

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 405, 412, 422, 489****[CMS-4105-F]****RIN 0938-AO41****Medicare Program; Notification of Hospital Discharge Appeal Rights****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule sets forth requirements for how hospitals must notify Medicare beneficiaries who are hospital inpatients about their hospital discharge rights. Notice is required both for original Medicare beneficiaries and for beneficiaries enrolled in Medicare Advantage (MA) plans and other Medicare health plans subject to the MA regulations. (For purposes of this preamble, these entities will collectively be known as "Medicare health plans"). Hospitals will use a revised version of the Important Message from Medicare (IM), an existing statutorily required notice, to explain the discharge rights. Hospitals must issue the IM within 2 days of admission, and must obtain the signature of the beneficiary or his or her representative. Hospitals will also deliver a copy of the signed notice prior to discharge, but not more than 2 days before the discharge. For beneficiaries who request an appeal, the hospital will deliver a more detailed notice.

EFFECTIVE DATE: These regulations are effective on July 1, 2007.

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SUPPLEMENTARY INFORMATION:**I. Background**

In recent years, we have published several rules regarding hospital discharge notice policy, as well as rules regarding required notices in other provider settings when Medicare services are terminated. (See our proposed rule published April 5, 2006 in the **Federal Register** (71 FR 17052) for a description of these rules.) In accordance with section 1866 of the Social Security Act (the Act), hospitals currently must deliver, at or about the time of admission, the "Important Message from Medicare" (IM) to all hospital inpatients with Medicare to explain their rights as a hospital patient,

including their appeal rights at discharge. In addition, a hospital must provide a Hospital-Issued Notice of Noncoverage (HINN) to any beneficiary in original Medicare that expresses dissatisfaction with an impending hospital discharge. Similarly, Medicare health plans are required to provide enrollees with a notice of noncoverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), when an enrollee disagrees with the discharge decision (or when the individual is not being discharged, but the Medicare health plan no longer intends to cover the inpatient stay). See section III of this preamble for more information about the HINN and NODMAR, under "Existing Notices."

On April 5, 2006, CMS published a proposed rule in the **Federal Register** (71 FR 17052) proposing revised discharge notice requirements for hospital inpatients who have Medicare. The provisions of that proposed rule, the related public comments and our responses, and the final regulations in this regard are set forth below.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule responds to comments on the April 5, 2006 proposed rule. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress's intent to ensure timely publication of final regulations.

II. Provisions of the Proposed Regulations

As noted above, on April 5, 2006, we published a proposed rule regarding hospital discharge notice requirements under both the original Medicare and the Medicare Advantage program. The proposed rule set forth a two-step notice process for hospital discharges similar to the process in effect for Medicare

service terminations in home health agencies (HHAs), skilled nursing facilities (SNFs), swing beds, comprehensive outpatient rehabilitation facilities (CORFs), and hospices. In general, we proposed to require hospitals to deliver, prior to discharge, a standardized, largely generic notice of non-coverage to each Medicare beneficiary whose physician concurs with the discharge decision. Hospitals or Medicare health plans, as applicable, would also deliver a more detailed discharge notice to beneficiaries who exercised their right to appeal the discharge. The specific details of the proposal are set forth below.

Proposed § 405.1205

We proposed to add a new § 405.1205, to require hospitals to deliver a standardized, largely generic discharge notice to original Medicare beneficiaries.

We proposed in § 405.1205 that hospitals would be required to deliver a standardized notice of non-coverage to beneficiaries on the day before the planned discharge from an inpatient hospital stay. The notice would include: (1) The date that coverage of inpatient hospital services ends; (2) the beneficiary's right to request an expedited determination including a description of the expedited determination process as specified in § 405.1206, and the availability of other appeal procedures if the beneficiary fails to meet the deadline for an expedited determination; (3) the beneficiary's right to receive more information as provided in § 405.1206(e); (4) the date that financial liability for continued services begins; and (5) any other information required by CMS.

Proposed § 405.1206

We proposed to replace existing § 405.1206 with a new provision similar to the notice requirement associated with the expedited review process for home health, hospice, skilled nursing, swing bed, and CORF settings set forth in § 405.1202. Proposed section 405.1206 set forth the responsibilities of the hospitals, Quality Improvement Organizations (QIOs), and beneficiaries relative to the expedited determination process. Most notably, we proposed in § 405.1206 that hospitals would be required to deliver a detailed notice to beneficiaries if beneficiaries exercise their right to request an expedited determination. The hospital would be required to deliver the detailed notice by the close of business of the day of the QIO's notification of the beneficiary's request for an expedited determination.

The detailed notice would include: (1) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered; (2) a description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy; (3) facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and (4) any other information required by CMS.

Proposed § 422.620 and § 422.622

In these two sections, we proposed to replace the existing NODMAR notice and review regulations for Medicare health plan enrollees with notice requirements that largely parallel those proposed for beneficiaries in original Medicare. That is, proposed § 422.620 would require the hospitals to deliver the standardized, largely generic notice to all enrollees who are hospital inpatients, on the day before a planned discharge. The content of the notice would be essentially the same as under original Medicare. Similarly, § 422.622 would require the Medicare health plan to deliver a detailed notice to those enrollees who request an immediate QIO review of the discharge decision. Again, the timing and content requirements paralleled those in proposed § 405.1206.

Section 422.622 also specified the procedural responsibilities of Medicare health plans, hospitals, and QIOs as well as any possible liability for hospitals and Medicare health plans during the immediate QIO review process.

Conforming Changes Proposed to § 489.27 and § 412.42

Finally, we proposed to make conforming changes to two related existing regulatory provisions. First, we proposed to amend the provider agreement requirements in § 489.27(b) to cross-reference the proposed notice requirements. Thus, proposed § 489.27(b) would specify that delivery of the hospital discharge notices consistent with proposed § 405.1205 and § 422.620 is required as part of the Medicare provider agreement. The other conforming change would affect § 412.42(c), which involves limitations on charges to beneficiaries in hospitals operating under the prospective payment system.

As revised, proposed § 412.42(c)(3) would simply include a cross-reference

to the notice and appeal provisions set forth in § 405.1205 and § 405.1206. This change would clearly establish that the provision of the appropriate expedited review notices would be one of the prerequisites before a hospital could charge a beneficiary for continued hospital services.

III. Analysis of and Responses to Public Comments

We received approximately 500 public comments on the proposed rule from healthcare professionals and professional associations, hospitals, State and national hospital associations, beneficiary advocacy groups, and managed care organizations.

Comments centered on the details of the proposed notice procedures and the relationship between those procedures and the current hospital discharge and notification processes, including the IM. In general, healthcare professionals, hospitals, and hospital associations strongly opposed the proposed notification process. Patient advocacy groups generally supported the rule as proposed. Managed care organizations also opposed the notice process and pointed out MA-specific issues with the rule. Summaries of the public comments received on the proposed provisions and our responses to those comments are set forth below.

The Proposed Notice Process

Comment: The overwhelming majority of commenters strongly opposed the hospital discharge notification procedures set forth in the April 5, 2006 proposed rule. Only a few commenters supported the process.

Those commenters supporting the proposed process stated that it would provide Medicare beneficiaries with a timely notice of the right to challenge a discharge decision that may be premature and harmful to that beneficiary's health. They believe that the proposed changes would serve as a check against existing financial incentives for hospitals and health plans to discharge beneficiaries too early. These commenters supported the proposed requirement that the generic notice be delivered on the day before discharge, stating that it gives beneficiaries the information they need to initiate an appeal at the time they need it, and allows beneficiaries enough time to consider their right to appeal and obtain the help of representatives, if needed. Several of these commenters suggested the generic notice be given 2 days in advance of discharge or even earlier when possible.

As noted, however, the vast majority of commenters opposed the proposed

process. These commenters focused their objections on two key issues—the overall need for the new notice and the timing of its delivery.

Need for Notice Process

Many commenters noted that, because hospitals are already required to deliver the Important Message from Medicare (IM) to all Medicare inpatients, the proposal actually constituted a 3-step notice process that adds unnecessary burden to hospitals and managed care plans. Many commenters stated that the current notice process—delivery of the IM at or near admission, and a Hospital Issued Notice of Noncoverage (HINN) if the beneficiary disputes the discharge decision—adequately informs beneficiaries of their appeal rights. They saw no compelling reason to warrant the implementation of the proposed notice process. Other commenters noted that there are problems with the current notice delivery process that CMS should address before deciding to add another notice. These commenters agreed with many others that CMS should strengthen the current notice delivery process, rather than adding an additional notice at discharge. Specifically, some commenters stated that the IM is often handed to the beneficiary at admission without any explanation, along with many other papers. Thus, more often than not, the IM ends up unread. Additionally, several commenters noted that the current process is not enforced by CMS and recommended that CMS sanction hospitals that are not complying with notice delivery requirements.

Many commenters made recommendations for improving the current notice delivery process including revising the IM to be a more complete notice of discharge appeal rights (similar to the proposed generic notice), or replacing the IM with the proposed generic notice and providing it at or near admission. Several commenters suggested we allow the generic notice to be given at admission or during the course of the hospital stay, and some commenters recommended that the hospital review the information with the beneficiary and that the beneficiary sign the notice.

