60 with which to affiliate under the emergency affiliation provisions. The emergency Medicare GME affiliation provisions are different from the regular Medicare GME affiliation provisions in

that regular Medicare GME affiliations are based upon the hospitals' FTE resident caps before any adjustments resulting from Medicare GME affiliation agreements.

Because they are likely to occur during an academic year, and cannot be anticipated before the beginning of the year, emergency Medicare GME affiliations are based upon hospitals' FTE resident caps as they are already modified by any existing Medicare GME affiliation agreement(s).

In order to provide each hospital with its correct payment, the CMS FIs involved need to be aware of both regular Medicare GME affiliation agreements and any emergency Medicare GME affiliation agreements in which a hospital is participating. Without the correct information on each hospital's Medicare GME affiliation agreements (whether regular or emergency affiliations), hospitals could be paid improperly for direct GME and IME based on application of incorrect FTE resident caps that do not reflect all Medicare GME affiliation agreements in effect (that is, regular and emergency affiliations).

Furthermore, to determine direct GME and IME payments under an emergency Medicare GME affiliation, the normal FTE-counting rules as specified at §413.78 will apply. For

example, residents beyond the initial residency period are counted at .5 FTE for direct GME purposes. The existing IME FTE-counting rules as specified at §412.105(f) apply in determining the IME adjustment. Therefore, when the CMS FI settles a cost report for a hospital in which an emergency Medicare GME affiliation agreement is reflected, each participating hospital would be held to its adjusted IME and adjusted direct GME caps as agreed to and specified in the emergency Medicare GME affiliation agreement.

We note that in the IPPS final rule published in the **Federal Register** on August 11, 2004 (69 FR 49142), we state "... hospitals that receive section 422 cap increases from CMS and participate in a Medicare GME affiliation agreement under §413.79(f) on or after July 1, 2005 may only affiliate for the purposes of adjusting their 1996 FTE caps (adjusted for new programs and any other reductions under section 1886(h)(7)(A) of the Act) for direct GME and IME. The additional slots that a hospital receives under section 422 of the MMA may not be aggregated and applied to the FTE resident caps of any other hospitals." Similarly, we are providing that any slots gained under section 422 of the MMA may not be used in any emergency Medicare GME

affiliation agreement.

We are providing examples below of the emergency Medicare GME affiliation agreements and discussing the ramifications of the provisions.

EXAMPLE I

For the training year beginning on July 1, 2005, Hospital A and Hospital B have a regular Medicare GME affiliation agreement in which Hospital A (which has IME and direct GME caps of 20 FTEs) agrees to transfer 10 FTEs to Hospital B (which has IME and direct GME caps of 15 FTEs). Under the regular affiliation agreement, Hospital B now has adjusted caps of 25 FTEs and Hospital A has adjusted caps of 10 FTEs for both IME and direct GME. As a result of Hurricane Zeta on November 1, 2005, Hospital A sustained damage to its inpatient facilities (reducing its occupancy by 20 percent or more) and has displaced residents that it needs to send to other hospitals for training. Hospital A is located in a section 1135 emergency area, and the first day of the section 1135 emergency period is November 1, 2005. In this case, Hospital A is a home hospital as defined under §413.75(b), and is permitted to enter into an emergency Medicare GME

affiliation agreement as specified at §413.79(f)(6).

In Example I above, Hospital B was not affected by the hurricane (that is, Hospital B was able to continue training residents at the same level it was before the hurricane, and is training the maximum number of residents under its FTE caps as adjusted by the existing Medicare GME affiliation agreement with Hospital A). We note that Hospitals A and B may modify their regular Medicare GME affiliation agreement, if necessary, no later than June 30, 2006, under the requirements as specified at §413.79(f)(5). In this case, Hospital B does not qualify as a home hospital since its inpatient occupancy was not reduced by 20 percent or more even though it was located in the area covered by the section 1135 waiver. Hospital A elects to enter into an emergency Medicare GME affiliation agreement with host Hospitals C and D in two other States because those hospitals are well-situated to provide residents displaced from Hospital A with an appropriate training experience.

Accordingly, all of the hospitals (A, C, and D) in the emergency Medicare GME affiliated group must submit copies of the emergency Medicare GME affiliation agreement to CMS

and to the CMS FIs servicing the hospitals participating in the emergency Medicare GME affiliation agreement by June 30, 2006 (in this case, June 30, 2006 is the later of 180 days after the section 1135 emergency period begins (November 1, 2005) or by June 30 of the relevant training year). In Table I below, we list the FTE resident cap information that the emergency Medicare GME affiliation agreement, included for the first effective period, which was submitted to CMS and the CMS FI on June 30, 2006.

