CMS Response to OMB on Comments Received on CMS-R-193
"The Important Message from Medicare"
(60-day public comment period)

Background

On April 5, 2006, we published two notices (CMS 10066) in the Federal Register concurrently with a proposed regulation (CMS-4105-P) regarding notification procedures for hospital discharges under both original Medicare and the Medicare Advantage Program. Both the regulation and the notices were the result of a settlement agreement reached as part of the Weichardt v. Leavitt lawsuit. The notices were the "Generic Notice of Non-Coverage" and the "Detailed Explanation of Hospital Non-Coverage". In general, we proposed to require hospitals to deliver, on the day before discharge, the "Generic Notice of Non-Coverage" to each Medicare beneficiary whose physician concurs with the discharge decision. Hospitals would also deliver the "Detailed Explanation of Hospital Non-Coverage" to beneficiaries who exercised their right to appeal the discharge. Both the generic notice and the detailed notice were published in the Federal Register at that time for a 60-day comment period as required by the Paperwork Reduction Act (PRA).

We received over 500 comments on both the proposed regulation and the notices. A vast majority of commenters

said that the proposed generic notice repeated much of the information in the statutorily-required “Important Message from Medicare” (IM), (OMB No. 0938-0692), that hospitals already deliver to Medicare beneficiaries at or near admission. As a result, we eliminated the requirement for a generic notice in the final rule, CMS-4105-F, published November 27, 2006. Instead, after July 1, 2007, hospitals will be required to deliver a revised version of the IM, which includes elements previously contained in the generic notice, to inform beneficiaries of their right to a QIO review of a discharge decision. The Detailed notice will still be used as part of the revised process and will be delivered to beneficiaries who request a QIO review.

On January 5, the revised version of the IM was published in the Federal Register for a 60-day comment period. The following is a summary of the comments we received from 22 commenters. We have revised the IM based on these comments as well as two rounds of consumer testing. We intend to publish both the IM and the detailed notice mentioned above, concurrently for a 30 day comment period.

Wording of the Notice

About fourteen commenters made comments on the actual wording of the IM.

Comment: The majority of commenters stated that the

wording on page 2 of the document, “The QIO accepts requests 24 hours a day” could potentially confuse beneficiaries. Although this process requires QIOs to review requests 7 days a week and have processes in place to receive requests 24 hours a day, commenters believed this wording would lead beneficiaries to think that someone would be available at the QIO to answer the phone 24 hours a day. They suggested we clarify this language. Other commenters suggested that we add instructions for what the beneficiary should do if they request a review after hours.

Response: We agree that the language used to describe the QIO’s availability is potentially confusing and have revised the language to read, “You can file a request for an appeal any day of the week.” Since each state has its own QIO, and each QIO may have its own process for accepting requests after business hours, we thought it best not to include that information on the notice. We did, however, add language stating that the appeal would be considered filed when the beneficiary speaks with someone or leaves a message with the QIO. We also added language stating that the beneficiary should ask the hospital if he or she needs help contacting the QIO.

Comment: A few commenters asked that we designate specific deadlines on the notice for various elements of the

process, such as the time by which the hospital must inform the beneficiary of discharge, the time by which a beneficiary must request a review, and the time by which the QIO will notify the hospital of the beneficiary's request. Commenters suggested various deadlines for each of these actions.

Response: Given the wide variety of hospital discharge practices and processes, we do not believe it is appropriate or practical to establish specific times, like 12 noon or 6 p.m., for elements of the notice and appeals process. Moreover, doing so would in effect, supersede the rulemaking process, where we already considered public comments on this issue. In general, a beneficiary has until midnight of the planned day of discharge to request an appeal, and before liability begins. The QIO will notify the hospital of the beneficiary's request as soon as possible, within their business hours.

Comment: Some commenters requested that we clearly define "Medicare and Medicare health plan" on the notice.

Response: We have worked with our beneficiary education group to develop language that encompasses original Medicare, Medicare Advantage, and other Medicare health plans. Thus, we are using, "Original Medicare" and "Medicare Advantage or other Medicare managed care plan" to

define these terms.

Comment: A few commenters asked us not to use language that implies that a health plan can order services or discharge a patient.

Response: We agree and have removed this language from the notice.

Comment: Several commenters asked that we add lines to the notice or allow hospitals to add lines to the notice so that hospitals can add additional information, for example, to track if the follow-up copy was given.

Response: We have included an Additional Information area at the end of the notice to accommodate this request, or other information such as adding signature lines or witness lines.

Comment: One commenter suggested we add to page 1, "… the physician or hospital staff will inform you of your discharge date…"

Response: We agree and have added this language to the notice.

Comment: A commenter suggested we move the signature line to the second page.

Response: Since beneficiaries will receive this notice at or near admission, when they are dealing with an acute illness, we believe, and heard from beneficiaries in

consumer testing, that it would be best to make the information on the notice as clear and streamlined as possible. Therefore, we included major information on the front of the notice, with the signature at the bottom, and left the step by step information on the second page for those beneficiaries who want to file an appeal.

Comment: Several commenters asked us to reconcile the fact that there is a line in instructions for hospitals to enter a health plan's contact information, but there is no line on the draft notice for such information. Commenters believed it was an added burden on hospitals to have to locate each beneficiary's health plan contact information.

Response: We agree and have removed the instructions that hospitals add the health plan contact information. However, we have added a line for hospitals to provide a hospital contact telephone number for someone within the hospital who can, if needed, assist patients with contacting plans.

