CMS Response to OMB regarding CMS 10066
May 15, 2007

The following is a list of comments received following the 30-day comment period on CMS 10066 (the Detailed Notice). 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 Important Message from Medicare (CMS-R-193); 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.

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

We received a substantial number of comments on the Detailed Notice of Discharge. This notice went through its 60-day comment period in April 2006, when the proposed regulation was published. Only a few comments were received at that time. The 30-day comment period was the first opportunity for the public to view and comment on this notice in light of the final rule.

Comment: One large hospital association recommended another comment period to review the Detailed Notice.

Response: A third comment period is not necessary. There has already been ample opportunity for public comment on the Detailed Notice via the 60-day and 30-day comment periods.

Comment: A large case management association suggested we rewrite the first paragraph on the notice to read: "…based on Medicare coverage policies, and in the medical judgment of your physician, with the agreement of the hospital (and your managed care plan, if you belong to one) that you no longer need to be in the hospital…" Another commenter said that instead of saying that the discharge decision was made based on medical judgment – state that it was made based on "your doctor's" medical judgment.

Response: We think that these are largely helpful changes and have incorporated a slightly modified version of this language into the first paragraph of the Detailed Notice.

Comment: Several commenters suggested we change the first bullet regarding "facts used to make this decision" to "Your hospital and physician believe you are ready to leave the hospital based on your current clinical condition, as described here."

Response: We agree with the recommended change and have added the words "medical condition" to the relevant section of the notice.

Comment: Several commenters suggested we revise the bullet that begins, "Explanation of Medicare coverage policies that we used to determine Medicare will no longer cover your hospital stay." These commenters discussed the difficulty hospital staff, who may not be familiar with these policies, will have in locating all specific Medicare coverage policies. Some asked how much detail was required in the explanation and suggested we allow hospitals to use certain discharge criteria that are used by hospitals to monitor readiness for discharge, such as InterQual criteria. These criteria can be technical and don't necessarily lend themselves to plain language. Some commenters suggested we preprint information in this section similar to language used on other hospital issued notices – "You can safely receive care in another setting, the care you need now is considered custodial care". Commenters also suggested hospitals be allowed to customize the form to have a menu of coverage policies with an area for narrative notes. Other commenters asked that we combine Medicare coverage guidelines with the third bullet about Medicare managed care policies.

Response: We agree this bullet should be revised. Commenters are correct that general Medicare coverage guidelines applicable to hospitals (at 42 CFR 411.15) refer to services that are custodial in nature and services that are not reasonable and necessary. Accordingly, we have revised this bullet to incorporate this regulatory language and instruct hospitals and plans to fill in the detailed and specific reasons why services are no longer reasonable or necessary for the beneficiary or no longer covered according to Medicare coverage guidelines.

Comment: Several commenters suggested we send the beneficiaries to 1-800-Medicare for copies of Medicare coverage policies.

Response: Hospitals are responsible for providing beneficiaries with information about the Medicare coverage policies they use to make discharge decisions. Hospitals may preprint some of these policies on the Detailed Notice and/or attach InterQual or similar criteria when additional information is requested.

Comment: Several commenters suggested that the beneficiaries go to the QIO for copies of the documents sent by the hospital. These commenters said that this was a burden to hospitals and one commenter asked if the hospital would have to sign a release to give the patient a copy of the records.

Response: We disagree with the commenter's suggestion. The regulation explicitly requires hospital to provide patients with a copy of the documents it sends to the QIO. This new process does not create any new requirements regarding disclosing protected

health information. Thus, hospitals should continue following their existing processes for sharing of health records.

Comment: Several commenters suggested that we add more information to the Detailed Notice about the QIO and its role in the process.

Response: Although the IM already includes a detailed description of the QIO, we have revised the Detailed Notice to include some of this information as well.

Comment: A few commenters suggested we add language that the beneficiary will receive a prompt decision and that he or she will receive the best, most appropriate care available.

Response: We do not believe this language is necessary. The final rule already requires the QIO to issue a decision within (1) calendar day of receiving all the necessary information.

Comment: One commenter asked that we require that the information inserted on the notice be legible.

Response: We agree. This is a longstanding CMS policy regarding beneficiary notices and is in the manual instructions. The instructions for the IM and Detailed Notice have now been revised to include this requirement as well.

Comment: Several commenters requested that we add a signature and date line to the bottom of the notice and remove "date issued" from the top of the notice.

Response: We are not revising the notices based on this comment because we do not agree that a dated signature is necessary on the Detailed Notice.