American Academy of Family Physicians

OCT 19 2005

October 4, 2005

Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6024-P
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan:

I am writing on behalf of the American Academy of Family Physicians, which represents more than 94,000 family physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed rule on "Prior Determination for Certain Items and Services" under the Medicare program, as published in the *Federal Register* on August 30, 2005.

Background

As noted in the proposed rule, Medicare beneficiaries can currently find out whether or not items or services are generally covered. However, when there is a question of whether Medicare will cover a specific item or service for a particular beneficiary under specific circumstances, there currently exists no process by which the beneficiary or his or her physician can find out if that item or service would be considered reasonable and necessary for that beneficiary before incurring financial liability.

To address this issue, section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Secretary to establish a process whereby eligible requesters may submit to the Medicare contractor a request for a determination, before the furnishing of the physician's service, as to whether the physician's service is covered consistent with the applicable requirements of section 1862(a)(1)(A) of the Social Security Act (relating to medical necessity). This MMA section also provides that an eligible requester is either:

- a participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits and who has consented to the physician making the request for those services; or
- an individual entitled to benefits, but only with respect to a physician's service for which the individual receives an advance beneficiary notice.

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Requesting a prior determination under this proposed process is at the discretion of the eligible beneficiary or physician, and prior determination of coverage is not required for submission of a claim. The proposed rule establishes reasonable limits on the physicians' services for which a prior determination of coverage may be requested (as allowed for in MMA section 938) and discusses generally CMS's plans for establishing the process by which eligible requesters may obtain prior determinations. CMS indicates that the procedures that Medicare contractors would use to make the prior determinations would be established in CMS's manuals, rather than by regulation.

Provisions of the Proposed Rule

Section 1869(h)(2) of the Social Security Act, as added by section 938 of the MMA, requires the Secretary to establish by regulation reasonable limits on the physicians' services for which a prior determination may be requested. This section provides that in establishing the reasonable limits, the Secretary may consider "the dollar amount involved with respect to the physician's service, administrative costs and burdens, and other relevant factors."

In response CMS proposes to establish an initial pool of eligible physicians' services comprised of at least those 50 services with the highest allowed average charges that are performed at least 50 times annually. CMS proposes to exclude from this initial pool any services for which a national or local coverage determination exists that, based on CMS' judgment, has sufficiently specific reasonable and necessary criteria to permit the beneficiary or physician to know whether the service is covered without a prior determination. In addition, CMS proposes to allow prior determination for plastic and covered dental surgeries that may be covered by Medicare and that have an average allowed charge of at least $1,000. CMS proposes to update the list annually.

CMS's rationale for this proposal is threefold:

- Beneficiaries are more likely to be discouraged from obtaining the most expensive physicians' services because they are uncertain whether or not they would have to incur financial liability if Medicare does not pay for the service. The plastic and dental surgeries included are also relatively expensive, and there may be significant individual considerations in determining what is covered and what is excluded.
- The majority of these services tend to be non-emergency surgical procedures generally performed in an inpatient setting. Since these services are not typically emergency services, beneficiaries would have adequate time to request a prior determination.
- Limiting prior determinations to these services is reasonable given the administrative cost to process each prior determination request.

We appreciate the need for CMS to consider administrative costs and other factors in setting "reasonable limits" on the physicians' services for which a prior determination may be requested. However, we believe CMS has erred on the side of being too restrictive in setting the initial pool of eligible services. Evidence of just how restrictive CMS proposes to be is found in both the number of services in the initial pool and in CMS's estimate of the number of prior determination requests it expects to receive on annual basis. As noted, the initial pool of eligible services would include approximately 50 services. This is less than one percent of the more than 5,000 services in the Medicare physician fee schedule. Furthermore, CMS estimates that 5,000 requests for prior determination will be made annually. Considering the hundreds of millions of physician services provided to Medicare beneficiaries annually, 5,000 is a miniscule amount.

The law allows the Secretary to consider "the dollar amount involved with respect to the physicians' service" in setting reasonable limits on the number of services eligible for redetermination. Accordingly, we think it would make more sense to include all services above a certain dollar amount (e.g., $100) (corresponding to the Medicare allowed amount) rather than limiting it to the top 50 services based on average allowed charges. We agree that beneficiaries are more likely to be discouraged from obtaining the most expensive physicians' services because they are uncertain whether or not they would have to incur financial liability if Medicare does not pay for the service. However, this does not mean that they will not be discouraged from obtaining other services for the same reason. Many Medicare beneficiaries have limited financial means or are on fixed incomes. As such, we suspect that they are much more price sensitive than CMS's proposal suggests.