TABLE 1--Emergency Medicare GME Affiliation Agreement Due to Hurricane Zeta for Effective Period-- November 1, 2005 to June 30, 2006

Hospital Name	Provider Number	IME cap before emergency affiliation	Direct GME cap before emergency affiliation	Adjusted IME cap under the emergency affiliation	Adjusted Direct GME cap under the emergency affiliation
Hospital A	19-9999	10	10	1 (-9)	1 (-9)
Hospital C	45-9999	10	10	14 (+4)	14 (+4)
Hospital D	33-9999	10	10	15 (+5)	15 (+5)

As indicated in Example I above, Hospital B was not affected by the hurricane, and therefore did not participate in an emergency Medicare GME affiliated group. However, Hospital A is required to attach a copy of the existing Medicare GME affiliation agreement it has with Hospital B to the emergency Medicare GME affiliation

agreement submitted to CMS and its FI to document its adjusted cap of 10 FTEs. Hospitals C and D are similarly required to attach copies of all existing Medicare GME affiliation agreements that they may be participating in as of July 1, 2005, (including any regular or emergency affiliation agreements) in order to document their caps.

To further illustrate this policy continuing with the above example, Hospital C, which has an adjusted direct GME cap under the emergency Medicare GME affiliation of 14 FTEs, could count up to four displaced FTE residents during the first effective year assuming that Hospital C can document that these FTEs are from programs in the section 1135 emergency area. However, upon cost report settlement, the CMS FI determined that Hospital C has actually trained a total of 16 FTEs during the cost reporting period. Since each participating hospital will be held to their adjusted IME and adjusted direct GME caps as agreed to and specified in the emergency Medicare GME affiliation agreement, the CMS FI would only allow four of the six additional FTEs Hospital C trained pursuant to the emergency Medicare GME affiliation agreement.

EXAMPLE II

Alternatively, assume that both Hospitals A and B from Example I above are affected by the same hurricane, both qualify as a home hospital, and both need to participate in an emergency Medicare GME affiliation with host Hospitals C and D in the other States.

We note that while Hospitals A and B may modify their existing Medicare GME affiliation agreement on or before June 30, 2006, Hospitals A and B may find it easier to reflect the changes in training (and the resultant shift of FTE resident caps) due to Hurricane Zeta through the emergency Medicare GME affiliation agreement. In this scenario, Hospitals A and B may execute an emergency Medicare GME affiliation agreement in which the emergency Medicare GME affiliated group includes Hospitals A, B, C, and D. In Table II below, we list the FTE cap information that the emergency Medicare GME affiliation agreement included for the first effective period, which was submitted to CMS and the CMS FI on June 30, 2006.

TABLE II-- Emergency Medicare GME Affiliation Agreement Due to Hurricane Zeta for Effective Period-- November 1, 2005 to June 30, 2006

Hospital Name	Provider Number	IME cap before emergency affiliation	Direct GME cap before emergency affiliation	Adjusted IME cap under the emergency affiliation	Adjusted Direct GME cap under the emergency affiliation
Hospital A	19-9999	10	10	1 (-9)	1 (-9)
Hospital B	19-8999	25	25	10 (-15)	10 (-15)
Hospital C	45-9999	10	10	19 (+9)	19 (+9)
Hospital D	33-9999	10	10	25 (+15)	25 (+15)

We note that the pre-existing regular Medicare GME affiliation agreement between Hospitals A and B which pre-dated the disaster is still in effect according to existing affiliation agreement rules; therefore Hospitals A and B must account for any FTE resident cap transfers specified in the regular affiliation agreement when they enter into the emergency Medicare GME affiliation agreement with host Hospitals C and D. In addition, a copy of Hospital A and B's regular Medicare GME affiliation agreement must be attached to the emergency Medicare GME affiliation agreement that is submitted to CMS and the hospitals' CMS FIs.

3. Submission Process

Submissions of emergency Medicare GME affiliation agreements should be sent to:

Centers for Medicare & Medicaid Services

Division of Acute Care

Attention: Elizabeth Truong or Renate Rockwell

Mailstop C4-08-06, 7500 Security Boulevard,

Baltimore, MD 21244

"Emergency Medicare GME Affiliation Agreement" should be clearly labeled on the outside envelope.

4. Application of Existing Rules

[If you choose to comment on issues in this section, please include the caption "APPLICATION OF EXISTING RULES" at the beginning of your comments.]

a. New Teaching Hospitals

Immediately after a disaster, home hospitals are in the best position to determine where their residents should be sent to continue with their residency training.