Timing of the Generic Notice

Commenters also strongly objected to the requirement that hospitals provide the proposed generic notice on the day before discharge, as proposed in § 405.1205 and § 422.620. They indicated that, given the rapidly changing conditions of most hospital patients, it is often difficult or impossible to predict the exact date of

discharge a day in advance.

Commenters pointed out that physicians often make discharge decisions and write the discharge order on the day of discharge. Several commenters stated that they cannot assume physician concurrence until the discharge order is written.

Many commenters pointed out that although hospitals begin the discharge planning process at admission, hospital staff, physicians (and health plans, if applicable) must wait for the results of blood work and other diagnostic tests and are constantly monitoring patients for signs of clinical progress before the discharge decision can be made.

Commenters offered many clinical examples in support of this contention, including the following: Surgical patients' diets are gradually progressed from liquids to solids based on their tolerance, which varies from patient to patient; patients on oxygen therapy must be evaluated frequently to determine if it is appropriate to wean and later to determine if home oxygen is appropriate; patients receiving medications such as narcotics or steroids must be weaned from these medications and observed for complications, and patients cannot be expected to respond in a predictable manner.

In addition, many commenters pointed out that giving a notice on the day before discharge to a beneficiary experiencing a short stay (1 or 2 day stay) would in practice necessitate that the discharge notice be given at admission, when the course of treatment may not be known. Others stated that many of these beneficiaries also are waiting for test results and the discharge decision will depend on the results of those tests.

Other commenters stated that predicting the discharge date a day or more in advance would be particularly difficult for beneficiaries with complicated cases, since many of these beneficiaries are under the care of more than one physician while in the hospital, requiring coordination among specialists regarding the discharge decision.

For beneficiaries who need to be placed in facilities such as a SNF or psychiatric facility, discharge will depend on that facility's acceptance of the beneficiary, and the hospital may not know about placement 24 hours in advance in order to give a notice. In addition, commenters noted that it is not unusual for a physician to discharge a patient earlier than anticipated because of that individual's progress, making notice delivery on the day before discharge impossible.

Commenters also stated that it often takes time to reach the representative of a beneficiary who is incompetent or unable to make informed decisions. Some commenters said representatives are often more available near the time of admission than on the day before discharge.

Response: We have carefully considered the numerous comments regarding the extent to which a new notice is needed and the timing of such a notice. We recognize that the proposed generic notice clearly contains nearly the same information as IM, which is already delivered at or near admission as required by Section 1866(a)(1)(M) of the Social Security Act (the Act). Moreover, we fully appreciate, as many commenters pointed out, the difficulties inherent in predicting the precise date of discharge in advance in the hospital setting. At the same time, we are committed to ensuring that all Medicare beneficiaries are made aware of their hospital discharge rights in an effective manner.

As the comments made clear, a hospital's frequent inability to predict a discharge in advance in acute care settings constitutes the fundamental obstacle to the 24-hour advance notice proposal. This problem is particularly pronounced for patients with complicated medical concerns, those under the care of more than one physician, and those requiring subsequent placement in other facilities. Clearly, discharge decisions are normally made by physicians, and physicians generally depend on test results, other outcome-related indicators, and observations gained from patient rounds in making these decisions. Many of these indicators may not become evident or available sufficiently early to permit 24-hour advance notice on a routine basis.

Thus, we considered other alternatives to the proposed "24-hour notice" requirement that could still ensure that beneficiaries are made aware of their discharge appeals rights in time to exercise them, without adversely affecting the hospital discharge process or the availability of hospital beds. This is consistent with our commitment in the proposed rule to consider comments on all aspects of hospital notice procedures. One option that we considered carefully was to establish the 24-hour advance notice requirement as a general rule, but allow for exceptions when this requirement was impractical, such as the situations described above where a beneficiary's discharge date could not reliably be predicted in advance. We concluded, however, that such a standard would be highly

subjective and difficult to administer, given the variety of reasons why a discharge decision could be made on the day of discharge, while still potentially leaving a large proportion of hospital patients unaware of their discharge rights until they would have little or no time to exercise them.

Moreover, we also had to take into account the high percentage of short stays in the hospital setting. (The most recent available CMS data—2003 data from the 2005 CMS Statistical Supplement—regarding acute inpatient hospital admissions show that over 43 percent of hospitals stays are 3 days or less in duration, and nearly 30 percent are 2 days or less.) In those situations, given the statutory requirement that hospitals deliver an IM to each patient at or about the time of admission, requiring a generic discharge notice as well would be of questionable value because they would be given at about the same time. As many commenters pointed out, the proposed generic notice contains much of the same information as the IM. Thus, requiring hospitals to deliver both notices at roughly the same time would place an administrative burden on hospitals without any apparent benefit to patients.

Based on all these considerations, we decided not to adopt an exception-based standard. Instead, we considered additional alternatives for meeting our goal of designing hospital notice procedures that balance a beneficiary's need to be informed about his or her appeal rights in an appropriate manner and at an appropriate time, and take into account the statutory requirements associated with the IM, but do not impose impractical requirements on hospitals, or interfere with appropriate discharge decision-making practices. As many commenters recommended, we concluded that the most viable approach would be to build on the existing requirement that hospitals deliver the IM to all beneficiaries, which already takes into account hospital discharge processes. Accordingly, under § 405.1205(b)(§ 422.620(b) for MA enrollees), this final rule establishes a revised version of the IM as the advance written notice of hospital discharge rights.

As revised, the IM will contain virtually all of the elements that would have been included in the proposed standardized generic notice, with the exception of the discharge date. Thus, the revised IM will continue to meet the requirements of section 1866(a)(1)(M) of the Act, including a statement of patients' rights, information about when a beneficiary will and will not be liable for charges for a continued stay in a

hospital, as well as a more detailed description of the QIO appeal rights that corresponds to the content of the proposed generic notice. We have revised requirements for notice content at § 405.1205(b) and § 422.620(b) to reflect these changes. Proposed § 489.27 has also been revised accordingly. However, similar to the generic notice, the revised IM must be signed by the beneficiary (or representative, if applicable) to indicate that he or she has received the notice and comprehends its contents. The hospital must provide the original, signed notice to the beneficiary and retain a copy of the signed notice. As with the proposed generic notice, we anticipate that the revised IM will also include language stressing the importance of discussing discharge planning issues with physicians, plans, or hospital personnel to try to minimize the potential for disputes. The precise language of the revised IM will be subjected to public review and comment through the Office of Management and Budget's Paperwork Reduction Act process.

Sections 405.1205(b) and 422.620(b) also establish the time frames for notice delivery. Specifically, hospitals must deliver the advance written notice at or near admission, but no later than 2 calendar days after the beneficiary's admission to the hospital. We believe that requiring this revised IM be delivered and signed at or near the time of admission gives the hospital flexibility in developing processes to deliver the notice in a timely manner and makes the IM a more meaningful notice for beneficiaries and representatives, allowing them ample time to consider acting on those rights.

At the same though, we continue to believe that it is important for beneficiaries to receive information about their discharge rights at or near the time of discharge when they may need to act on this information. Therefore, § 405.1205(c), and § 422.620(c) for Medicare health plan enrollees also requires that hospitals deliver a copy of the signed IM to each beneficiary before discharge. The notice should be given as far in advance of discharge as possible, although not more than 2 calendar days before the day of discharge. This time frame would be consistent with the suggestions of several commenters who advocated for delivery of discharge rights notices 2 days before discharge.

This follow-up notice would serve as a reminder of the earlier notification about the beneficiary's discharge rights. It would not be required if the initial delivery and signing of the IM took place within 2 days of discharge. This

means that hospitals will have some flexibility to tailor their notice delivery practices to meet their own needs, with the possibility of eliminating the need to deliver a copy of the notice for stays of up to 5 days. (We note that the average hospital length of stay in an acute care setting for a Medicare beneficiary is approximately 5 days and, again, large numbers of beneficiaries experience stays ranging from overnight to 2 or 3 day stays.) Although the follow-up notice often would not be needed in short-stay situations, it would serve as an important reminder of beneficiary rights in longer stay cases. Thus, all individuals will receive the original notice at or near admission, in addition to receiving a copy of the signed notice if the original notice is delivered more than 2 days before discharge.

Section 405.1206(b)(1) and § 422.622(b)(1), will allow beneficiaries to request an expedited determination at any time up through the day of discharge, either in writing or by telephone. However, we believe that the better alternative will be for beneficiaries to be aware of their rights as early as possible and then communicate with their physicians, plans and appropriate hospital staff to reach a consensus on their appropriate discharge date.

Given that there is no longer a noon deadline for a beneficiary to request an expedited QIO determination, we recognize that such requests could be made near or after the close of the business day. Thus, we have revised the appropriate sections to specify that the subsequent deadline for the hospital or plan to provide beneficiaries with detailed notices as soon as possible but no later than noon of the day after the QIO notifies the hospital or plan that the beneficiary has requested QIO review. We have also specified that the hospital or plan must submit necessary information to the QIO as soon as possible, but no later than noon of the day after the QIO notifies the hospital or plan of the request. We note that a beneficiary's liability protection would continue throughout this process.

In summary, we believe that the revised notification process being set forth in this final rule will offer several advantages over the proposed approach, while still containing many similar elements and achieving the same goals. The process is consistent with the existing IM requirements—while also establishing much greater hospital accountability (and enforceability) for delivering the IM—promotes beneficiary understanding of their discharge rights, and gives hospitals appropriate discretion in notice delivery practices

and, more importantly, in discharge decision-making, rather than letting notice delivery rules dictate when patients are discharged.