We also think that CMS has erred in excluding those services for which a national or local coverage determination exists that, based on CMS' judgment, has sufficiently specific reasonable and necessary criteria to permit the beneficiary or physician to know whether the service is covered without a prior determination. First, from our perspective, the presumption that beneficiaries will access and understand either national or local coverage determinations is ludicrous. Second, the exclusion of such services on this basis seems contrary to the statute. We note that section 1869(h)(4)(B)(i), as added by MMA section 938 requires Medicare contractors to include "a brief explanation of the basis of the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based," when issuing notices of noncoverage in response to prior determination requests. If services with national or local coverage determinations were meant to be routinely excluded from prior determination, there would be no need to reference them in notices of noncoverage that respond to prior determination requests.

Along these lines, in the proposed rule, CMS states that it will instruct its contractors that, in cases where a prior determination is requested but a national coverage decision or local coverage decision exists, the contractor will send the beneficiary a copy of that policy along with the explanation of why a prior determination will not be made. Again, this seems contrary to section 1869(h)(4)(B)(i), which clearly seems to anticipate that the beneficiary will receive a decision based on the coverage determination rather than no decision based on the existence of such a national or local coverage decision. From our perspective, CMS should not exclude from its initial pool of services eligible for prior determination those services for which a national or local coverage determination exists, whether CMS judges the coverage determination sufficiently specific or not.

Finally, we would like to comment on the proposed timeframe for responding to prior determination requests. The statute provides that Medicare contractors must respond to prior determination requests within the same time period as the time period applicable to contractor providing notice of initial determinations on a claim for benefits. This translates into 45 days after the request is received under current Medicare rules. CMS indicates that it will instruct its contractors to process the requests as quickly as possible (but no longer than 45 days), taking into consideration the beneficiary's physical condition, the urgency of treatment, and the availability of the necessary documentation. We would hope and expect that Medicare contractors could process such requests in much less than 45 days. Assuming they have all the necessary information when the request is received, we would expect Medicare contractors to be able to respond in a matter of days, rather than weeks. This is a matter of customer service to both beneficiaries and physicians.

In summary, we believe the proposed rule effectively guts what would otherwise be a wonderful benefit to beneficiaries and their physicians by limiting its applicability in the extreme. To add insult to the injury, CMS proposes to allow beneficiaries and physicians to wait up to a month and a half for a decision on the few services it will consider for prior determination. We urge CMS to reconsider its limits on the initial pool of services eligible for prior determination and improve its customer service by requiring contractors to respond more quickly. Otherwise, this proposal will represent just another wasted opportunity as far as the Medicare program is concerned.

Thank you for the opportunity to comment on this aspect of the Medicare program.

Sincerely,

Mary E. Frank, MD

Mary E. Frank, M.D.
Board Chair

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BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

October 31, 2005

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Ms. Misty Whitaker
The Centers for Medicare & Medicaid Services
Department of Health & Human Services
File Code: CMS-6024-P
P.O. Box 8017
Baltimore, MD 21244-8017

Attention: CMS-6024-P
By Electronic Mail

Re: Comments on: Medicare Program; Prior Determination for Certain Items and Services; a Proposed Rule (CMS-6024-P).

Dear Ms. Whitaker:

The Blue Cross and Blue Shield Association ("BCBSA") appreciates the opportunity to comment on establishing a process for prior determinations of Medicare coverage (70 Fed. Reg. 51321; August 30, 2005). As you are aware, many BCBS Plans are under contract with CMS as Medicare contractors. Overall, BCBS Plans process 72 percent of Medicare's Part B claims and 88 percent of Part A claims.

BCBSA believes that many provisions of this rule, if implemented, will require new resources and processes in order to fulfill all requirements and the subsequent Change Request that would be developed by CMS for contractors. In general, BCBSA strongly recommends that CMS:

- Ensure Medicare contractors have the necessary funding to perform the new and highly labor-intensive functions outlined in the proposed rule;
- Establish a Multi-disciplinary Technical Advisory Group (TAG) to collaboratively develop the Medicare Change Request. Ideally, the TAG should consist of representatives from CMS, Fiscal Intermediaries, Part B Carriers, QIOs, Data Centers, and administrators of the Fiscal Intermediary Shared System, Multi-Carrier System, and Common Working File;
- Provide Medicare contractors with ample time to review and provide comment during the draft Change Request comment period, since a final rule would defer specific implementation provisions to CMS Manual Instructions; and
- Allow Medicare contractors sufficient time for final implementation.