Although home hospitals may send their residents to train at existing teaching hospitals, in some cases, hospitals affected by a disaster may need to send residents to non-teaching hospitals (that is, hospitals that have not included any residents training in approved medical residency training programs on a previous Medicare cost

report) to continue their training.

The following discussion is intended to inform hospitals of how CMS will determine the GME payments to the host hospital in the case where home hospitals choose to send displaced residents to host hospitals that were previously non-teaching hospitals. These host hospitals will become new teaching hospitals once they begin to train residents from the home hospitals as part of an approved medical residency training program. As a new teaching hospital, such a hospital initially will have IME and direct GME FTE resident caps of zero (based on the number of residents training in the 1996 base year for FTE resident caps). However, the new teaching hospital, by participating in an emergency Medicare GME affiliation agreement, can receive a temporary cap increase in order to count the displaced FTE residents for purposes of IME and direct GME payments.

As a new teaching hospital, the hospital will not have an existing per resident amount for direct GME payment purposes. The per resident amounts for these hospitals will be established as specified at §413.77(e) (just as any other new teaching hospital would have its per resident

amount established). The new teaching hospital's per resident amount is established based on the lower of the hospital's direct GME costs per resident in its base year, or the updated weighted mean value of the per resident amounts of all hospitals located in the same geographic wage area as specified at §413.77. Therefore, it is very important for a new teaching host hospital to incur direct GME costs in its base year and to document all of the direct GME costs it incurs (for example, the residents' salaries, fringe benefits, any portion of the teaching physician salaries attributable to GME, and other direct GME costs) for the displaced residents it is training; otherwise the host hospital risks being assigned a very low per resident amount in accordance with our regulations. If the host, new teaching hospital incurs no GME costs in the relevant base year, its per resident amount would be zero dollars. We advise hospitals to refer to the provisions at §413.77(e) for the rules concerning the establishment of a new teaching hospital's per resident amount. In accordance with section 1886(h) of the Act and our regulations at §413.77, once the base year per resident amount is established, it is fixed and not subject to adjustment to

reflect costs incurred in years subsequent to the base year that might be associated with new programs or additional residents.

b. Shared Rotational Requirements

As specified at §413.79(f)(2), each hospital in a regular Medicare GME affiliated group must have a shared rotational arrangement with at least one other hospital participating in the Medicare GME affiliation agreement. All of the hospitals within the Medicare GME affiliated group would therefore be connected by a series of shared rotational arrangements. As defined at §413.75(b), a shared rotational arrangement "means a residency training program under which a resident(s) participates in training at two or more hospitals in that program." We are specifying at §413.79(f)(6) that hospitals that are members of an emergency Medicare GME affiliated group are not required to participate in a shared rotational arrangement with the other hospitals participating in the emergency Medicare GME affiliation agreement. We are implementing this provision because we recognize that members of an emergency Medicare GME affiliated group may be geographically dispersed across the country, which would

make it difficult for residents to participate in shared rotational arrangements. Additionally, after a disaster, affected hospitals may not have the resources available to participate in shared rotational arrangements with host hospitals situated around the country. For example, hospitals may not have the financial capability to continuously transport residents between States. Therefore, we are exempting participants in emergency Medicare GME affiliations from the shared rotational requirements.

c. Weighted FTE counts ("3-year rolling average")

As specified at §412.105(f)(1)(v) and §413.79(d), a "3-year rolling average" is applied to a hospital's count of FTE residents to calculate IME and direct GME payments for a cost reporting period (that is, the number of FTEs used to calculate payments is the average of the number of FTE residents reported for the current year, the prior year, and the penultimate year). For example, if the hospital trained 115 FTE residents (for IME) in the current cost reporting period, 100 FTEs in the prior cost reporting period, and 100 FTEs in the penultimate cost reporting period, then the IME payment would not be based solely on

the 115 residents trained in the current year. Rather, the IME payment in the current year would be based on the 3-year rolling average FTE count (that is, $(115 + 100 + 100) / 3$ which equals 105 FTEs).

Thus, if a hospital increases its number of FTE residents, as a result of the 3-year rolling average rule, the hospital would be able to count only one third of the additional FTE residents in that year, two-thirds of the additional FTEs for the next year, and the full number in the third year (assuming there are no other changes in the number of FTE residents training in subsequent years). Conversely, if a hospital decreases its number of FTE residents in the current year, then the 3-year rolling average minimizes the effect of the reduced GME payments based on the reduced level of training over the next 3 years. Home hospitals that have reduced the number of FTE residents training at their hospitals would benefit under this provision since only one third of the FTE resident reduction will apply in the first cost reporting year in which an emergency period is declared. The 3-year rolling average provision, as specified at §412.105 and §413.79(d), will be applied to all hospitals in the

emergency Medicare GME affiliation, and their associated FTE resident counts while the agreement is in effect. This provision is the same as applied under existing regulations in which hospitals participating in a Medicare GME affiliation agreement(s) are subject to the 3-year rolling average.

