CMS Response to OMB regarding CMS-R-193
May 15, 2007

The following is a list of comments received following the 30-day comment period on CMS-R-193 (the Important Message from Medicare (IM)). This notice is associated with CMS 4105-F, the final rule on notification of hospital discharge appeal rights. In total, we received 46 timely comments on this notice and the Detailed Notice (CMS 10066); however two sets of comments appear to be in reference to the proposed rule (CMS-4105-P) that was published in April 2006.

Delay Implementation Date

Comment: Several commenters said that since CMS does not anticipate having the notices and instructions finalized before the end of May, hospitals will have insufficient time to print the notices, prepare internal policies and instructions, make significant changes to electronic record processes, and train staff. Commenters requested that hospitals be allowed at least 60 days minimum before they are expected to implement the new requirements.

Response: Final regulations established the implementation date as July 1, 2007. We have no discretion to delay this effective date, particularly given that the implementation schedule is closely tied to the Weichardt v. Leavitt lawsuit. The final rule was published in November 2006, so providers have been on notice about the new notice delivery process for almost 6 months. Although the IM and Detailed Notice are not available for pre-printing, hospitals can and should be training staff on the new process as described in the final rule. We anticipate that the notices will be available in late May, which will allow nearly 40 days before required implementation.

Burden

Comment: The majority of commenters believed the revised burden estimate associated with the notices is still conservative and does not reflect the higher wages of case managers, printing and copying costs, training, etc. Many commenters recommended that CMS either delay and reconsider these requirements or perform an evaluation after the first year to determine whether the new process has yielded sufficient benefit to warrant the increase in administrative costs.

Response: Although many commenters took issue with our burden estimate, no one suggested an alternate method of calculating the burden. Therefore, we continue to believe the burden estimate is reasonable. We do plan on monitoring the QIO review rate in the same way we are currently monitoring the number of expedited reviews performed by QIOs.

Comment: Several commenters repeated concerns about bed capacity issues, ability to treat patients waiting in the Emergency Department, and increased burden on small hospitals and rural hospitals that may not have the staff to track timely delivery of the notices.

Response: The right to request QIO review of discharge decisions is a longstanding statutory right, as is the requirement that hospitals are responsible for delivering the IM to inpatients. In this new process, we have made every effort to minimize the burden on providers by allowing hospitals to deliver the initial IM within (2) days of admission and the follow-up copy as much as (2) calendar days in advance of discharge. We have also given providers the flexibility to determine how the notice is delivered and tracked. Finally, as we pointed out in the final rule, most patients who are being discharged are eager to leave the hospital and are not looking to use this process to extend their hospital stay.

Comment: One commenter was concerned about how length of stay (LOS) participation requirements related to Critical Access Hospitals (CAHs) will be addressed. Can CAHs report additional days a patient may stay for the review in a different way? Can QIOs turn around the decisions more quickly? Another commenter said that CAH's should be exempt from the follow-up copy because their LOS is 3 days.

Response: How CAHs may report the additional days patients spend in a facility while the QIO is performing its review, is beyond the scope of this rule and needs to be settled by CMS payment policy staff. However, we did ask the policy staff for a preliminary response, and they noted that CAHs will most likely be permitted to report these additional days separately from the rest of the inpatient stay.

Although we are not going to exempt CAHs from delivering the follow-up copy of the signed IM, the final rule provides that if the initial copy of the IM is delivered within (2) calendar days of discharge, a hospital is not required to provide a follow-up copy of the signed IM.

Comment: A few commenters stated that CMS should bear some responsibility in educating beneficiaries about their rights before they get to the hospital.

Response: We fully agree and note that CMS does inform Medicare beneficiaries of their right to request QIO review of inpatient hospital discharge decisions through annual publications such as, "Medicare & You" and "Your Rights and Protections". Managed care enrollees will also receive information about this new process in the Explanation of Coverage (EOC) sent by plans at the start of the plan year.

Delivery of the IM

Comment: Several commenters suggested we allow provision and explanation of the initial notice during preadmission testing and registration. Commenters also suggested we provide some flexibility on the timing of the first notice to allow for late Friday and Saturday admissions. These commenters suggested that delivery of the notices on weekends will be difficult because many hospitals do not have case managers or discharge planners on staff to deliver the notices or handle questions related to the appeal process.