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Deleted: that CMS ensures Medicare contractors have the necessary funding to perform the various new and highly labor-intensive functions contemplated in the proposed rule.

Deleted: In addition, since the proposed rule defers the bulk of its specific implementation provisions towards forthcoming CMS Manual Instructions, BCBSA also highly recommends that CMS provide Medicare contractors with ample time to review and provide comments so as to guarantee a sufficient opportunity to provide input on both the final rule and manual instructions.

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Our comments on the Proposed Rule are as follows:

1. Adequate Funding for New Processes

The following are new processes should this rule be adopted in final form and CMS subsequently issues a Change Request. These processes will have a significant impact on contractor operations and their allocated budgets:

- The implementation of a system of prior coverage determinations requires Medicare contractors to make greater use of health care professionals, such as physicians and nurses. Such persons require funding at a considerably higher level than general program staff. BCBSA is concerned that neither the "Supplementary Information" section nor the Proposed Rule discusses how CMS will allow for necessary cost adjustments to the Medicare contractor budgets for this staffing.
- Sections 410.20(d)(5)(ii)(B)(1) and 410.20(d)(5)(ii)(D) both require the Medicare contractor to send a copy of the NCD/LCD/LMRP to the beneficiary (if applicable) which will necessitate a manual (and thereby costly) process. Compliance will require additional funding for increased print and mail costs. Implementation will also result in expanded customer service operations, as beneficiaries will likely need assistance in understanding the content and implications of these coverage determinations.
- The anticipated increase in demand from beneficiaries on Medicare contractors' customer service operations will also apply to Medicare providers. We anticipate providers will ask for prior determinations to reduce their rates of denial of some services. The volume for these reviews may be relatively high. A high volume could have a significant impact on contractor operations.
- This rule will require Medicare contractors to implement changes to their claims processing systems. Again, these changes could be significant and result in a need for additional funds.

BCBSA recommends that CMS work with Medicare contractors to determine fair and accurate payment adjustments to Medicare contractor budgets for the increased costs incurred by implementing these provisions. In addition, since changes to claims processing systems are typically complex, BCBSA requests that CMS provide contractors with sufficient time to develop and test changes needed for implementation.

2. Requests for Clarification

BCBSA has also identified the following areas that require clarification to more efficiently implement these new requirements:

(1) How often does CMS anticipate revising the list of services for which prior determinations may be made?

BCBSA recommends that CMS follow a predictable annual review schedule that "builds-in" a Medicare contractor review and comment period in order to provide a stable and reliable regulatory environment that eases compliance for all affected parties. BCBSA recognizes, however, the possibility that circumstances may arise whereby adjustments to the list of services will need to be made before an annual review period. Under such circumstances, BCBSA suggests that CMS provide Medicare contractors with as much lead time as possible to provide for an opportunity to comment on any changes.

(2) How does CMS anticipate handling requests submitted for services not on the contractor's list? Will these requests be returned to the provider and/or beneficiary and/or handled as technical denials?

BCBSA recommends, for purposes of protection against exposure to liability, that such requests be returned to the provider and the applicable beneficiary with a statement that the service is not on the list of CMS-approved services for prior determinations, and therefore cannot be expedited under this process.

(3) How will CMS address the need for communication between the different entities for claims processing? It is apparent that a Medicare carrier's role in communicating prior determinations to all affected parties will be essential to fostering coordination during and after implementation of this new process. Since the majority of services on the list will be inpatient non-emergency surgical procedures, does CMS intend that carriers making prior determinations provide notice of the results to the QIOs and fiscal intermediaries? This issue becomes critical once a claim for a pre-approved service is submitted by the provider, as situations may arise where a service may be pre-determined as "approved" by a carrier, while the hospital's bill may be denied by the QIO and/or fiscal intermediary.

BCBSA recommends that CMS clarify the means by which a carrier's pre-approval of coverage for a surgical service (e.g. hernia surgery) will provide notice to, and become "binding" on, other affected CMS contractors throughout the claims process. Issues such as these should be resolved by consultation between CMS and a multi-disciplinary Technical Advisory Group to ensure the development of coordinated solutions that promote efficiency in claims processing.

(4) Would the operational efficiency of contractors conducting prior determinations be improved by allowing them to develop policies in response to a high volume of prior determination requests for a particular service, even if data is insufficient to warrant a national or local coverage determination for that service?

BCBSA recommends that CMS allow contractors to develop policies in response to high volumes of prior determination requests for a particular service, especially when a particular coverage determination follows a demonstrable pattern whereby a positive or negative response seems most appropriate in almost every case. By providing for exclusion of services for which NCD/LCDs already exist, the rule could promote efficiency by removing the obligation of the contractors to research every circumstance surrounding a prior determination request. BCBSA believes that allowing contractors to develop standardized responses for certain areas of prior determinations would achieve similar operational efficiencies by reducing duplicative research for such requests.

