PRIOR DETERMINATIONS: HOW HELPFUL WILL THEY BE?

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Introduction

On February 22, 2008, the Centers for Medicare and Medicaid Services ("CMS") published the Final Rule on "Prior Determination for Certain Items and Services" (the "Final Rule").[1] The Prior Determination process is being developed pursuant to an instruction contained in Section 938 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA").[2] The Final Rule follows a Proposed Rule which was published on August 30, 2005[3], in response to which CMS received seven timely comments.[4] Commenters expressed many valid concerns regarding the limited usefulness of the proposed process, including the limited number of "eligible services" for which requests can be made, the lengthy timeframe for processing such requests, and the exclusion of services with a National or Local Coverage Determination from the process. Unfortunately, CMS did little to address these concerns and thus, the Final Rule is substantially unchanged.

Background

The ABN Process

In order to fully understand the potential value of an effective prior determination process, it is helpful to review the Medicare program's "reasonable and necessary" criteria as well as its Advance Beneficiary Notice ("ABN") provisions.

Pursuant to Section 1862 of the Social Security Act, Medicare only pays for services that are deemed to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[5] Subject to two exceptions, a provider is financially liable for services that a CMS contractor determines were not "reasonable and necessary."[6] The first exception exists where the provider did not know or could not have reasonably known that the service would not be covered.[7] The second exception occurs where the provider gives the beneficiary an "Advance Beneficiary Notice" or "ABN" before performing the service or procedure.[8] To be accepted as proof of prior notice to the beneficiary, an ABN must be in a form approved by CMS and must include a description of the particular service or services for which payment is likely to be denied, as well as the physician's reasons for believing the Medicare payment will be denied.[9] Thus, if a provider has any doubt about coverage, it may be in his or her best interest to give the patient an ABN, even though it might deter the patient from going forward with the service. Likewise, a beneficiary who receives an ABN is faced with the difficult task of deciding whether to have the procedure, knowing that he or she may end up paying out of pocket if Medicare denies the claim.

In order to eliminate some of the provider's and beneficary's uncertainty under the ABN process, Congress enacted Section 938 of the MMA, amending Section 1869 of the Social Security Act (the "Act") to require the Secretary of CMS to establish a "prior determination process" to be followed by CMS contractors.[10]

Prior Determinations

A "prior determination," as defined by the Final Rule, is "an individual decision by a Medicare contractor, before a physician's service is furnished, as to whether or not the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity."

The stated goal of the prior determinations process is to "give beneficiaries and doctors a process to find out with greater certainty whether an item or service will be considered reasonable and necessary."

Summary of the Final Rule

Procedure in General

The Final Rule provides that Medicare contractors will allow requests for prior determinations of medical necessity from "eligible requestors" in accordance with physician services established in the CMS manual system.[11] Requests for prior determinations may only be made for physicians' services and surgeries that are included on one of two national lists that will be developed by CMS and posted on the Medicare contractors' websites.[12] CMS may require that a request be accompanied by a description of the physician's service, supporting documentation related to the medical necessity of the service, and other appropriate documentation.[13]

Eligible Requestors

Either a physician or a beneficiary may make a request for a prior determination if certain conditions are met. A physician may request a prior determination for a beneficiary, so long as the beneficiary is entitled to receive the services and the beneficiary consents to the request.[14] A beneficiary may make a request for a prior determination only after receiving an ABN.[15]

Eligible Services

The first national list of services for which prior determinations may be requested will consist of the most expensive physicians' services that are included in the Medicare physician fee scheduled and are performed across the country at least fifty times annually.[16] The exact number of services that will be included on the list will be communi-

cated by CMS through manual instructions and adjusted as CMS deems necessary.[17] In the Proposed Rule, certain physician services meeting these criteria would have been excluded from the list if they were addressed by a local or national coverage determination ("LCD" or "NCD") deemed by CMS to contain "sufficiently specific reasonable and necessary criteria to permit the beneficiary or physician to know whether the service is covered without a prior determination."[18] In the Final Rule, these services will not be removed from the list. However, Medicare contractors may respond to a request for prior determination simply by sending the requestor a copy of the LCD or NCD if the Medicare contractor determines that the LCD or NCD contains "specific reasonable and necessary criteria addressing the particular clinical indication for the procedure."[19]