However, there is an exception to the application of the 3-year rolling average rules for closed program and closed hospital regulations as specified at §413.79(d)(6). In the case of host hospitals that participate in emergency Medicare GME affiliated groups relating to the section 1135 emergency declared following Hurricanes Katrina and Rita, which occurred in 2005, we understand that, based on the Q&A we posted on the CMS website discussing application of the closed program and closed hospital regulations to these hospitals, there was an expectation among host hospitals that the displaced FTE residents they accepted for training would be exempt from application of the 3-year rolling average, and that the host hospitals would immediately be permitted to include all of those residents in their FTE resident counts. Many host hospitals, believing that the existing regulations regarding closed hospitals and closed

programs would be applied, took in displaced residents with the reasonable expectation that they would be able to count those additional residents as FTEs not subject to the 3-year rolling average rules specified at §412.105 and §413.79(d). In recognition of this expectation, we are providing for a time-limited exception to the 3-year rolling average rules so that a host hospital participating in an emergency Medicare GME affiliation agreement relating to Hurricanes Katrina and Rita and training residents in excess of its cap, consistent with the rolling average provisions applicable for closed programs as specified at §413.79(d)(6), will exclude from the 3-year rolling average FTE residents associated with displaced residents from August 29, 2005, to June 30, 2006. All host hospitals in an emergency Medicare GME affiliated group will be subject to the existing 3-year rolling average requirements beginning on July 1, 2006.

Accordingly, we revised §413.79(f) by adding a new paragraph (6) to provide for more flexibility in Medicare GME affiliations for home hospitals located in section 1135 emergency areas to allow the home hospitals to efficiently find training sites for displaced residents. Under the

flexibility provided by the emergency Medicare GME affiliated group provisions as specified at §413.79(f)(6), decisions regarding the transfer of FTE resident cap slots, including how to address situations where the home hospital was training a number of residents in excess of its cap before the disaster, and the tracking of those FTE resident slots, would be left to the home and host hospitals to work out among themselves. The home and host hospitals are, however, required to include much of this information in their emergency Medicare GME affiliation agreements as specified under §413.79(f)(6). Furthermore, since hospitals may amend the emergency Medicare GME affiliation agreement (on or before June 30 of the relevant academic year) to reflect the actual training situation among the hospitals participating in the emergency Medicare GME affiliated group, hospitals are provided with greater flexibility to accommodate any changing residency training circumstances within the emergency Medicare GME affiliated group. We note that the emergency Medicare GME affiliated group provisions promulgated herein are intended for the purpose of providing for continued training of residents displaced from a section 1135 emergency area, and not to

enable hospitals to merely shift and change FTE resident caps with other hospitals in the country (for instance, in order to maximize Medicare IME and direct GME payments).

III. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption "PROVISIONS OF THE INTERIM FINAL RULE" at the beginning of your comments.]

We are revising the Medicare GME regulations at §412.105, §413.75(b), and §413.79(f) to implement an emergency Medicare GME affiliated group policy that will only apply to certain home hospitals in a section 1135 emergency area and host hospitals that accept displaced residents from a home hospital.

§412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

In §412.105, we revised paragraph (a)(1)(i) to specify that special treatment for hospitals that incur indirect costs for GME programs also applies to the emergency Medicare GME affiliated groups.

In addition, we revised paragraph (f)(1)(vi) to specify that hospitals that are part of the same Medicare

GME affiliated group or emergency Medicare GME affiliate group may elect to apply the limit at paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in §413.97(f).

§413.75 Direct GME payments: General requirements.

In §413.75(b), we added the definition of an "Emergency Medicare GME affiliated group," and within this definition, we specify the meaning of "Home hospital" and "Host hospital," and we define "Section 1135 emergency area or section 1135 emergency period."

§413.79 Direct GME payments: Determination of the weighted number of FTE residents.

In §413.79(f), we revised the introductory text to specify that a hospital may receive a temporary adjustment to its FTE cap, which, except as provided in subsection (6)(iv), is subject to the averaging rules at §413.79(d), to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group or an emergency Medicare GME affiliated group as defined at §413.75(b).