Consequences of the 24-Hour Notice Requirement

Many commenters believed that if hospitals were not able to deliver the generic notice on the day before discharge, that patients would be entitled to stay an additional day in order to meet the 24-hour requirement. We received many comments regarding what commenters believed would be the consequences of this additional day.

Comment: Many commenters addressed the perceived consequences of their belief that, in most cases, hospitals would not be able to give the notice until the actual day of discharge. In general, commenters indicated that beneficiaries would then be entitled to stay another day in order to decide if they want to appeal. Commenters contended that delaying discharge an additional day to allow hospitals to satisfy the notice requirement conflicted with the discharge planning process set forth at section 1861(ee)(2) of the Act, which directs the Secretary to develop guidelines to ensure a smooth and timely discharge to the most appropriate setting. Several commenters pointed to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements at LD.3.15 that require hospital leadership to mitigate impediments to efficient patient flow throughout the hospital. Other commenters stated that the Hospital Conditions of Participation (COP) for patients' rights at § 482.13 already makes clear that a patient has the right to make informed decisions, and has the right to a process for submitting grievances, including concerns about quality of care and premature discharge.

Many commenters feared that the proposed process and the possibility of an additional day would severely impact the hospital's bed capacity, ability to move patients within and outside of the hospital, and costs. Many commenters believed that this requirement would cause unnecessary delays in a patient's discharge or transfer to a more appropriate level of care.

Several commenters gave the example of the Medicare beneficiary who has secured a bed in another facility such as a skilled nursing facility (SNF). If the hospital were not able to provide the generic notice until the day of discharge, and Medicare beneficiaries were able to stay an additional day to ensure they received the notice at least 24 hours in advance of discharge,

commenters said, this beneficiary would risk losing that bed and finding another bed could take several more days. Commenters believed that hospitals would then be required to provide additional notices to this beneficiary and work within new timeframes.

Response: We agree with the commenters that to the extent that hospitals are not able to deliver the generic notice until the day beneficiaries are ready to be discharged, the proposed 24-hour notice requirement could potentially affect the hospital's compliance with the requirement for a smooth and timely discharge to a more appropriate setting. As noted above, we find persuasive comments regarding the fluidity of the discharge process. Thus, as explained in detail above, we have modified the proposed notification procedures to attempt to mitigate the potential for disruption of the discharge planning process.

Existing Notices

Comment: Hospitals asked whether the existing HINN and NODMAR would continue to be necessary.

Response: Currently, hospitals or plans issue a HINN or NODMAR at discharge only when the patient disagrees with the discharge decision. In this context, the HINN and NODMAR are used to tell a patient why a hospital or plan believes their stay will no longer be covered, to provide information about the QIO review process, and to describe the patient's potential liability. Under the process set forth in this final rule, ALL individuals will be provided with information upon admission about the QIO review process and associated liability, and individuals who disagree with the discharge decision will receive detailed information about why the hospital or plan believes their stay will no longer be covered. Thus, with this new process, the HINN and NODMAR will no longer be used to notify patients of their right to a QIO review of a stay. In the vast majority of cases, a beneficiary will agree to the discharge decision. In almost all other cases, beneficiaries who disagree with the discharge decision will initiate a QIO review, so that their stay can continue without liability until the QIO confirms the discharge decision or determines that the stay should continue. Only in the extremely rare instance where patients decide to remain in the hospital past the ordered discharge date and do not choose to initiate a review would they be notified of liability via a traditional liability notice akin to the existing HINN. (Note that the term "HINN" actually refers to several

different notices, used under various circumstances, to inform patients under original Medicare that all or part of a hospital stay may not be covered by Medicare. For example, a HINN is also used in pre-admission situations. This final rule addresses only HINNs now used at the end of a hospital stay when a patient disputes a discharge decision. Under these circumstances, the HINN is no longer needed.) The NODMAR will be discontinued.

Aligning Hospital Discharge Notice Processes With Those of Other Settings

We received multiple comments on our proposal to align hospital discharge notice processes with those used in other settings such as HHAs, SNFs, and CORFs.

Comment: Many commenters indicated that it was unrealistic and of little value to achieve consistency between hospital discharge notice processes and those of other providers such as SNFs and HHAs. Commenters stated that hospitals are fundamentally different from these non-hospital settings because of hospitals' focus on the provision of acute medical care. The commenters stated that hospital lengths of stay are generally shorter, the conditions of acutely ill patients are more unpredictable, there is a greater volume of discharges per day, and they contended that discharge decisions are generally made on the day of discharge often based on the availability of diagnostic tests results. Conversely, commenters stated that SNFs and other settings have more predictable patient outcomes and longer lengths of stay that allow advance notice of discharge under most circumstances. Moreover, they pointed out that in the non-hospital setting, beneficiaries could be liable for additional days if they request a review; conversely, in the hospital setting, beneficiaries may stay without additional liability while the QIO's decision is pending. Finally, unlike hospitals, other providers are not required to provide the IM that already includes an explanation of the discharge appeal rights. Thus, they urged that CMS reconsider its proposed hospital notice approach.

A few commenters did support aligning the provider notice procedures. These commenters believe that uniformity among appeals notice process in all settings would increase public understanding and utilization of the QIO appeal process. The commenters noted that protections against premature discharge are even more necessary in the hospital setting than in other settings because of the vulnerability and acute care needs of

hospital patients. Further, they argued, inpatient hospital providers are at least as capable of complying with these requirements, as are SNFs and other outpatient providers.

Response: We agree that there are notable differences between the hospital setting and the other provider settings where an expedited determination notice process is in effect. As commenters pointed out, the critical differences for purposes of this rule are the presence of the IM in the hospital setting, the shorter and less predictable lengths of stay, and the statutory liability protections afforded to hospital inpatients in accordance with section 1869(c)(3)(C)(iii)(III) of the Act. We found the comments on these issues to be especially persuasive. Thus, in developing this final rule, we have attempted to set forth a process that better takes into account the unique circumstances of the hospital setting.

Discharge Planning Process

Many commenters stated that the hospital notice requirements needed to take into consideration the discharge planning requirements in the Conditions of Participation (COPs).

Comment: A number of commenters stated that the existing discharge planning process carried out by hospitals already informs beneficiaries of discharge plans and facilitates smooth transitions to post-hospital settings. The commenters stated that the discharge planning COP at § 482.43 addresses the development of a discharge plan and requires that the patient and representative be involved in the discharge planning process. Commenters also stated that discharge decisions are made by physicians, not hospitals.

Commenters noted that discharge planners are very effective at developing individualized discharge plans, making arrangements for post-hospital care, and preparing patients and caregivers for discharge. Commenters also pointed out that because discharge planners are involved in arranging patients' post-hospital care, they are able to identify patients early on who will have special needs at discharge and work with them (or their representatives) to address their issues. Thus, many commenters questioned the need for written discharge notices, given the extensive discharge planning process already required in hospitals. Alternatively, several commenters suggested that we add language to the notice that informs beneficiaries of the discharge planning process.

Response: We recognize the important work of hospital discharge planners in

the development of individualized discharge plans and preparing patients for post-hospital care, and we agree that any process to notify beneficiaries of their appeal rights must be consistent with the discharge planning process required by section 1861(ee)(2) of the Act and the COPs at § 482.43. However, we note that while hospitals must have in effect discharge planning procedures that apply to all patients, discharge planning generally focuses on identifying individuals who are likely to have special or ongoing needs following discharge. Obviously, not all hospital inpatients will require post-hospital care, therefore some patients will have very limited involvement with the discharge planning process. Thus, we are not convinced that it is appropriate to rely on the discharge planning process as the mechanism for ensuring all patients receive timely notification of discharge rights under the Medicare program. Instead, we believe that the Medicare discharge notice should be able to stand alone, or complement discharge planning.

To reflect the importance of discharge planning, we intend to incorporate language into the revised IM about planning for discharge and encouraging beneficiaries to talk to their physician or other hospital staff if they have a concern about being discharged. If beneficiaries are still not satisfied with their discharge decision, they can request a QIO review.

Liability

Many commenters were concerned about the prospect of hospitals being financially liable for additional patient care days during the QIO process.

Comment: Many commenters asked that CMS clarify who would be liable for the extended days during the appeal. They stated that because the beneficiary will have no liability, Medicare should pay the hospital for the additional days or the additional days should be incorporated into the DRG payment. A few commenters stated that the liability protections set forth in section 1879(a)(2) of the Act should relieve the hospital of any liability because the hospital would not have known that payment would not be made for hospital services beyond the planned day of discharge.

Response: This rule has no effect on existing policy with respect to liability during a QIO review. All operating costs incurred during the beneficiary's inpatient stay are considered part of the overall DRG payments.

Impact on Number of Appeals

Many commenters believe that this notification process would increase in the number of appeals to the QIO.

Comment: Many commenters believe that once beneficiaries become aware of their right to a review without liability, there will be a large increase in the number of beneficiaries appealing and staying additional days during the review. Many commenters stated these extra days could seriously affect hospital processes, have a significant effect on hospital costs. Longer lengths of stay, they contended, would hinder the hospital's ability to move patients through the system, seriously affecting bed capacity. Hospitals would not be able to accept new admissions, would experience backups in already crowded emergency rooms, and would not be able to move patients out of post-anesthesia care units or intensive care units. Most importantly, commenters said, the longer Medicare beneficiaries remain in the hospital, the greater their risk of hospital-acquired infections, falls and other negative outcomes.