The second national list will consist of plastic and dental surgeries that may be covered by Medicare with a fee of at least $1,000 on the physician fee schedule (not including adjustments for location).[20]

The lists will be disseminated on the contractors' websites and, in response to commenters' concerns, CMS also stated in the Final Rule that it would look at additional ways to disseminate the information to both providers and beneficiaries.[21]

Processing Timeframe

A contractor must notify the requester of its decision within 45 days from the date it received the prior determination request.[22] However, neither the Final Rule nor the statute imposes a penalty for noncompliance with this deadline.

In response to commenters' concerns that the 45 day timeframe is too long to be of any help to either providers or beneficiaries, CMS stated that the contractors would be instructed to process requests "as quickly as possible, taking into consideration the beneficiary's physical condition, the urgency of the treatment, and the availability of necessary documentation."[23]

Response and Effect of Decisions

The contractor's response must include notification that the service is covered, that the service is not covered, or that the contractor lacks sufficient information to make a coverage determination.[24] If the contractor states that more information is needed, it must also include a description of the additional information that is required to make the decision.[25]

A determination of coverage is binding. The contractor cannot later change its coverage determination unless there is evidence of fraud or misrepresentation of facts.[26] If a beneficiary or provider receives a negative determination, or chooses not to seek a prior determination, the beneficiary is not precluded from later appealing a denial through the Medicare appeals process.[27]

Criticisms of the Proposed Rule and CMS' Response

Diminutive List of Physician Services

In the Proposed Rule, CMS projected that the initial list of physician services would most likely include fewer than fifty procedure codes because of the exclusion of services with "adequate" NCD or LCD determinations as discussed above.[28] However, CMS left the door open for the expansion of the list if the need should arise.[29] Commenters expressed concern that the initial list should be expanded, or should include all services above a certain dollar amount or services with a high denial rate.[30] In response to the general concerns that the list represented too few physician services, CMS added a provision to the Final Rule that would allow CMS to expand or contract the number of services eligible for prior determination through manual instructions.[31] CMS refused to consider including all claims above a certain dollar amount because administrative constraints require that they control the number of eligible services and a monetary cut-off would lead to uncertainty as inflation increases the cost of services.[32] Finally, the use of denial rates as a criterion for inclusion was rejected because denial rates vary from contractor to contractor and a high denial rate may be insignificant if the procedure is performed very infrequently.[33]

The result of this very limited list of physician services is that very few Medicare beneficiaries will actually submit a request for prior determination. In fact, by CMS' own estimates, only 5,000 requests will be made on an annual basis.[34] In light of the fact that there are over 44 million Medicare beneficiaries, this number is quite insignificant.[35]

Time Frame Diminishes Usefulness

The length of time it may take to obtain a prior determination decision may deter people from making a request. It will likely take some time for beneficiaries and/or their physicians to compile the information necessary to make a request in accordance with the contractors' instructions, since documentation supporting medical necessity may be required. While the contractor is supposed to act on the request within 45 days of receipt, there are no penalties or consequences for failing to comply with the timeframes. Even if the contractor responds within the deadline, 45 days can be a very long time for a beneficiary who is in need of anything other than a cosmetic type of procedure. Also, as discussed previously, the contractor may respond with a request for more information, rather than a decision.

Ability of Contractors to Use LCD or NCD as Prior Determination Decision Diminishes Usefulness Process

If an LCD or NCD provides "sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the physician's service for

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which the prior determination is requested," the LCD or NCD will serve as the prior determination.[36] No further explanation is necessary.