In §413.79(f)(6), we set forth the requirements for emergency Medicare GME affiliated group.

In paragraph (f)(6)(i), we specify the requirements for the emergency Medicare GME affiliation agreement that each hospital participating in the emergency Medicare GME affiliated group must submit. Specifically, each participating hospital must submit an emergency Medicare GME affiliation agreement that is written, signed, and dated by responsible representatives of each participating hospital, and the emergency Medicare GME affiliation agreement must include the following:

- Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of two academic years following the academic year in which the section 1135 emergency period began).
- List each participating hospital's IME and direct GME FTE caps in effect before the emergency Medicare GME affiliation agreement (including any adjustments to those caps in effect as a result of other Medicare GME affiliation agreements but not including any slots gained under §413.79(c)(4)).

- Specify the total adjustment to each participating hospital's FTE caps in each academic year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to the host hospital's direct and indirect FTE caps that is offset by a negative adjustment to the home hospital's (or hospitals') direct and indirect FTE caps of at least the same amount. The sum total of adjustments to all the participating hospitals' FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted FTE caps of the hospitals participating in the emergency Medicare GME affiliated group. A home hospital's IME and direct GME FTE cap reductions in an emergency Medicare GME affiliation agreement are limited to the home hospital's IME and direct GME FTE resident caps at §413.79 (c) (1) through (c) (3) or §413.75(b), that is, as adjusted by any and all existing affiliation agreements as applicable.

- Attach copies of all existing Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements in which the hospital is

participating at the time the emergency Medicare GME affiliation agreement is executed.

In paragraph (f) (6) (ii), we specify that each participating hospital must submit the emergency Medicare GME affiliation agreement to CMS and submit a copy to the CMS FI. Specifically, an emergency Medicare GME affiliation agreement must be submitted to CMS with a copy to the CMS FI by the later of 180 days after the section 1135 emergency period begins or by July 1 of the academic year in which the emergency Medicare GME affiliation agreement is effective.

In paragraph (f) (6) (iii), we specify that during the effective period of the emergency Medicare GME affiliation agreement, hospitals in the emergency Medicare GME affiliated group are not required to participate in a shared rotational arrangement as defined at §413.75(b).

In paragraph (f) (6) (iv), we specify the host hospital exception from the rolling average for the period from August 29, 2005 to June 30, 2006. We also specify how to determine the FTE resident count for a host hospital that is counting a number of displaced residents in excess of its cap for the period from August 29, 2005, through

June 30, 2006.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Effective date and Waiver of Proposed Rulemaking

[If you choose to comment on issues in this section, please include the caption "EFFECTIVE DATE AND WAIVER OF PROPOSED RULEMAKING" at the beginning of your comments.]

The Administrative Procedure Act (APA) normally requires a 30-day delay in the effective date of a final rule. This delay may be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary or contrary to the public interest, and incorporates a statement of the finding and the reasons for it in the rule issued. The Secretary is subject to a similar requirement pursuant to section 1871(e)(1)(A)(ii)

of the Act. Further, under section 1871(e)(1)(A) of the Act, the Secretary is prohibited from applying substantive changes in policy retroactively unless the Secretary determines that retroactive application is necessary to comply with statutory requirements, or that the failure to apply the change retroactively would be contrary to the public interest.

We find that good cause exists to waive the 30-day delay in effective date because it would be contrary to the public interest to delay the effective date of this interim final rule with comment period. We find further that failure to apply the provisions of this interim final rule with comment period retroactively to August 29, 2005, which is the first date on which there was an emergency area and emergency period under section 1135 of the Act resulting from the impact of Hurricane Katrina, would be contrary to the public interest. Due to the infrastructure damage and disruption of operations experienced by medical facilities, and the consequent disruption in residency training, caused by Hurricanes Katrina and Rita in August of 2005, there is urgent need for the regulation changes provided in this interim final rule with comment period to be applied

retroactively. Existing regulations do not adequately address the issues relating to Medicare GME payment policy faced by hospitals that are located in the emergency areas addressed in this rule, or those faced by hospitals that assisted the storm-impacted hospitals with their residency programs. We believe failure to apply the regulatory changes retroactively would be contrary to the public interest because hospitals affected by Hurricanes Katrina and Rita could otherwise face dramatic disruptions in their Medicare GME funding, with possible dire effects on their GME programs and financial stability.