Several commenters said CMS should assess whether the 1 to 2 percent estimate of the number of beneficiaries who currently request QIO reviews in the nursing home or home health settings would hold up in the hospital setting where liability is not an issue for beneficiaries while their appeal to the QIO is pending.

Response: The right to a QIO review without beneficiary liability is a longstanding statutory feature of the Medicare inpatient hospital prospective payment system. To the extent that commenters are correct that beneficiaries are not aware of the existing QIO review right, there could be an increased use of the process under the new notice rules. However, we view this contention as evidence of the need for a more effective notice process, as opposed to an argument against notification.

At the same time, however, we have historically believed, based on the limited evidence available, that hospital beneficiaries who are notified of their discharge rights are not significantly more likely to exercise them. For example, as discussed in previous rulemaking, the proportion of Medicare health plan enrollees that disputed their discharge historically has been no higher than that of original Medicare beneficiaries, despite the more stringent notice requirements under the Medicare + Choice program (68 FR 16664). Moreover, several commenters noted, and we agree that the vast majority of inpatients welcome their discharge.

Therefore, we believe that the revised notice process will not increase the number of requests for a QIO review nor have a significant impact on hospital bed capacity, patient access, or hospital revenue.

Impact on Beneficiaries

Many commenters were concerned about the impact of the proposed notice process on beneficiaries, and the possibility that some beneficiaries would use the process to game the system. Some commenters offered suggestions on how to better educate beneficiaries about their rights.

Comment: Many commenters were concerned that the notices in the proposed process would confuse beneficiaries and increase their anxiety level during an already stressful time. Many commenters stated that beneficiaries are under an inordinate amount of stress during a hospital stay and that issuing a notice regarding potential financial liability would only serve to alarm them. Several other commenters stated that the notices as written would be difficult for many frail elderly Medicare beneficiaries to understand. Other commenters stated that beneficiaries are already overwhelmed by the number of notices they receive and that an additional notice would exacerbate the problem. Still other commenters stated that many beneficiaries these days are cautious about signing forms.

Conversely, some commenters felt that Medicare beneficiaries generally are not aware of their right to appeal a discharge and that the current process for communicating the information to them is not effective.

Response: We believe that it is important for Medicare beneficiaries to understand their discharge appeal rights and be able to act on them. Moreover, based on the often conflicting comments received on the proposed rule, we believe that not all beneficiaries are made aware of these rights uniformly under the current process. We recognize that liability issues in particular can be difficult for beneficiaries to understand, and we intend to make sure the revised IM is as clear as possible in this regard. We also intend to consumer test the notices prior to requesting OMB approval. Finally, it is important to keep in mind that hospitals will be expected to review the notices with beneficiaries (or representatives when appropriate), answer any questions and, if necessary, help them to initiate the QIO review process. We believe these efforts will serve to reduce confusion and enhance beneficiaries' understanding of their rights and their ability to act on them.

Comment: Many commenters stated that this proposed process would encourage beneficiaries who do not want to leave the hospital to “game” the system in order to stay for reasons other than medical necessity. These commenters said that some beneficiaries might want to remain in the hospital, either for reasons of convenience, because the hospital offers a more secure and comfortable environment, or because a bed is not available in a setting of their choice. Additionally, a few commenters pointed out that beneficiaries who do not meet the 3-day qualifying stay for a nursing facility might use the appeal process to get the extra day(s) in order to qualify.

Response: We understand that hospitalized beneficiaries and their family members may be anxious about discharge for many reasons. Nevertheless, we expect the vast majority of beneficiaries who exercise their statutory right to a QIO review to do so for legitimate purposes. As discussed above, we also recognize the benefits of an effective discharge planning process in identifying those beneficiaries who may have concerns about their discharge and in working with these patients early on in order to facilitate a smooth discharge.

Finally, in accordance with § 409.30, a 3-day qualifying stay must be for medically necessary hospital or inpatient CAH care. Therefore, if a patient has not met the 3-day qualifying stay and requests a review, the QIO will determine whether the decision to discharge was the correct one.

Thus, we do not expect significant numbers of individuals to use this process to “game” the system, although we note that opportunity has always existed. Again, we believe that patients should be informed of their statutory rights.

Comment: Some commenters recommended that, instead of adding to the number of notices that hospitals are required to deliver, we educate consumers about their discharge rights through other methods. Several commenters recommended specific measures such as educational campaigns, mailings, or printing appeal rights on the back of the Medicare card. Comments were mixed as to whether Medicare beneficiaries are knowledgeable about their rights or are confused by the complexity of the program and the large number of notices they already receive.

Response: The IM is a statutorily required notice that hospitals are required to deliver at or about the time of an individual’s admission as an inpatient to the hospital. Neither

educational campaigns nor mailings can meet that requirement. We do agree with commenters, however, that it is necessary to educate beneficiaries about their discharge appeal rights using other means. Currently, information about these rights is in the “Medicare and You Handbook” and the Medicare health plans’ “Evidence of Coverage” (EOC), and we will work with hospitals, beneficiary advocates, and other partners to help educate beneficiaries about their rights.

Burden

We received a large number of comments on the burden estimates for both the proposed generic and detailed notices.

Comment: The vast majority of commenters believed that the 5-minute time estimate by CMS for the delivery of the generic notice was much too low, and did not acknowledge the time necessary to complete the notice, explain it to the beneficiary, answer questions, or contact a representative, particularly in cases where the beneficiary’s competency is at issue or there is a language barrier. Generally, commenters offered a range of 10 to 30 minutes to complete the notice, deliver and explain the notice and obtain a signature, with more time required when interpreters or representatives were involved.

In addition, some commenters thought the time required to complete the detailed notice would be comparable to the current notification process that utilizes the HINN and NODMAR. A few commenters stated that the detailed notice could take from 120 to 180 minutes to fill out, accounting for additional tasks such as calling the QIO, or providing evidence to the QIO for its review in their estimate. Also included in this estimate was the burden associated with having to research specific Medicare coverage rules and citations.

Response: Although this final rule no longer requires issuance of the separate generic notice, as specified in the proposed rule, we have taken these comments into consideration in estimating the time required for delivery of a revised, signed IM. Thus, we now estimate the average time for IM delivery at 12 minutes—which represents an 11 minute increase over the estimated time for delivery of the current IM. We note that this estimate reflects an “average” amount of time needed to deliver the notice; some beneficiaries will be able to read the notice easily and others will need more time and assistance. Further, we estimate that delivery of the signed copy

of the IM that may be required for longer hospital stays should only take an average of 3 minutes to deliver to the beneficiary or representative because it is essentially a review of information received at or near admission and questions regarding the process can also be referred to the QIO.

Regarding the detailed notice, in response to suggestions that it would be especially difficult for hospital staff to research and list specific citations to applicable Medicare policy rules, we no longer require the notice to list specific citations to the applicable Medicare policy rules. We have, however, maintained the requirements that the detailed notice explain why services are no longer necessary and describe relevant Medicare coverage rules, instruction or other policy. Commenters recognized that the detailed notice essentially replaces the HINN and NODMAR processes when beneficiaries and enrollees do not agree with the discharge. Therefore, we believe that the detailed notice will not constitute a new burden, but will essentially replace the time associated with filling out and delivering the HINN and NODMAR. We believe that, in addition to the time it currently takes to complete the HINN and NODMAR, an extra 60 minutes is sufficient for filling out and delivering the detailed notice. We intend to permit, in guidance, that hospitals and plans may use predetermined language regarding medical necessity and other Medicare policy. Both the IM and the detailed notice will be published for public comment through the OMB Paperwork Reduction Act process. Therefore, we welcome further input on the form and content of the detailed notice through the OMB approval process.

QIOs

Several commenters noted that the current QIO schedule for hospital reviews could delay the appeal process.

Comment: Several commenters stated that QIOs do not currently review hospital stays on weekends, which could cause additional delay in the processing of these appeals.

Response: QIO reviews of disputed hospital discharges are a long-standing feature of the Medicare program. However, we will work closely with the QIOs to ameliorate any difficulties associated with the notice procedures. We note that the QIO review process for other providers requires QIO involvement 7 days a week.

Information Technology (IT)

Some commenters were concerned that the notice process would affect their IT systems.

Comment: A few commenters stated that hospitals, especially larger centers, would have to develop or change their IT process to, for example, track “next day” discharges, based on the proposed rule. Several commenters stated that the proposed rule was contrary to the movement toward electronic medical records.

Response: As described above, based on the comments, we have revised the requirement for delivery of the notice so that it may be delivered up to 2 days prior to discharge. We believe this added flexibility will relieve hospitals of any burden of developing an IT process to track “next day” discharges. We also agree that the movement toward electronic medical records is an important advancement. However, given that section 1866(a)(1)(M) of the Act requires a written statement of rights, there is still a need for a hard copy delivery of the IM. Hospitals may choose to store the signed copy of the notice electronically.

Delivery to a Representative

Several commenters asked that we allow hospitals to provide notification to representatives via a telephone call.

Comment: Several commenters requested that CMS clarify what “valid delivery” means if a beneficiary is incompetent and a representative must be contacted. Other commenters suggested that we allow telephone notification to beneficiary representatives.