Response: The overarching goal of the new notice delivery process is to ensure delivery of the IM as close as possible to the time the beneficiary would need to act on the information. We recognize that hospitals need some flexibility in determining how best to meet this goal within their existing processes. Thus, the final regulation requires delivery of the initial copy of the IM at or near admission, but no more than (2) calendar days after admission and delivery of the follow-up copy of the signed IM as close to discharge as possible, but no more than (2) calendar days in advance of discharge.

We agree with commenters that giving the IM to patients during the preadmission process may afford them a better opportunity for explaining the notice to patient. Accordingly, providers may give the IM to patients as part of the preadmission process, but not more than (7) calendar days in advance of admission. This policy strikes a balance between beneficiaries' need to receive timely notification of their appeal rights and providers' need for flexibility in providing these notices to patients.

Delivery of the Follow-Up Copy

Comment: The majority of commenters recommend that the follow up copy not be required, stating that it is unnecessary and burdensome. If this is not possible, they requested that providers be allowed to deliver the notice on the day of discharge. They also recommended that we clarify that hospitals could meet the requirement for a follow-up copy by providing the generic information on page 2 of the IM or another unsigned IM, or by delivering another IM and obtaining the patient's signature.

Response: As noted previously, we have given hospitals a significant amount of flexibility in determining how the initial and follow-up copies of the IM are delivered. If hospitals cannot anticipate the discharge, the final rule permits delivery of the follow-up copy on the day of discharge. Hospitals may not however, have policies that allow routine delivery of the follow-up copy of the notice on the day of discharge, since such a policy would inappropriately limit patients' ability to fully consider their discharge appeal rights.

We do not think it is appropriate to allow providers to issue only page 2 of the IM or an unsigned copy of the IM in place of issuing a copy of the signed IM at discharge. However, it is reasonable and consistent with the regulations to allow hospitals to deliver a new IM at discharge and obtain the patient's signature on that new notice. To the extent that hospitals choose to use this means of delivering the follow-up copy of the IM, we note that this would address concerns by some commenters, including the Center for Medicare Advocacy, that we require a patient signature on the follow-up copy.

Comment: Two advocacy groups suggested we ensure timely delivery of the second Important Message to afford patients the opportunity to exercise their appeal rights.

Because there is no deadline for delivering the follow-up copy, they believe that many patients could receive it too late or as they are packing to leave or being wheeled out the door.

These advocacy groups suggested we require a signature with date and time of delivery of the follow-up copy in order for CMS to monitor when the notices are actually given. Also, they recommended that CMS devise a standard to measure whether the notices are actually delivered "as far in advance of discharge as possible"; that all beneficiaries receive the notice on the day before discharge unless specific, identified information is not available; and that if notices are delivered on the day of discharge, beneficiaries be given at least 5 hours to consider their rights. These commenters also recommended that CMS specifically prohibit hospitals from adopting a blanket policy of delivering the notices on the day of discharge.

Response: CMS is aware of the possibility that patients who receive the notice on the day of discharge may not be given enough time to consider their rights. We will clarify that hospitals must allow beneficiaries at least four hours to consider their rights, if the notice is delivered on the day of discharge. As noted above, hospitals may not develop policies that allow for routine delivery of the notices to all beneficiaries on the day of discharge.

We do not believe that devising a standard that requires delivery of the notice on the day before discharge is reasonable. This was our approach in the proposed rule and we changed it because we concluded, based on the comments we received, that in the hospital setting where the patients are acutely ill and their status is constantly changing, it is too difficult to predict a discharge in advance. Hospitals must be able to document delivery of the follow-up copy of the notice and may do so within existing hospital processes. We do not believe that documentation of the time the follow-up copy is delivered will assist us in monitoring whether the hospital allowed the beneficiary sufficient time to consider their appeal rights because once the notice is issued and a patient is discharged, he/she may leave the hospital at any time.