Specifically, the training programs at many teaching hospitals in New Orleans and surrounding areas were temporarily closed or significantly reduced in the aftermath of the hurricanes, and the displaced residents were transferred to other hospitals to continue their training programs in other parts of the country. While some residents may eventually return to the hurricane-affected hospitals, others may need to remain where they were transferred for an extended period of time. Immediate regulatory changes are required in order to maintain Medicare GME funding relating to displaced

residents training at various hospitals outside of the emergency area, and at the same time, to enable the hurricane-affected hospitals to rebuild incrementally their GME programs. Existing regulations relating to closed hospitals and closed residency training programs, and relating to Medicare GME affiliation agreements, contain certain limitations, explained more fully in section II.A above, that render them inapplicable or ineffective to address the issues faced by hospitals as a result of disruptions caused by Hurricanes Katrina and Rita.

We also ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary or contrary to the public interest and incorporates a statement of the finding and supporting reasons in the rule issued. We find that good cause exists to waive the

requirement for publication of a notice of proposed rulemaking and public comment prior to the effective date of this rule because such a procedure would be impracticable and contrary to the public interest. In order to respond to the urgent needs of the hospitals and GME programs affected by Hurricanes Katrina and Rita, as described more fully above, it is necessary for these regulations to take effect retroactively to August 29, 2005. The ordinary notice-and-comment procedures would serve to delay (or, in some cases, preclude) hurricane-affected hospitals and GME programs from responding effectively to their circumstances by availing themselves of the flexibility permitted under this interim final rule effective as of August 29, 2005.

VI. Collection of Information Requirement

[If you choose to comment on issues in this section, please include the caption "COLLECTION OF INFORMATION REQUIREMENT" at the beginning of your comments.]

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of

information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

§413.79 Direct GME payments: Determination of the weighted number of FTE residents.

Section 413.79(f)(6)(ii) states that each hospital in

the emergency Medicare GME affiliated group must submit an emergency Medicare GME agreement in the manner specified in paragraph (iv) and include the following information:

(A) Each participating hospital and its provider number.

(B) Specify the effective period of the emergency Medicare GME affiliation agreement.

(C) List each participating hospital's IME and direct GME FTE caps in effect before the emergency Medicare GME affiliation agreement. If the hospital was already a member of a Medicare GME affiliated group as defined at §413.75(b) before entering into the emergency Medicare GME affiliation agreement, the emergency Medicare GME affiliation agreement must be premised on the FTE caps of the hospital as adjusted per the Medicare GME affiliation agreement.

(D) Specify the total adjustment to each hospital's FTE caps in each year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct

and indirect FTE caps of at least the same amount. The sum total of adjustments to all the participating hospital's FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted caps of the affiliated group.

(E) Attach copies of all existing Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements the hospital is participating in at the time the emergency Medicare GME affiliation agreement is executed.

The burden associated with this requirement is the time and effort it would take for the GME affiliated hospital to develop and submit the emergency Medicare GME affiliation agreement. It is difficult for us to determine estimated annual burden because we do not know how many hospitals will be affected in any given disaster. It would depend on what resources are available to the affected hospitals after sustaining damage from the disaster. This could take a few hours per hospital or much longer depending on if they keep records available and current. Hospitals also have to coordinate with other hospitals to draw up an affiliation agreement which may take more time

if the hospitals have to negotiate.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attn.: Melissa Musotto, CMS-1531-IFC

Room C5-14-03, 7500 Security Boulevard,

Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Carolyn Lovett, CMS Desk Officer, CMS-1531-IFC,

carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

VII. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption "REGULATORY IMPACT ANALYSIS" at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule is not a major rule since we anticipate that the cost to the Medicare program will be \$32.3 million for the 10-month period between August 29, 2005 and June 30, 2006.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit

organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year (for details, see the Small Business Administration's regulation that set forth size standards for health care industries at (65 FR 69432)). We believe that the impact on the affected hospitals will not be significant and will not affect a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. 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 100 beds. This rule is not anticipated to have a significant effect on small rural hospitals since the provisions of this rule will most likely be used by large teaching hospitals that have established residency programs and the capacity to train a larger complement of displaced residents. The

majority of this type of teaching hospital is located in non-rural areas.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule will not have an effect on State, local, or tribal governments in the aggregate and the private sector costs will be less than the \$120 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State or local governments.

B. Anticipated Effects

This interim final rule with comment period modifies the current GME regulations as they apply to Medicare GME affiliated groups to provide for greater flexibility in

training residents in approved residency programs during times of disaster. Specifically, this rule implements provisions for "emergency Medicare GME affiliated groups" to address the needs of teaching hospitals that are forced to find alternate training sites for residents that were displaced by a disaster.