Response: We intend to provide guidance regarding how hospitals and health plans may deliver the appropriate notice in cases where a beneficiary’s representative may not be immediately available.

Managed Care

Several commenters noted there were specific issues with regulation in terms of managed care and also commented on the scope of the regulation and coordination issues among hospitals, plans and the QIO.

Comment: Several commenters pointed out coordination issues among Medicare health plans, hospitals, and QIOs, regarding the proposed process. Several commenters specifically described issues of coordination regarding delivery of the proposed detailed notice. One commenter stated that an MA private-fee-for-service (PFFS) plan may not have knowledge of the hospital stay to comply with these

rules. Another commenter stated that plans may not have a contract with the treating hospital in order to delegate responsibility for the detailed notice delivery. Other commenters stated that plans are too far removed from the hospital setting to have the information to fill out and deliver a meaningful detailed notice in a timely manner. Some stated that it would be unworkable for the plan to provide the detailed notice by close of business of the day the beneficiary contacts the QIO. In this case, commenters suggested requiring plans to provide written explanation of the discharge decision to the enrollee by the close of business on the day following notification of the plan by the QIO. Some commenters pointed out difficulties hospitals have following two different sets of regulations, one for original Medicare and one for MA.

Response: We believe, consistent with the immediate QIO review process in the non-hospital settings at § 422.622, that Medicare health plans are in the best position to deliver the detailed notices regarding their specific policies and the criteria that they applied in evaluating an enrollee for discharge. Moreover, in view of the fact that Medicare health plans are responsible for making coverage determinations for their enrollees, we believe it is appropriate that plans be responsible for preparing and delivering the detailed notice in a timely manner. Therefore, we are maintaining the requirement that the plan be responsible for delivery of the detailed notice. Although we expect that the plans will deliver the detailed notice as soon as possible, we have revised the timeframe for delivery of the detailed notice as well as any information the QIO needs to complete the review, to noon of the day following the QIO’s notification of the enrollee’s request, as discussed previously.

We recognize that the PFFS model presents unique challenges to plans in terms of notice delivery requirements. We believe hospitals, as part of their daily business practices, should be informing all plans, including PFFS plans, of an enrollee’s admission as soon as possible, and have a financial interest in doing so. Therefore, we are maintaining requirements that plans participate in the discharge process and deliver the detailed notice to their enrollees when appropriate.

In addition, we have attempted to create a consistent notification and appeal process by aligning the regulations for original Medicare and the MA program. Thus, we have reordered the requirements at § 422.620 and § 422.622 to parallel those at

§ 405.1205 and § 405.1206. For example, QIO requirements at § 422.622 have been revised to parallel those at § 405.1206, and requirements that hospitals provide information needed for the QIO review at § 422.622 now parallel those at § 405.1206. We believe this will strengthen beneficiary rights regarding hospital discharges and make the QIO review process easier to understand and administer.

Comment: Some commenters asked if these rules apply to Medicare Cost Plans.

Response: In accordance with 42 CFR 417.600(b), Medicare Cost Plans are subject to the regulations at 42 CFR part 422, Subpart M. Therefore, these rules apply to them to the same extent that they apply to all other Medicare health plans.

Comment: Some commenters expressed concern that MA organizations might be responsible for additional costs if hospitals fail to provide a timely generic notice on the day before discharge and the enrollee needed to stay an extra day to request an appeal.

Response: As discussed in detail above, we have removed the 24-hour requirement for delivery of the generic notice and replaced the generic notice with a signed IM given at or near admission. Under this revised approach, a patient will not need to stay in a hospital an extra day merely to request an appeal. We believe our revised approach addresses the commenters’ concern.

Definition of Discharge

We received a few comments on the definition of discharge provided in proposed § 405.1205 and § 422.620.

Comment: Some commenters asked that we clarify the definition of discharge. Specifically, they asked that we clarify that a transfer to another hospital does not constitute a discharge. Commenters suggested that, for purposes of the proposed notice process, the definition of discharge should not include beneficiaries who exhaust Part A benefits.

Response: In response to these comments, we have revised the definition of discharge in both § 405.1205 and § 422.620 to state that a discharge is the formal release of a beneficiary or enrollee from an inpatient hospital. This definition is consistent with the definition at § 412.4 for hospitals paid under the prospective payment system. We removed the term “complete cessation of coverage” from the proposed definition in order to reduce confusion about beneficiaries who exhaust Part A days. We believe

that the number of beneficiaries who exhaust Part A days during a hospital stay is low. However, if this were to occur, hospitals would not be required to issue a follow up copy of the signed IM. Current guidance states that the HINN may be used voluntarily by hospitals to notify beneficiaries who exhaust Part A days (See Transmittal 594, Section V) and Medicare health plans would give the Notice of Denial of Medical Coverage. Under this new process, hospitals would use a liability notice akin to the HINN for this purpose. Hospitals will be required to deliver the IM at or near admission, thus all beneficiaries and enrollees will receive information on their right to a QIO review.

Content of Notices

We received many comments that the wording of the generic notice does not reflect hospital processes and is not beneficiary friendly.

Comment: Many commenters stated that the generic notice was alarmist and focused too much on termination of Medicare payment and financial liability and not enough on the fact that the discharge decision was made based on whether the beneficiary could safely go home or could safely receive care in another setting. For example, they believed that the use of the words such as “liability,” “noncoverage” and “immediate review” might upset some beneficiaries who are facing discharge. In the commenters opinion, hospitals must give beneficiaries the confidence they need to transition to a different level of care and the wording of the notice would cause beneficiaries to doubt the discharge decision unnecessarily.

Response: As discussed above, the process set forth in this final rule no longer entails a new, generic notice. However, we have taken these comments into consideration as we have developed the revised IM. For example, as discussed above, we intend to include information about discharge planning in the IM.

Please note that the precise wording and content of the notices is generally not subject to the rulemaking process, but instead is subject to OMB’s Paperwork Reduction Act process. Thus, we intend to republish these notices through that process, providing an additional opportunity for public input prior to implementation.

Other Recommendations

Many commenters made other recommendations for how CMS could get feedback on the proposed notification process.

Comment: Some commenters recommended that CMS pilot the proposed process and notices. Others said that the notices themselves should be tested with beneficiaries. Other commenters recommended that CMS convene a national workgroup to review the hospital notices and recommend changes.

Response: The process set forth here builds on existing hospital notice requirements regarding a patient’s right to a QIO review of a discharge decision. Thus, we do not believe that a pilot of either the proposed process or the proposed notices is appropriate or necessary. However, as noted above, there will be ample opportunity for public input on the notices through the PRA process. We also intend to carry out consumer testing of the notices prior to implementation of the new process.

Scope

Several commenters asked for clarification on issues related to the scope of the rule.

Comment: Several commenters asked if the notification process would be applicable to observation stays.

Response: The notice requirements set forth in this rule apply only to inpatient hospital stays.

Comment: Several commenters stated that Medicare beneficiaries who are transferred from an acute hospital to another hospital should not receive the generic notice because they are still using their hospital Medicare benefit days. Other commenters recommended that no notice be required in the following situations: when a beneficiary is moved to the same level of care or to a hospital that provides more complex medical/surgical care, when there is an emergency transfer from a psychiatric hospital to an acute care hospital for an acute problem, when a beneficiary is discharged to a rehabilitation hospital, psychiatric hospital or skilled nursing facility when the hospital has been waiting for a bed in one of those facilities. Another commenter requested that CMS distinguish between inter-hospital transfers and intra-hospital transfers.

Response: Although this comment was made in response to the proposed generic notice that is required to be given prior to discharge, we believe that it is important to restate that, in the context of the final rule, hospitals are required to deliver the IM at or near admission to all beneficiaries and enrollees with a copy at or near discharge except in short stay situations. For purposes of this rule, and consistent with the revised definition of discharge at § 405.1205 and § 422.620, any patient

who is formally released from a hospital, whether that patient is going to another inpatient hospital, to a lower level of care such as a SNF (even a swing bed within the hospital), or to home, is considered discharged from that hospital.

Comment: A few commenters said that the proposed notice process conflicted with other federal regulations that prohibit Medicare beneficiaries from being treated differently from other hospital patients. These commenters stated that the notice requirements give Medicare beneficiaries rights to which other patients are not entitled. None of these commenters cited a specific rule.

Response: Although the hospital conditions of participation do establish standards that hospitals must meet for all patients, these final notice requirements stem directly from sections 1866(a)(1)(M) and section 1869(c)(3)(C)(iii)(III) of the Act and are only applicable to Medicare beneficiaries. However, without further specifics on which federal regulations the commenters are talking about, we are unable to address these comments.

IV. Provisions of the Final Regulations

The key provisions of this final rule are as follows:

- Section 405.1205(a) defines the scope of this rule for original Medicare and, as stated above, includes a revised definition of discharge consistent with § 412.4.

- Section 405.1205(b) states that hospitals must deliver valid, written notice of hospital discharge rights using a standardized notice specified by CMS.

As discussed earlier, this section has been revised to reflect the substitution of the IM for the generic notice and describes the revised notice delivery timeframes, the required content of the notice, and valid delivery requirements, including beneficiary signature, as stated above.

- Section 405.1205(c) outlines the requirements for the follow-up copy of the signed notice, as previously described, including timeframes for delivery of the copy.

