hospital will incur all or substantially all of the costs of the training program in the nonhospital site.

Comment: One commenter representing a particular medical specialty recommended that CMS use proof of program accreditation as evidence of a written agreement between hospitals and nonhospital settings. The commenter pointed out that written agreements between hospitals and nonhospital sites are required by the specialty's accreditation process. Therefore, the commenter added, time spent in these nonhospital sites is eligible for reimbursement.

Response: Under our existing regulations, the written agreement between a hospital and a nonhospital site must include several specific elements as follows:

- The hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site.
- The hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities.
- The agreement must indicate the compensation the hospital is providing for supervisory teaching activities.

We must be able to verify that the written agreement conforms to these requirements of the regulation. Therefore, the actual written agreement must be used as proof rather than using proof of the program's accreditation as a proxy, because the proof of accreditation may not include all of the required information specified at redesignated § 413.78(d)(2).

Comment: One commenter requested that we place language in the regulations regarding the timing of nonmonetary compensation made available to supervising physicians that train residents in nonhospital settings. The commenter notes that while the preamble to the proposed rule addresses the timeframe for making in-kind compensation available to supervising physicians, the text of the regulations does not.

Response: The purpose of the preamble to a rule is to further explain, and often, to provide practical examples and guidance on the policy laid out in the regulation text. It would be highly impractical to address every specific circumstance to which our policies would apply in the text of our regulations. In this case, we believe the preamble to this final rule is sufficient to convey the policy regarding the timing of in-kind compensation made available to supervising physicians at nonhospital settings.

Comment: Several commenters asked for clarification regarding in-kind compensation for supervisory physicians in nonhospital settings. We proposed that in order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly. The commenters asked that we elaborate on in-kind arrangements and give examples. The commenters also asked for examples of in-kind arrangements between a hospital and a solo physician that is training residents at a nonhospital site.

Response: There are situations where rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is providing compensation through non-monetary, in-kind arrangements. If the hospital is using the written agreement option to show that it will incur all or substantially all of the cost of training residents in the nonhospital setting(s), our regulations require that the written agreement describe the arrangements that are involved. For example, the hospital may provide continuing education and other professional and educational support for supervising physicians in the nonhospital site in lieu of financial support. Another example of in-kind compensation is office space provided by the hospital to the supervising physician. The value of this space may be substituted for monetary compensation for teaching activities. This type of support must be described in the written agreement in lieu of a monetary amount for the hospital. If the hospital is opting to pay all or substantially all of the cost of training in the nonhospital setting(s) concurrently with the training that occurs during the cost reporting period, we had proposed that the in-kind arrangements must be provided or made available to the teaching physician at least quarterly, to the extent that there are residents training in a nonhospital setting(s) in a quarter. However, in order to make the policy regarding monetary and in-kind compensation consistent, we are requiring in the final rule that in-kind compensation be provided or made available by the end of the third month following the month in which the training occurs.

We note further that, in the case of a solo practitioner, compensation at the practice is based solely and directly on the number of patients that the solo practitioner treats and for which the solo practitioner bills. Section 1886(h)(4)(E) of the Act requires that hospitals pay all or substantially all of the cost of training at the nonhospital site in order to count the FTE residents at that site. In this instance, we recognize that there are no costs associated with the supervisory teaching physician's time because the physician is not receiving compensation in any form or from any source while conducting teaching activities. Under these circumstances, we acknowledge that no direct or in-kind payment needs to be made to the supervising physician in order for the hospital to incur all or substantially all of the costs of the training program in the nonhospital setting, and to count the FTE residents' training time in the nonhospital setting.

Out of scope comments relating to GME:

Comment: Several comments addressed miscellaneous IME and direct GME issues, including accreditation of dental programs, community education programs, community support, per resident amounts, the general application of affiliated groups, and redistribution of costs.

Response: We did not make any proposals relating to these issues in the May 18, 2004 proposed rule. Therefore, we decline to respond to these comments in this final rule. However, we will consider them for purposes of future rulemaking.

P. Rural Community Hospital Demonstration Program

Section 410A(a) of Public Law 108–173 requires the Secretary to establish a demonstration to test the feasibility and advisability of establishing ''rural community hospitals'' for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or treated as being so located under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH.