We believe that there are limited effects to modifying the existing Medicare GME affiliations to allow for emergency affiliation agreements. We note that we are not allowing hospitals to count for Medicare IME or direct GME payment purposes additional FTE residents that had not been counted by Medicare before a qualifying emergency. Hospitals participating in emergency Medicare GME affiliated groups are held to their respective FTE resident caps as specified by the emergency affiliation agreement. IME and direct GME payments to the hospitals under this provision will not be based upon any FTE residents in excess of the caps specified under the emergency Medicare GME affiliation agreements. However, Medicare spending may be affected by differences in the per resident amounts, resident to bed ratios, and Medicare utilization rates of host hospitals and home hospitals.

For purposes of comparing the existing closed program or closed hospital provisions to the emergency Medicare GME affiliation provisions, we have calculated a financial impact of the time-limited exception to the 3-year rolling average provision for the 10-month period between August 29, 2005, and June 30, 2006. This impact is premised on the fact that for 10 months, host hospitals would be permitted to count an additional two-thirds of displaced FTE residents, rather than only one-third of the displaced FTEs that they could count if the displaced FTEs would be included in the 3-year rolling average.

In estimating the impact of the 10-month exception, we estimated the cost based on the FY 2006 projected national average per resident amount and the average Medicare utilization rate for direct GME purposes, and the average resident to bed ratio for IME purposes. In addition, we estimate that approximately 293 FTE residents will be affected. Accordingly, we believe that the impact on combined direct GME, operating IME and capital IME payments will be approximately \$32.3 million for the 10-month period between August 29, 2005 and June 30, 2006.

C. Alternatives Considered

We considered amending the closed program regulations, at §413.79(h), to apply to partially closed programs. However, due to the complexity of training programs where residents train at multiple hospitals, there are many potential difficulties that can arise in applying this policy to address disaster situations. Typically, residents in a program spend time training during the year at multiple hospitals, some of which may have been affected by the disaster, while others may not have been affected. Additional complexity can arise through the interaction of the home and host hospital's FTE resident caps. Each one of the home hospitals involved could be training a number of FTE residents above their respective IME and direct GME FTE resident caps. Since the closed program provisions are resident-specific, that is, the host hospital's cap adjustment is tied to the specific resident who was displaced, as specified at §413.79(h), documentation would be required to account for each resident's FTE time spent training at each of the home and host hospitals. Additionally, because the policy under §413.79(h) is "resident-specific", the host hospital would only receive a temporary cap adjustment for as long as the specific

residents are displaced. Therefore, home and host hospitals would need to provide a very detailed accounting of each resident's training as required at §413.79(h). The documentation that would be required if the change in policy was to amend the closed program regulations would prove to be too burdensome for many hospitals.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 412

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney disease, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

**PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT
HOSPITAL SERVICES**

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), Sec. 124 of Pub. L. 106-113, 113 Stat. 1515, and Sec. 405 of Pub. L. of 108-173117, Stat. 2266.

**Subpart G--Special treatment of certain facilities under
the prospective payment system for inpatient operating
costs**

2. Section 412.105 is amended by--
 - A. Republishing the introductory text.
 - B. Revising paragraph (a)(1)(i).
 - C. Republishing paragraph (f) introductory text.
 - D. Revising paragraph (f)(1)(vi).

The revisions read as follows:

§412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

CMS makes an additional payment to hospitals for indirect medical education costs using the following procedures:

(a) * * *

(1) * * *

(i) Except for the special circumstances for Medicare GME affiliated groups, emergency Medicare GME affiliated groups, and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

* * * * *

(f) Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.

* * * * *

(vi) Hospitals that are part of the same Medicare GME affiliated group or emergency Medicare GME affiliated group (as defined in §413.75(b) of this subchapter) may elect to apply the limit as paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in §413.79(f) of this subchapter.

* * * * *

PART 413-- PRINCIPLES OF REASONABLE COST REIMBURSEMENT;

PAYMENT FOR END-STAGE RENAL DISEASE SERVICES:

PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861 (v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh,

1395rr, 1395tt, and 1395ww) Sec 124 of Pub. L. 106-113, 113 Stat. 1515.

Subpart F--Specific categories of costs

4. In §413.75, paragraph (b) introductory text is republished, and the definition for "Emergency Medicare GME affiliated group" is added in alphabetical order to read as follows:

§413.75 Direct GME payments: General requirements.