- Section 405.1206(a) describes a beneficiary’s right to request an expedited determination.

- Section 405.1206(b) explains the process for requesting an expedited determination by a QIO including the timeframes for requesting such an appeal, which as discussed in earlier sections, has been amended to require that a beneficiary must submit a request for a QIO review no later than the day of discharge.

This paragraph also explains the conditions for financial liability

protections including when the beneficiary makes an untimely request for a QIO review.

- Section 405.1206(c) states that the burden of proof lies with the hospital to demonstrate that discharge is the appropriate decision, and § 405.1206(d) describes the procedures that the QIO must follow in reviewing a discharge, including notification requirements for timely and untimely requests.

- Section 405.1206(e) explains the responsibilities of hospitals in the expedited determination process, including the delivery and content requirements of the detailed notice. Although a description of the applicable Medicare coverage rules or other Medicare policy is still required, as discussed above, we have removed the requirement that the notice must list specific citations to the applicable Medicare policy rules.

- Section 405.1206(f) describes the specific financial liability protections and limitations, including the beneficiary's right to pursue a reconsideration or appeal through the general claims appeals process.

- Section 405.1208 describes the process for when a hospital requests a QIO review because the physician does not concur with the hospital's determination that inpatient hospital care should end. We have made one technical change in this paragraph by adding a cross reference to § 405.1206(f)(4), in order to clarify beneficiary liability when the QIO concurs with the hospital's determination.

- Section 412.42(c)(3) includes a cross-reference to the notice and appeal provisions set forth in § 405.1205 and § 405.1206 and clearly establishes that the provision of the appropriate expedited review notices would be one of the prerequisites before a hospital could charge a beneficiary for continued hospital services.

- Section 422.620(a) defines the scope of this rule for MA enrollees and, as indicated above, includes a revised definition of discharge consistent with § 412.4.

- Section 422.620(b) requires hospitals to deliver valid, written notice of hospital discharge rights using a standardized notice specified by CMS. This section describes the revised provisions regarding notice delivery timeframes, the content of the notice, and valid delivery requirements, including enrollee signature.

- Section 422.620(c) outlines the requirements for the follow-up copy of the signed notice previously discussed, including timeframes for delivery of the copy.

- Section 422.622(a) describes an enrollee's right to request an immediate review by a QIO.

- Section 422.622(b) explains the process for requesting an immediate review including the timeframes for requesting such an appeal and the conditions for financial liability protections, including when the enrollee makes an untimely request for a QIO review.

- Section 422.622(b)(1), as described above, states that an enrollee must submit a request for a QIO review no later than the day of discharge.

- Section 422.622(c) states that the burden of proof lies with the MA organization to demonstrate that discharge is the appropriate decision, and § 422.622(d) describes the procedures that the QIO must follow, including notification requirements for timely and untimely requests.

- Section 422.622(e) explains the responsibilities of the MA organizations and hospitals in the immediate review process, including the delivery and content requirements of the detailed notice. Although a description of the applicable Medicare coverage rules or other Medicare policy is still required, as stated above, we have removed the requirement that the notice must list specific citations to the applicable Medicare policy rules.

- Section 422.622(f) describes the specific financial liability protections and limitations, including the enrollee's right to pursue a reconsideration or appeal through the standard appeal process.

- Section 489.27(a) has been revised to state that hospitals must furnish each Medicare beneficiary or enrollee the notice of discharge rights under section 1866(a)(1)(M) of the Act in accordance with § 405.1205 and § 422.620. We have also made two technical changes to § 489.27(b) to add cross references to requirements for other notices associated with expedited or immediate QIO reviews in both the hospital and non-hospital settings.

First, current § 489.27 contains a cross reference to § 405.1202. We inadvertently omitted this reference from the proposed rule, so we are adding it back in this final rule. Second, we are adding a reference to § 405.1206, the detailed notice in this rule. Therefore, § 489.27(b) states that hospitals and other providers participating in the Medicare program must provide the applicable notices in advance of discharge or termination, as required under § 405.1200, § 405.1202, § 405.1206, and § 422.624.

V. Collection of Information Requirements

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

The information collection requirement associated with administering the hospital discharge notice is subject to the PRA.

Several commenters addressed the burden associated with the proposed notice provisions, and these comments are discussed in detail above in section III of this final rule. As discussed there, this final rule contains changes to these provisions based on public comments. Our estimates of the revised information collection requirements are set forth below, and we welcome further comments on these issues during the Paperwork Reduction Act approval process.

Section 405.1205 Notifying Beneficiaries of Hospital Discharge Appeal Rights

As discussed in detail in section III of this preamble, this final rule does not include the proposed requirements with respect to delivering a separate, standardized generic notice. Instead, we have modified the existing IM in order to provide the information about discharge appeal rights. The IM is currently approved under OMB # 0938-0692 and will be revised to reflect any additional burden and the following PRA requirements associated with this final rule.

The hospital must provide, explain, and obtain the beneficiary signature (or that of his or her representative) on the IM within 2 calendar days of admission, followed by delivery of a copy of the signed IM no more than 2 calendar days before discharge, in accordance with the requirements and procedures set forth

in this rule. If the date the signed IM is delivered falls within 2 calendar days of discharge, no additional copy is given.

Since the IM is already required by statute to be provided to all Medicare beneficiaries who are admitted to the hospital (at an estimated delivery time of 1 minute per notice) and the notice would be disseminated during the normal course of related business activities, we estimate that, to explain the form and obtain a signature, it would take hospitals an extra 11 minutes on average to explain and provide a signed IM. We thus use an average of 12 minutes, meaning that some beneficiaries will be able to read and understand the notice in less time, and some beneficiaries will need more time and assistance reading and understanding the notice. In 2003, there were approximately 11.3 million fee-for-service Medicare inpatient hospital discharges. The total annual burden associated with this requirement is 2,071,667 hours. We estimate that approximately 60 percent of the beneficiaries will receive a copy of the signed IM in order to meet the requirements that a copy of the IM also be delivered no more than 2 days before discharge. We estimate that it will take 3 minutes to deliver a copy of the signed IM to the roughly 6.78 million beneficiaries. We estimate that the total annual burden associated with the requirement will be 339,000 hours.

Section 405.1206 Expedited Determination Procedures for Inpatient Hospital Care

Section 405.1206(b) requires any beneficiary wishing to exercise the right to an expedited determination to submit a request, in writing or by telephone, to the QIO that has an agreement with the hospital. We project that 1 percent of the 11.3 million fee-for-service beneficiaries who are discharged from inpatient hospital settings, (that is, 113,000 beneficiaries) will request an expedited determination. This estimate is based on our experience with the non-hospital expedited determination process in both original Medicare and MA, where approximately 1 percent of patients request an expedited review. However, we believe that this estimate may be high, given previous use of a standard discharge notice, the NODMAR in managed care settings

showed an appeal rate of less than .5 percent.

The burden associated with this requirement is the time and effort it would take for the beneficiary to either write or call the QIO to request an expedited determination. We estimate it would take 5 minutes (average) per request. Therefore, the total estimated burden hours associated with this requirement is 9,417 hours.

Section 405.1206(e) requires hospitals to deliver a detailed notice of discharge to the beneficiary and to make available to the QIO (and to the beneficiary upon request) a copy of that notice and any necessary supporting documentation. Hospitals are presently responsible for providing the Hospital Issued Notice of Non-Coverage (HINN) when a beneficiary disagrees with the discharge. Therefore, we believe that the detailed notice will not constitute a new burden, but will essentially replace the time associated with filling out and delivering the HINN. We believe that, in addition to the time it currently takes to complete the HINN, an extra 60 minutes is sufficient for filling out and delivering the detailed notice.

Therefore, for these 113,000 cases, we estimate that it would take providers an average of 60 extra minutes to prepare the detailed termination notice and to prepare a case file for the QIO. Based on 113,000 cases, the total annual burden associated with this proposed requirement is approximately 113,000 hours.

Section 422.620 Notifying Enrollees of Hospital Discharge Appeal Rights

The hospital must provide, explain, and obtain the enrollee's signature (or that of the representative) on the IM within 2 days of admission, followed by delivery of a copy of the signed IM no more than 2 calendar days before discharge in accordance with the requirements and procedures set forth in this rule. If the date the signed IM is delivered falls within 2 calendar days of discharge, no additional copy is given.

Again, we estimate that it would take hospitals an average of 11 extra minutes to explain and provide a signed IM. In 2003, there were approximately 1.7 million Medicare health plan inpatient hospital discharges. The total annual burden associated with this proposed requirement is 311,667 hours.

As mentioned above, we estimate that it will take 3 minutes (average) to

deliver a copy of the signed IM to approximately 60 percent of the 1.7 million inpatient enrollees. We estimate that the total annual burden associated with delivering a copy to 1.02 million enrollees will be 51,000 hours.

Section 422.622 Requesting Immediate QIO Review of Decision To Discharge From Inpatient Hospital Care

This section states that an enrollee who wishes to appeal a determination by a Medicare health plan or hospital that inpatient care is no longer necessary, may request QIO review of the determination. On the date the QIO receives the enrollee's request, it must notify the plan that the enrollee has filed a request for immediate review. The plan in turn must deliver a detailed notice to the enrollee.