Sections 410A(a)(2) and (4) of Public Law 108–173 specify that the Secretary is to select for participation not more than 15 rural community hospitals in rural areas of States that the Secretary identifies as having low population densities. As we indicated in the May 18, 2004 IPPS proposed rule (69 FR 28317) and corrected in the June 25, 2004 correction notice (69 FR 39521),

using 2002 data from the U.S. Census Bureau, we identified 10 States with the lowest population density in which rural community hospitals must be located to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau Statistical Abstract of the United States: 2003)

Under the demonstration, participating hospitals will be paid the reasonable costs of providing covered inpatient hospital services (other than services furnished by a psychiatric or rehabilitation unit of a hospital that is a distinct part), applicable for discharges occurring in the first cost reporting period beginning on or after implementation of the demonstration program. For discharges occurring in subsequent cost reporting periods, payment is the lesser of reasonable cost or a target amount, which is the prior year's cost or, after the second cost reporting period, the prior year's target amount, adjusted by the inpatient prospective payment update factor. Covered inpatient hospital services means inpatient hospital services (defined in section 1861(b) of the Act) and includes extended care services furnished under an agreement under section 1883 of the Act.

Sections 410A(a)(5) and (a)(6) require the demonstration to be implemented not later than January 1, 2005, but not before October 1, 2004. The demonstration is to operate for 5 years. The payment change for a participating hospital under this demonstration will be implemented with the hospital's first cost reporting period beginning on or after October 1, 2004.

Section 410A of Public Law 108–173 requires that ''in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.'' Generally, when CMS implements a demonstration on a budget neutral basis, the demonstration is budget neutral in its own terms; in other words, aggregate payments to the participating providers do not exceed the amount that would be paid to those same providers in the absence of the demonstration. This form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration participants. These reduced expenditures offset increased payments elsewhere under the demonstration, thus ensuring that the demonstration as a whole is budget neutral or yields savings. However, the small scale of this demonstration, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration could be viable under the usual form of budget neutrality. Specifically, cost-based payments to 15 small rural hospitals is likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these providers.

In order to achieve budget neutrality, as we proposed, we are adjusting national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. This is because the statutory language refers merely to ensuring that ''aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented,'' and does not identify the range across which aggregate payments must be held equal. In the May 18, 2004 proposed rule, we invited public comment on this proposal. We discuss the payment rate adjustment that would be required to ensure the budget neutrality of this demonstration in the Addendum of this final rule.

Comment: One commenter requested that the demonstration be opened to a larger number of States. The commenter stated that arbitrarily designating a number of States does not serve Medicare beneficiaries and is contrary to the intent of legislation that was proposed prior to the enactment of Public Law 108–173.

Response: Because Public Law 108–173 allows no more than 15 demonstration sites, we targeted the program in the States with the lowest population densities, consistent with the legislative language. We recognize that there are many hospitals serving people in sparsely populated rural areas in other States. Given the limitations imposed by Public Law 108–173, unfortunately we are unable to include many hospitals in additional States that could benefit from this provision. We have selected the demonstration areas to conform to the requirements of the law and to allow a reasonable process for determining the eligibility of applicants, given the legislative language of the statute.

Comment: One commenter stated that CMS has historically implemented demonstration projects on a budget neutral basis within the context of the given demonstration. The commenter opposed our proposal to fund the Rural Community Hospital Demonstration Program by reducing the payment rate to all hospitals paid on the basis of DRGs, and indicated that requiring nonparticipating hospitals to fund hospitals participating in a demonstration project is a bad policy precedent.

Response: The Rural Community Hospital Demonstration Program is mandated by section 410A of Public Law 108–173. It is aimed at testing the feasibility and advisability of reimbursement based on reasonable cost for covered inpatient services for rural hospitals as defined by the legislation. The commenter is correct in stating that CMS usually implements demonstrations in which savings occurring among participants guarantee budget neutrality. However, we believe that the statutory authority allows us to define budget neutrality across the payment system. In short, we believe that the method that we proposed to ensure budget neutrality, which is mandated by law, is permissible under the statute.

To participate in this demonstration, a hospital must be located in one of the identified States and meet the criteria for a rural community hospital. Eligible hospitals that desire to participate in the demonstration must submit an application to CMS. Information about the demonstration and details on how to apply can be found on the CMS Web site: *http://www.cms.hhs.gov/researchers/demos/rch.asp.*

The data collection instrument for the demonstration has been approved by OMB under the title ''Medicare Waiver Demonstration Application,'' under OMB approval number 0938–0880, with a current expiration date of July 30, 2006.

Q. Special Circumstances of Hospitals Facing High Malpractice Insurance Rate Increases

In the May 18, 2004 proposed rule (69 FR 28318), we indicated that we had received comments from several hospitals about the effects of rapidly