The determination as to whether a particular LCD or NCD is "sufficiently specific" will be left to the discretion of the contractors.[37] In light of the fact that sending a copy of the LCD or NCD involves substantially less work than an individual analysis of a specific clinical situation, there is an incentive for contractors to exercise this discretion.

In some cases, it may be that the provider or beneficiary did not know of the existence of a particular LCD or NCD, and in those situations the response will be helpful. However, where the provider or beneficiary is seeking clarification or interpretation of the LCD or NCD, as they apply to a particular condition, a copy of the document without further explanation or interpretation will not likely be useful or helpful.

Conclusion

Because of the various components of this process that require an exercise of discretion on the part of CMS and the Medicare contractors, the eventual usefulness of the process will likely be determined by CMS's willingness to expand the lists of eligible services as necessary and the actual response times of the contractors. Although the Final Rule was effective March 24, 2008, contractors have not yet received final instructions for handling requests for prior determinations and no timeframe has been set for the publication of final instructions[38]. Thus it will be some time before the effectiveness of the process in practice can be determined.

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Endnotes

1 73 Fed. Reg. 9672 (2008).

2 Pub.L. No. 108-173 (2003).

3 70 Fed. Reg. 51321 (2005).

4 73 Fed. Reg. 9672 (2008).

5 42 CFR §411.15 (k) (2008).

6 42 CFR §411.408(a)(2008).

7 42 CFR §411.408 (d)(1)(2008); *See also* 42 CFR §411.406 which sets forth the criteria for establishing that the provider or beneficiary had knowledge or should have known that the service was not "reasonable and necessary," including (1) Notice from a CMS contractor; (2) Notice from a utilization review committee or the beneficiary's attending physician; (3) Notice from the provider, practitioner or supplier to the beneficiary; and (4) Knowledge based on experience, actual notice or constructive notice.

8 42 CFR §411.408 (d)(2)(2008).

9 42 CFR §411.408 (f) (2008).

10 Pub.L. No. 108-173 (2003).

11 42 CFR §410.20(d)(2) (2008).

12 42 CFR §410.20(d)(2)(i) (2008).

13 42 CFR §410.20(d)(5)(i)(b) (2008).

14 42 CFR §410.20(d)(1)(ii)(A) (2008).

15 42 CFR §410.20(d)(1)(ii)(B)(2008).

16 42 CFR §410.20(d)(2)(i)(2008).

17 42 CFR §410.20(d)(4) (2008); 73 Fed. Reg. 9676 (2008).

18 70 Fed. Reg. 51323 (2005).

19 42 CFR §410.20(d)(3) (2008); 73 Fed. Reg. 9674 (2008).

20 42 CFR §410.20(d)(2)(ii) (2008).

21 73 Fed. Reg. 9675 (2008).

22 42 CFR §410.20(d)(5)(ii)(C)(2008).

23 73 Fed. Reg. 9674 (2008).

24 42 CFR §410.20 (d)(5)(ii)(A) (2008).

25 42 CFR §410.20 (d)(5)(ii)(B) (2008).

26 42 CFR §410.20(d)(5)(iii)(2008).

27 42 CFR §410.20(d)(5)(iv)(B) (2008).

[28] 70 Fed. Reg. 51323 (2005).

[29] 70 Fed. Reg. 51323 (2005).

[30] 73 Fed. Reg. 9674 (2008).

[31] 73 Fed. Reg. 9674 (2008); 42 CFR §410.20 (d)(4) (2008).

[32] 73 Fed. Reg. 9674 (2008).

[33] 73 Fed. Reg. 9676 (2008).

[34] 73 Fed. Reg. 9677 (2008).

[35] CMS Medicare Overview located at: http://www.cms.CMS.gov/ReportsTrustFunds/

[36] 42 CFR §410.20(d)(3) (2008).

[37] 73 Fed. Reg. 9674 (2008).

[38] Information obtained through e-mail communication with Debbie Skinner of CMS, April 29, 2008.