Comment: One commenter asked that we add several more patient rights under the patient rights section at the top of page 1.

Response: Delivery of the IM is required by §1866(a)(1)(M) of the Act. This section also describes certain patient rights, which are listed on the draft IM and on

current CMS-R-193. We are using those rights which are found in section 1866(a)(1)(M) of the Act and are listed on current CMS-R-193, and have revised the wording based on consumer testing.

Notice Delivery Process

Comment: We received several comments regarding the notice delivery process in the final rule, where delivery of both an initial and a follow-up copy of the revised IM is required. A few commenters believed that coordination of delivery of the initial and follow-up notice would be difficult since hospitals may have one department, like the admission department, responsible for delivery of the initial copy and another department, such as the care management department, responsible for giving the follow-up copy of the signed notice.

Response: We recognize that hospitals vary widely in their processes for admission, discharge, and delivery of patient information. Thus, we took this into account in the final rule which gives hospitals the flexibility to determine the best process for delivering the initial and follow-up copies of the IM given their particular operational structure.

Comment: Some commenters wanted to know if the notice

should be given to beneficiaries who have Medicare as a secondary payer or to patients whose status is being changed from inpatient to outpatient and consistent with recent CMS guidance.

Response: Section 1154 of the Social Security Act applies to all patients who are under Medicare, regardless of where Medicare falls in the sequence of payers. Therefore, beneficiaries who have Medicare as a secondary payer, or who are dually eligible for Medicare and Medicaid, have the right to a QIO review of their discharge and should receive the Important Message from Medicare.

As noted CMS has recently issued guidance on situations in which a hospital utilization review committee determines that an inpatient admission does not meet the hospital's inpatient criteria. Under this guidance, hospitals may change the patient's status from inpatient to outpatient (while the patient is still in the hospital) and submit an outpatient claim for medically necessary Medicare Part B services, furnished to the beneficiary under certain conditions described in the CR. These inpatient requirements would not apply under those circumstances.

Comment: One commenter suggested that we clarify the process for verifying valid delivery of the notice, saying that hospitals should be able to document delivery of the

notice in the medical record or by another process, including a paperless system.

Response: Hospital must be able to demonstrate compliance with delivery of the IM, and they have the flexibility to develop processes that work in their particular setting, including electronic scanning and storing of the notices. Compliance with the notice process will be incorporated into the survey and certification process.

Comment: One commenter suggested that CMS provide copies of the notice in other languages besides Spanish.

Response: CMS' general approach for all notices and publications has been to make them available in English and Spanish. Since these notices require hospital staff to assess the beneficiary's comprehension of the information, and since not all hospital staff speak these various languages, we do not believe that translating notices that inform beneficiaries' of their rights and potential liability is prudent. Hospitals should continue to make interpreter services available to non-English speaking beneficiaries.

Comment: One commenter was concerned about beneficiary comprehension of the IM and of notices in general. This commenter stated that hospital staff does not currently take

the time to explain the notices, the notices are often too long, the print is too small, or the beneficiaries are too ill to sign them or will sign anything that is handed to them.

Response: We have substantially revised the current Important Message from Medicare based on plain language guidance and CMS guidance for beneficiary materials in general (such as on notice length, font size, and delivery procedures). In addition, the revised notice has been successfully consumer tested and revised based on the results of that testing. Thus, we believe beneficiary comprehension should be significantly improved.

Burden

Comment: Several commenters stated that the time estimate for delivery of the IM, an average of 12 minutes, is too low considering the potential coordination issues that may exist among various hospital departments and the fact that hospitals may have to contact a representative to explain the notice. Commenters also objected to the 3-minute estimate for delivery of the follow-up copy, when necessary.

Response: We believe that the 12-minute time estimate for IM delivery accurately reflects the <u>average</u> amount of time needed to deliver the notice. We note that this estimate represents an 11-minute increase over the estimated

time for delivery of the current IM. We expect that some beneficiaries will be able to read the notice easily and others will need more time and assistance. However, we have revised the estimated time needed for delivery of the follow-up signed copy of the IM, which may be required for longer hospital stays. Our initial average of 3 minutes has been increased to an average of 5 minutes. Delivery of the follow up copy essentially involves a review of information received at or near admission.

Comment: Several commenters stated that the estimates for the anticipated number of appeals were too low.

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.

Comment: A few commenters asked that we delay the implementation date and conduct a pilot.

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 is appropriate or necessary. Instead, we are providing ample opportunity for public input on the notices through the PRA process and we are undertaking consumer testing of the notices prior to implementation of the new process.

Comment: One commenter requested clarification on the expectations regarding methods for QIOs to accept beneficiary requests (e.g., voice mail, fax, email). Another

commenter stated that QIOs would need weekend coverage with the new process. Another commenter asked that we reconsider the requirement that QIOs will make a determination within one day after it receives all necessary information.

Response: QIOs need to have processes in place to accept requests for appeals 7 days per week during normal business hours as well as after business hours. QIOs already accept requests, and should have processes in place to receive requests, 7 days per week from non-hospital providers. The regulatory requirement in the final rule, CMS-4105-F, states that the QIO will make a determination within one calendar day after it receives all necessary information. This is essentially the same as existing 405.1206(e)(5)(i) which says that when a beneficiary makes a timely request, the QIO will make a determination and notify all parties by close of business of the first working day after it receives all requested pertinent information.