Notice Delivery to Representatives

Comment: Commenters requested that CMS provide latitude to hospitals in how they provide the notice to beneficiary representatives if the beneficiary is unable to receive the notice. In addition, they requested further clarification on what to do if no representative is in place. One commenter asked if documentation of unsuccessful efforts to reach a representative would be acceptable, since it is often difficult to reach representatives.

Response: This new notice delivery process does not alter the rules regarding representation of beneficiaries. In general, hospitals should follow state or other applicable laws in determining who can act as a representative for an incapacitated or incompetent beneficiary.

Longstanding CMS policy allows beneficiary notices to be delivered to representatives in a variety of ways, including telephone delivery. Telephone notification, must be

followed immediately by mailing, faxing or emailing the notice – consistent with all HIPAA privacy and security requirements. We have also included instructions for mailing the notice, receipt requested, to document delivery to a representative who does not respond.

Translation

Comment: Several commenters suggested we translate the notices into the15 languages that hospitals frequently encounter; a few others requested Spanish specifically.

Response: At this time, the notices will only be translated into Spanish. For non-English speaking patients, the IM is just one of any number of notices and other information that must be communicated by the hospital. Thus, the IM should be provided in the same way other hospital forms and notices are provided to non-English speaking patients.

Notice language

Comment: The Center for Medicare Advocacy suggested changing the title of the notice to "An Important Message From Medicare about Your Inpatient and Discharge Rights".

Response: We did not make this change because the current notice title, "An Important Message from Medicare About Your Rights" was developed based on specific wording changes suggested during consumer testing. Also, the notice does include a prominent section heading titled "Your Medicare Discharge Rights" in bold, capital letters.

Comment: Three advocacy groups, including the Center for Medicare Advocacy, recommended removing the bullet that says: "If you do not believe you have enough time to act on your rights, call 1-800-Medicare" since those operators to not have authority to extend the deadline for patients, nor the authority to intervene. Another provider recommended we remove or revise the bullet since we are adding instructions that hospitals must give beneficiaries several hours to consider their rights if they receive the notice on the day of discharge. This provider believed that the bullet could cause unnecessary confusion for beneficiaries about who they should go to about the appeals process.

Response: As suggested, we have removed this bullet from the IM.

Comment: Some commenters requested that we replace the term "Attending Physician" with "Physician" because often the attending physician is not known at the time of an emergency admission. (The IM and Detailed Notice both have a blank for insertion of the name of the "Attending Physician") Additionally, the attending physician is not always the physician who writes the discharge order.

Response: We agree and have removed the word "Attending" from the physician blank on the IM and Detailed Notice.

Comment: Add more space under the signature line to document refusals to accept and/or sign the IM. Move the "Additional Information" section to the first page.

Response: We have revise the form instructions to state that the "Additional Information" space on page 2 of the IM can be used to document a patient's refusal to sign or accept the IM, or alternatively, providers may attach an additional sheet of paper to the notice for this purpose.

Comment: Bold the deadline for requesting a review.

Response: We agree and have bolded the text.

Comment: Add a bullet alerting beneficiaries that they will get a follow-up copy of the IM.

Response: We did not accept this comment because not all beneficiaries will receive a follow-up copy of the signed IM. For example, if a patient receives the initial copy of the IM within (2) calendar days of discharge, hospitals are not required to provide a follow-up copy of the IM at discharge.

Comment: Add hospital provider name and provider ID to the IM.

Response: This is a good suggestion that will benefit both patients and QIOs, and will be easy for hospitals to preprint. The IM and the corresponding instructions have been revised to include this new field.

Comment: One commenter requested that CMS allow the form to be modified in terms of formatting and spacing, so that the form will be compatible with electronic records.

Response: As with other standardized CMS forms, users who are downloading the form and filling it out should not alter the format of the document, but may adjust the spacing, by printing it on legal-size paper. Hospitals that are integrating the form into their automated processes however, may make minor modifications, beyond printing on legal-sized paper, that are consistent with existing CMS guidance.

Comment: One commenter asked that we clarify the liability language on the notices regarding timing of the appeal and charges/liability.

Response: We are not making any changes based on this comment because the commenter seems to have a fundamental misunderstanding of the process. Many other commenters, including the advocacy groups, said the notices overall are clearer and more understandable, particularly the description of rights and liability language on the notice.