

contracts with providers to incorporate these requirements, citing that the change in the conditions of participation at § 489.27(b) should be sufficient to ensure compliance.

Response: We agree that the change in conditions of participation at § 489.27(b) is sufficient to ensure that providers comply with the notice requirements at § 422.624. Although we believe that it would be in the best interests of providers and M+C organizations to include these notice requirements in their contracts, we do not intend to require that providers and M+C organizations renegotiate their contracts solely for the purpose of including a clause regarding notice delivery requirements. Therefore we have removed proposed § 422.502(i)(3)(iv).

Comment: One commenter wanted to know if M+C organizations could charge enrollees a reasonable flat fee for the costs of duplicating and mailing case files to enrollees upon request.

Response: In accordance with the Privacy Act and 45 CFR 5b.13, “[f]ees may only be charged where an individual requests that a copy be made of the record to which he is granted access.” No fee is permissible unless the copying costs are at least \$25. Thus, an M+C organization may not charge a fixed fee for the costs of duplicating and mailing case files to enrollees, but may apply the fee schedule outlined in § 5b.13(b). This would allow an M+C organization to charge \$.10 per page for photocopied records above the \$25 threshold, or the actual cost determined on a case-by-case basis for records not susceptible to photocopying.

Comment: One commenter noted that the proposed rule was silent on the type of entity that could serve as an IRE. The commenter (an organization representing Quality Improvement Organizations) recommended that QIOs should be designated as IREs since QIOs already interact on a daily basis with families who question whether the timing of a provider discharge is appropriate. The commenter indicated that relying on an entity other than QIOs would be confusing to enrollees. The commenter recommended that CMS change all references from IRE to QIO so that CMS would not have to develop and maintain a costly and unnecessary contractual and regulatory structure that duplicates the QIO program.

Response: Although we recognize that QIOs have experience with making similar determinations, we do not believe that it is appropriate to designate in a final rule that QIOs will carry out the fast-track reviews. We are still evaluating whether these reviews are more appropriately accomplished

through a single IRE, or multiple entities, as well as the extent to which these procedures can be linked with expedited reviews required under the new BIPA provisions. There are various independent entities, including QIOs, which already have contractual relationships with CMS to make coverage decisions. As we attempt to develop improved, more efficient appeals procedures under both M+C and original Medicare, CMS will determine whether it is prudent to use these existing contractors to fulfill the requirements of this regulation, or whether it is necessary to seek bids for this important work.

Comment: One commenter expressed concern that the proposed rule did not require that IRE reviewers include clinicians or practicing physicians. The commenter also believed that a reviewer should have a background in the specialty or subspecialty relevant to the case.

Response: The regulations at §§ 422.624 and 626 are part of the overall M+C appeals process under subpart M. These fast-track reviews effectively replace M+C organization’s reconsiderations on SNF, HHA, and CORF termination cases. Thus, similar to the requirement under § 422.590(g)(2) for reconsideration decisions by M+C organizations, we intend to require through our contract with the IRE(s) that decisions involving denial of coverage based on a lack of medical necessity “must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.”

C. Hospital Discharge Notices (§§ 422.620 and 489.27)

Comment: Many commenters strongly opposed the proposed requirements under 422.620 and 489.27 that hospitals issue a standardized notice of appeal rights for a second time on the day before discharge to all Medicare beneficiaries, including those that are enrolled in a Medicare managed care health plan. They believe that this requirement poses a significant administrative burden in both delivering and explaining the form and takes away from time better spent on providing services and discharge planning. They contend that the notice is unnecessary in either the managed care or fee-for-service context and indicated that, in many cases, beneficiaries are confused by the notice. One commenter stated that after the enactment in 1998 of the requirement

under 422.620 that all M+C enrollees receive discharge notices the day before the end of their hospital stay, the Quality Improvement Organizations (QIO) received many phone calls from confused beneficiaries not understanding the notice. The commenters believe that very few beneficiaries have any interest in disputing their hospital discharges and thus the cons of this requirement far outweigh any benefits.

Two commenters supported the proposal that hospitals issue notices, both near admission and the day before discharge, to all Medicare beneficiaries. They supported CMS’s efforts to combine the Important Message from Medicare (IM) with the Notice of Discharge & Medicare Appeals Rights (NODMAR), and Hospital Issued Notice of Noncoverage (HINN). The commenters found the notices largely duplicative and welcomed the simple one page document. (Please note that since the publication of the proposed rule, the required notices and the distribution process have also been the subject of public comment through the Office of Management and Budget (OMB) approval process required under section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA).)

Response: After careful consideration of the public comments on these requirements, the many comments received on the notices themselves through the PRA process, and evaluation of CMS data on the hospital discharge appeals process, we are convinced that changes are needed in the proposed notice requirements. Consistent with the notice requirements discussed above for other provider termination situations, we are revising 422.620 to eliminate the requirement that hospitals provide a written notice of noncoverage to each M+C enrollee the day before discharge. Section 489.27 will continue to require that hospitals furnish the Important Message from Medicare, which explains a beneficiary’s appeal rights to every Medicare inpatient during their stay, but will not specify that the notice be delivered the day before discharge.

We continue to strongly believe that all beneficiaries need to be informed of their Medicare appeal rights when admitted as inpatients to hospitals, and this will continue to take place in compliance with section 1866(a)(1)(M) of the Act. However, we have reached the conclusion that requiring that this notice in effect be delivered twice, once upon admission and again before discharge, would be an unnecessarily burdensome requirement on hospitals. We have reviewed data from the QIOs