Again, we project that 1 percent of affected enrollees that is, 17,000 enrollees, will request an immediate review. We estimate that it will take 5 minutes (average) for an enrollee who chooses to exercise his or her right to an immediate review to contact the QIO. For these 17,000 cases, the total estimated burden is 1,417 hours.

As specified in § 422.622(c) and (d), Medicare health plans would be required under this rule to deliver a detailed notice to the enrollee and to make a copy of that notice and any necessary supporting documentation available to the QIO (and to the enrollee upon request). Plans are presently responsible for providing the NODMAR when an enrollee disagrees with the discharge or he or she is being moved to a lower level of care. Therefore, we believe that the detailed notice will not constitute a new burden, but will essentially replace the time associated with filling out and delivering the NODMAR. We believe that, in addition to the time it currently takes to complete the NODMAR, an extra 60 minutes is sufficient for filling out and delivering the detailed notice.

Therefore, we estimate that it would take plans an extra 60 minutes to prepare the detailed notice and to prepare a case file for the QIO. Based on 17,000 cases, the total annual burden associated with this requirement is approximately 17,000 hours.

The information above is summarized in the table below:

AGGREGATE HOURLY BURDEN FOR THIS REQUIREMENT

Notices	Time per delivery (minutes)	Fee-for-service beneficiaries	Managed care enrollees	Annual burden hours
First IM	11	11.3 million	1.7 million	2,383,334
Copy of IM	3	6.78 million	1.02 million	390,000
Detailed Notice	60	113,000	17,000	140,834
Total Burden	2,914.168

The aggregate new hourly burden estimate associated with this final rule is 2,914,168 hours per year. The burden increase is mainly due to the extra 11 minutes on average to explain and provide a signed IM. As discussed above, the estimate of the hourly burden associated with the new IM does not include the burden associated with current OMB #0938-0962, which is now estimated at 1 minute per delivery. There are no current burden estimates for delivery of the HINN or the NODMAR. As noted above, the actual burden will be developed through the PRA process.

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-4105-F, 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-4105-F, carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this final 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 final rule will not reach the economic threshold and thus is not considered a major rule.

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 government 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 purposes of this RFA, all providers affected by this regulation are considered to be small entities.

We did not prepare analyses for either the RFA or section 1102(b) of the Act because we have determined that this final rule will not have a significant economic impact on a substantial number of small entities. (We estimate a total cost of approximately \$15,200 per provider as discussed below.) Although a regulatory impact analysis is not mandatory for this final rule, we believe it is appropriate to discuss the possible impacts of the new discharge notice on beneficiaries, enrollees, and hospitals, regardless of the monetary threshold of that impact. Therefore, a brief voluntary discussion of the anticipated impact of this final rule is presented below.

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. We do not expect these entities to be significantly impacted.

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 final rule did not require an assessment under the Unfunded Mandates Reform Act.

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. Since this regulation will not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

B. Overview of the Changes

This final rule sets forth new requirements for hospital discharge notices for all Medicare inpatient hospital discharges. This final rule specifies that hospitals must provide, explain, and have signed by the beneficiary (or his or her representative) the modified Important Message for Medicare (IM) within 2 calendar days of admission, followed by delivery of a copy of the signed IM no later than 2 calendar days prior to discharge (if 2 or more days have passed since the original IM was signed). Additionally, a detailed notice must be delivered if the beneficiary requests a QIO review of the decision. As discussed above, these notices would replace existing notice requirements under which only those beneficiaries who express dissatisfaction with a hospital's (or Medicare health plan's, if applicable) discharge determination or whose level of care is being lowered in the same facility, receive a notice of describing the right to a QIO review in detail. In general, we believe that these changes will enhance the rights of all Medicare beneficiaries who are hospital inpatients without imposing undue paperwork or

financial burdens on hospitals or Medicare health plans.

C. Notifying Beneficiaries and Enrollees of Hospital Discharge Appeal Rights (§ 405.1205 and § 422.620)

We project that providers will be responsible for explaining and delivering (and obtaining the beneficiary's or representative's signature) the IM to approximately 13 million Medicare beneficiaries per year. This includes about 11.3 million fee-for-service beneficiaries and 1.7 million MA enrollees. The IM is already required by statute to be provided to all Medicare beneficiaries at an estimated time of 1 minute per notice. Therefore, as discussed above, we estimate that it will take approximately 11 extra minutes on average to explain and deliver a signed IM, at a cost of approximately \$5.50 (based on no more than \$30 per hour rate if the notice is delivered by health care personnel). Based on an estimated 13 million notices annually, we estimate the cost of delivering these new notices to be roughly \$71.5 million. We estimate that it will take 3 minutes to deliver a copy of the IM to 7.8 million beneficiaries (we assume that 60 percent of inpatient stays will involve delivering a signed copy of the IM since, for short stays, hospitals may only need to deliver the IM once). We estimate that the cost of delivering these copies will be \$11.7 million. Since there are roughly 6,000 affected hospitals, the total average costs associated with this provision would be roughly \$13,900 per provider. We believe that this impact is significantly outweighed by the benefits of establishing a clear, consistent, accountable process for ensuring that all Medicare beneficiaries are made aware of their statutory discharge rights on a timely basis, without interfering with the hospital discharge process.

D. Providing Beneficiaries and Enrollees With a Detailed Explanation of the Discharge Decision (§ 405.1206 and § 422.622)

As discussed in section V of this final rule (Information Collection section), we project that providers will be responsible for delivering detailed notices to approximately 1 percent of the 13 million Medicare beneficiaries per year, or 130,000 beneficiaries and enrollees. The detailed notice will provide a detailed explanation of why services are either no longer reasonable and necessary or are otherwise no longer covered; a description of any relevant Medicare (and Medicare health plan as applicable) coverage rule, instruction, or other Medicare policy, and information about how the

beneficiary may obtain a copy of the Medicare policy, facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to his or her case; and any other information required by CMS. Hospitals and plans are presently responsible for providing the HINN or the NODMAR when a beneficiary disagrees with the discharge or he or she is being moved to a lower level of care. As discussed earlier, the detailed notice will essentially replace the HINN and NODMAR. Therefore, we believe that, in addition to the time it currently takes to complete the HINN and NODMAR, an extra 60 minutes is sufficient for filling out and delivering the detailed notice. We estimate the per-notice cost will average \$30, based on a \$30 per hour rate if the notice is prepared and delivered by health care personnel. Based on an estimated 130,000 notices annually, we estimate the aggregate cost of delivering these notices to be roughly \$3.9 million. Since there are roughly 6000 affected hospitals, the average costs associated with this provision would be about \$650 per provider.

We do not anticipate that the provisions of this final rule will have a significant financial impact on individual hospitals. We note that the actual discharge notices must be approved through OMB's Paperwork Reduction Act process and are also subject to public comment.

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 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and record keeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare Advantage, Penalties, Privacy, Provider-sponsored organizations (PSO), Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1866, 1869, 1871, 1874, 1881 and 1886(k) of the Social Security Act (42 U.S.C. 1302, 1395cc, 1395ff, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

■ 2. Section 405.1205 is added to read as follows:

§ 405.1205 Notifying beneficiaries of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, the term "hospital" is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals.

(2) For purposes of § 405.1204, § 405.1205, § 405.1206, and § 405.1208, a discharge is a formal release of a beneficiary from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary's rights as a hospital inpatient, including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the beneficiary's admission to the hospital.

(2) *Content of the notice.* The notice must include the following information:

(i) The beneficiary's rights as a hospital inpatient including the right to benefits for inpatient services and for post-hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The beneficiary's right to request an expedited determination of the

discharge decision including a description of the process under § 405.1206, and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination.

(iii) The circumstances under which a beneficiary will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) A beneficiary's right to receive additional detailed information in accordance with § 405.1206(e).

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The beneficiary (or the beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the beneficiary (or beneficiary's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under § 405.1205(b) is delivered within 2 calendar days of discharge.

■ 3. Section § 405.1206 is revised to read as follows:

§ 405.1206 Expedited determination procedures for inpatient hospital care.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement

with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The beneficiary may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) A beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraphs (f)(1) and (f)(2) of this section, as applicable.

(5) A beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, and remains in the hospital without coverage, still may request an expedited QIO determination at any time during the hospitalization. The QIO will issue a decision in accordance with paragraph (d)(6)(ii) of this section, however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(6) A beneficiary who fails to make a timely request for an expedited determination in accordance with paragraph (b)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after the date of discharge, or at any time for good cause. The QIO will issue a decision in accordance with paragraph (d)(6)(iii) of this section; however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(c) *Burden of proof.* When a beneficiary (or his or her representative, if applicable) requests an expedited determination by a QIO, the burden of proof rests with the hospital to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the hospital should supply any and all information that a QIO requires to sustain the hospital's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 405.1205(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the beneficiary (or the beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the discharge is appropriate.

(6)(i) When the beneficiary requests an expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination within one calendar day after it receives all requested pertinent information.

(ii) When the beneficiary makes an untimely request for an expedited determination, and remains in the hospital, consistent with paragraph (b)(5) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and the physician of its determination within 2 calendar days following receipt of the request and pertinent information.

(iii) When the beneficiary makes an untimely request for an expedited determination, and is no longer an inpatient in the hospital, consistent with paragraph (b)(6) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(7) If the QIO does not receive the information needed to sustain a hospital's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the hospital may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues an expedited determination, the QIO must notify the beneficiary, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services.