* * * * *

(b) Definitions. For purposes of this section and §413.76 through §413.83, the following definitions apply:

* * * * *

Emergency Medicare GME affiliated group means at least one home hospital and one or more host hospitals, as those terms are defined below, that meet the requirements at §413.79(f)(6). For purposes of an emergency Medicare GME affiliated group, the following definitions apply:

(1) Home hospital means a hospital that--

(i) is located in section 1135 emergency area;

(ii) had its inpatient bed occupancy decreased by 20 percent or more as the result of a section 1135 emergency period so that it is unable to train the number of

residents it originally intended to train in that academic year; and

(iii) needs to send the displaced residents to train at a host hospital.

(2) Host hospital means a hospital training residents displaced from a home hospital.

(3) Section 1135 emergency area or section 1135 emergency period mean, respectively, a geographic area in which, or a period during which, there exists—

(i) An emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(ii) A public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

* * * * *

5. Section 413.79 is amended as follows:

A. Revising paragraph (f) introductory text.

B. Adding a new paragraph (f)(6).

The revisions and additions read as follows:

§413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(f) Medicare GME affiliated group. A hospital may receive a temporary adjustment to its FTE cap, which, except as provided in paragraph (f)(6)(iv) below, is subject to the averaging rules at §413.79 (d), to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group or an emergency Medicare GME affiliated group (as defined at §413.75(b)). Under this provision--

* * * * *

(6) Emergency Medicare GME affiliated group.

Effective on or after August 29, 2005, home and host hospitals as defined at §413.75(b) may form an emergency Medicare GME affiliated group by meeting the requirements provided in this section. The emergency Medicare GME affiliation agreement may be made effective beginning on or after the first day of a section 1135 emergency period, and terminates no later than at the conclusion of two academic years following the academic year during which the section 1135 emergency period began.

(i) Each hospital in the emergency Medicare GME affiliated group must submit an emergency Medicare GME affiliation agreement that is written, signed, and dated by responsible representatives of each participating hospital in the manner specified in paragraph (ii) and includes the following information:

(A) List each participating hospital and its provider number; and indicate whether each hospital is a home or host hospital.

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of two academic years following the academic year in which the section 1135 emergency period began).

(C) List each participating hospital's IME and direct GME FTE caps in effect before the emergency Medicare GME affiliation agreement (including any adjustments to those caps in effect as a result of other Medicare GME affiliation agreements but not including any slots gained under §413.79(c)(4)).

(D) Specify the total adjustment to each

participating hospital's FTE caps in each academic year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to the host hospital's direct and indirect FTE caps that is offset by a negative adjustment to the home hospital's (or hospitals') direct and indirect FTE caps of at least the same amount. The sum total of adjustments to all the participating hospitals' FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted FTE caps of the hospitals participating in the emergency Medicare GME affiliated group. A home hospital's IME and direct GME FTE cap reductions in an emergency Medicare GME affiliation agreement are limited to the home hospital's IME and direct GME FTE resident caps at §413.79 (c) or §413.79(f) (1) through (f) (5), that is, as adjusted by any and all existing affiliation agreements as applicable.

(E) Attach copies of all existing Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements in which the hospital is participating at the time the emergency Medicare GME affiliation agreement is executed.

(ii) Time for submission of the emergency Medicare GME affiliation agreement. For the year during which the section 1135 emergency was declared, each participating hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to the CMS fiscal intermediary by the later of 180 days after the section 1135 emergency period begins or by June 30 of the academic year in which the emergency Medicare GME affiliation agreement is effective. Emergency Medicare GME affiliation agreements for the subsequent 2 academic years must be submitted by the later of 180 days after the section 1135 emergency period begins or by July 1 of each year.

(iii) Exemption from the Shared Rotational Arrangement Requirement. During the effective period of the emergency Medicare GME affiliation agreement, hospitals in the emergency Medicare GME affiliated group are not required to participate in a shared rotational arrangement as defined at §413.75(b).

(iv) Host Hospital Exception from the Rolling Average for the Period from August 29, 2005 to June 30, 2006. To determine the FTE resident count for a host hospital that is training residents in excess of its cap, a two step

process will be applied. First, subject to the limit at paragraph (f)(6)(i)(D) of this section, a host hospital is to exclude the displaced FTE residents that are counted by a host hospital in excess of the hospital's cap pursuant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, from the current year's FTE resident count before applying the three-year rolling averaging rules under §413.75 (d) to calculate the average FTE resident count. Second, the displaced FTE residents that are counted by the host hospital in excess of the host hospital's cap pursuant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, are added to the hospital's 3-year rolling average FTE resident count to determine the host hospital's FTE resident count for payment purposes.

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(Catalog of Federal Domestic Assistance Program No. 93.778,
Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: _____

Mark B. McClellan,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: _____

Michael O. Leavitt,
Secretary.

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