(iv) Information about the beneficiary's right to a reconsideration

of the QIO's determination as set forth in § 405.1204, including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of hospitals.* (1) When a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary as soon as possible but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation why services are either no longer reasonable and necessary or are otherwise no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare policy.

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case.

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required as specified in § 405.1205 (b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by noon of the day after the QIO notifies the hospital of the request for an expedited determination. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate such a request by no later than close of business of the first day after the material is requested.

(f) *Coverage during QIO expedited review*—(1) *General rule and liability while QIO review is pending.* If the beneficiary remains in the hospital past midnight of the discharge date ordered by the physician, and the hospital, the

physician who concurred with the discharge determination, or the QIO subsequently finds that the beneficiary requires inpatient hospital care, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductible) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO, and notifies the beneficiary with a notice consistent with 405.1205 (c).

(2) *Timely filing and limitation on liability.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, the beneficiary is not financially responsible for inpatient hospital services (other than applicable coinsurance and deductible) furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely request and liability.* When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (b) of this section, but remains in the hospital past the discharge date, that beneficiary may be held responsible for charges incurred after the date of discharge or as otherwise stated by the QIO.

(4) *Hospital requests an expedited review.* When the hospital requests a review in accordance with § 405.1208, and the QIO concurs with the hospital's discharge determination, a hospital may not charge the beneficiary until the date specified by the QIO.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *Right to request a reconsideration.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 405.1204.

(2) *Right to pursue the general claims appeal process.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

■ 4. In § 405.1208 the following amendments are made:

■ A. In paragraph (a), redesignate the text after the heading "General rule" as paragraph (a)(1) and add a new paragraph (a)(2) to read as set forth below:

■ B. In paragraph (e)(1), in the third sentence, remove the words "paragraph (d)(1) of this section" and add in their place, "§ 405.1204(b)(1)".

§ 405.1208 Hospital requests expedited QIO review.

(a) *General rule.* (1) * * *

(2) When the hospital requests review, and the QIO concurs with the hospital's discharge determination, a hospital may not charge a beneficiary until the date specified by the QIO in accordance with 405.1206(f)(4).

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

■ 5. The authority citation from 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 108–173, 117 Stat. 2266, 42 U.S.C. 1305. 1395.

■ 6. Section 412.42(c) is amended by—

■ A. Republishing the introductory text.

■ B. Revising paragraphs(c)(2) and (c)(3) to read as follows:

§ 412.42 Limitations on charges to beneficiaries.

* * * * *

(c) *Custodial care and medically unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 411.15(g) of this chapter (custodial care) or § 411.15(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

* * * * *

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the QIO as described in § 405.1208 of this chapter. Concurrence by the QIO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or his or her representative) of his or her discharge rights in writing consistent with § 405.1205 and notifies the beneficiary, in accordance with § 405.1206 of this chapter (if applicable) that in the hospital's opinion, and with the attending physician's concurrence

or that of the QIO, the beneficiary no longer requires inpatient hospital care.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 7. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395cc, and 1395hh).

■ 8. Section 422.620 is revised to read as follows:

§ 422.620 Notifying enrollees of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of § 422.620 and § 422.622, the term hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of § 422.620 and § 422.622, a discharge is a formal release of an enrollee from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare Advantage enrollees, hospitals must deliver valid, written notice of an enrollee's rights as a hospital inpatient including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the enrollee's admission to the hospital.

(2) *Content of the notice.* The notice of rights must include the following information:

(i) The enrollee's rights as a hospital inpatient, including the right to benefits for inpatient services and for post hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The enrollee's right to request an immediate review, including a description of the process under § 422.622 and the availability of other appeals processes if the enrollee fails to meet the deadline for an immediate review.

(iii) The circumstances under which an enrollee will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) The enrollee's right to receive additional information in accordance with section § 422.622(e).

(v) Any other information required by CMS.

(3) *When delivery of notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If an enrollee refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the enrollee (or enrollee's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under 422.620(b) is delivered within 2 calendar days of discharge.

(d) *Physician concurrence required.* Before discharging an enrollee from the inpatient hospital level of care, the MA organization must obtain concurrence from the physician who is responsible for the enrollee's inpatient care.

■ 9. Section 422.622 is revised to read as follows:

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

(a) *Enrollee's right to an immediate QIO review.* An enrollee has a right to request an immediate review by the QIO when an MA organization or hospital (acting directly or through its utilization committee), with physician concurrence determines that inpatient care is no longer necessary.

(b) *Requesting an immediate QIO review.* (1) An enrollee who wishes to exercise the right to an immediate review must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The enrollee, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The enrollee may, but is not required to, submit written evidence to

be considered by a QIO in making its decision.

(4) An enrollee who makes a timely request for an immediate QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraph (f) of this section, as applicable.

(5) When an enrollee does not request an immediate QIO review in accordance with paragraph (b) of this section, he or she may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (f) of this section do not apply.

(c) *Burden of proof.* When an enrollee (or his or her representative, if applicable) requests an immediate review by a QIO, the burden of proof rests with the MA organization to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the MA organization should supply any and all information that a QIO requires to sustain the organization's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the enrollee's request for an immediate review under paragraph (b), the QIO must notify the MA organization and the hospital that the enrollee has filed a request for an immediate review.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 422.620(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the enrollee (or his or her representative) who requested the immediate QIO review.

(5) The QIO must provide an opportunity for the MA organization to explain why the discharge is appropriate.

(6) When the enrollee requests an immediate QIO review in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the enrollee, the hospital, the MA organization, and the physician of its determination within one calendar day after it receives all requested pertinent information.

(7) If the QIO does not receive the information needed to sustain an MA organization's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the MA

organization may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues its determination, the QIO must notify the enrollee, the MA organization, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

- (i) The basis for the determination.
- (ii) A detailed rationale for the determination.
- (iii) An explanation of the Medicare payment consequences of the determination and the date an enrollee becomes fully liable for the services.
- (iv) Information about the enrollee's right to a reconsideration of the QIO's determination as set forth in § 422.626(f), including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of the MA organization and hospital.* (1) When the QIO notifies an MA organization that an enrollee has requested an immediate QIO review, the MA organization must, directly or by delegation, deliver a detailed notice to the enrollee as soon as possible, but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

- (i) A detailed explanation of why services are either no longer reasonable and necessary or are no longer covered.
- (ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy including information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.
- (iii) Any applicable MA organization policy, contract provision, or rationale upon which the discharge determination was based.
- (iv) Facts specific to the enrollee and relevant to the coverage determination sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.
- (v) Any other information required by CMS.

(2) Upon notification by the QIO of a request for an immediate review, the MA organization must supply any and all information, including a copy of the notices sent to the enrollee, as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section, that the QIO needs to decide on the determination. The MA organization must supply this information as soon as possible, but no later than noon of the day after the QIO notifies the MA organization that a request for an expedited determination has been received from the enrollee. The MA organization must make the

information available by phone (with a written record made of any information not transmitted initially in writing) and/or in writing, as determined by the QIO.

(3) In response to a request from the MA organization, the hospital must supply all information that the QIO needs to make its determination, including a copy of the notices required as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by close of business of the day the MA organization notifies the hospital of the request for information. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(4) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO by the MA organization, including written records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the documentation for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(f) *Coverage during QIO expedited review.* (1) An MA organization is financially responsible for coverage of services as provided in this paragraph, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

(2) When the MA organization determines that hospital services are not, or are no longer, covered,

(i) If the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in § 422.2 and § 422.112(c)), the MA organization continues to be financially responsible for the costs of the hospital stay when an appeal is filed under paragraph (a)(1) of this section until noon of the day after the QIO notifies the enrollee of its review determination, except as provided in paragraph (b)(5) of this section. If coverage of the hospital admission was never approved by the MA organization or the admission does not constitute emergency or urgently needed care as described in § 422.2 and § 422.112(c), the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital

stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the non-coverage determination made by the MA organization.

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the MA organization must provide the enrollee with a notice consistent with § 422.620(c) when the hospital or MA organization once again determines that the enrollee no longer requires acute inpatient hospital care.

(4) If the hospital determines that inpatient hospital services are no longer necessary, the hospital may not charge the enrollee for inpatient services received before noon of the day after the QIO notifies the enrollee of its review determination.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the enrollee, physician, hospital, and MA organization except in the following circumstances:

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(f).

(2) *Right to pursue the standard appeal process.* If the enrollee is no longer an inpatient in the hospital and is dissatisfied with this determination, the enrollee may appeal to an ALJ, the MAC, or a federal court, as provided for under this subpart.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 10. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, and 1395hh).

■ 11. Section 489.27 is revised to read as follows:

§ 489.27 Beneficiary notice of discharge rights.

(a) A hospital that participates in the Medicare program must furnish each Medicare beneficiary or enrollee, (or an individual acting on his or her behalf), timely notice as required by section 1866(A)(1)(M) of the Act and in accordance with § 405.1205 and § 422.620. The hospital must be able to demonstrate compliance with this requirement.

(b) *Notification by hospitals and other providers.* Hospitals and other providers (as identified at 489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or representative, applicable CMS notices in advance of discharge or termination of Medicare services, including the notices required under

§ 405.1200, § 405.1202, § 405.1206, and § 422.624 of this chapter.

(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: October 13, 2006.

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

Approved: November 15, 2006.

Michael O. Leavitt,
Secretary.

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