(5) How does this proposed plan take into account instances where the clinical situation determines whether or not a service is medically necessary per Medicare policy, and where physicians might disagree as to whether clinical criteria are met in borderline cases? How should these cases be handled?

BCBSA recommends that CMS clarify this issue in the final rule for purposes of improving both the quality and timeliness of health care delivered to the beneficiary, and to provide some measure of protection against exposure to liability.

BCBSA appreciates the opportunity to comment on this Proposed Rule. We would be pleased to assist CMS with any issues related to implementation of this new process. Questions concerning these comments may be directed to my office at 202.626.8651, or by e-mail at Jane.Galvin@bcbsa.com.

Thank you

Jane Galvin
Director, Regulatory Affairs
Blue Cross and Blue Shield Association

American Association of Oral
and Maxillofacial Surgeons

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October 31, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6204-P
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RE: CMS-6024-P

The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents approximately 8,000 oral and maxillofacial surgeons in the United States. The mission of the AAOMS is to provide a means of self-government relating to professional standards, ethical behavior and responsibilities of its fellows and members; to contribute to the public welfare; to advance the specialty; and to support its fellows and members through education, research and advocacy.

BACKGROUND:
The AAOMS applauds the administration for addressing section 948 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) through this notice of proposed rule making (NPRM). Currently, our members have no way of knowing whether certain services provided to a Medicare beneficiary may be found reasonable and necessary and subsequently covered and reimbursed. The Association believes the adoption of a prior determination policy will in fact clarify the intention and utilization of the Advanced Beneficiary Notice, which is frequently misunderstood.

PROVISIONS OF PROPOSED RULE:
The AAOMS recognizes and appreciates the intention of the Administration's plan to develop detailed standard operating procedures addressing this new prior determination process. While we are confident that the carrier's manuals will be updated accordingly, the AAOMS would like to ask the Administration how this information will be disseminated to the provider, specifically the oral and maxillofacial surgeon. The AAOMS welcomes the opportunity to partner with the Administration in an effort to reach out to our members and instruct them on how the prior determination should be handled before the physician's services are rendered.

As noted in the proposed rule, the administration proposes "to allow prior determination for plastic and covered dental surgeries that may be covered by Medicare and that have an average allowed charge of at least $1,000.00." While we are comfortable with attempting to establish a dollar amount as a cut-off point, clarification regarding this amount is necessary. Is that $1,000.00 based on the physician's actual or estimated charge for the services in question or the anticipated Medicare reimbursement amount?

We commend the Administration for recognizing this challenging administrative burden that is often encountered by the practicing oral and maxillofacial surgeon (OMS) and their patients. The majority of the conditions for which a Medicare beneficiary seeks treatment from an OMS are in fact strictly "dental" in nature and it is recognized and accepted that no benefit is allowed for these services. The difficulty arises when an OMS treats a patient for a condition that may not be "dental" in nature but may have a "dental" component such as the reconstruction of a lower jaw following an aggressive tumor resection. Although the tumor may have been odontogenic in nature, the pathology is as destructive as a malignant bone tumor and must be treated accordingly. Part of the reconstruction process may include any or all of the following surgeries: resection with or without bone graft, separate unique bone graft for reconstructive purposes, and surgical placement of endosteal implants to be used to anchor a dental prosthesis. In these instances, and many others, the oral and maxillofacial surgeon may be unsure as to what procedures are covered. The eventual outcome of this NPRM should assist not only the OMS, but most importantly, the beneficiary that has to undergo these necessary procedures and provide clear and concise prior determination of this proposed surgical reconstruction.

The AAOMS welcomes the opportunity to work with the Administration to identify possible procedures that may be impacted by this proposed rule. Variances regarding coverage currently exist from state to state and although the AAOMS understands the local medical review and coverage policies, the Association would like to see those codes identified by CMS which will impact oral and maxillofacial surgeons.

The AAOMS would like to inquire as to the feasibility of submitting these prior determination requests electronically. Is it the intention of the Administration to instruct the CMS contractors to accept these submissions in a recognized and HIPAA compliant format? The AAOMS would encourage the Administration to do so.

Finally, the AAOMS commends the administration for attempting to provide clarity to the provider and the beneficiary by establishing a process for Medicare contractors to provide eligible participating physicians' services before the services are furnished. The AAOMS believes that this will represent an additional benefit to our members who are participating providers and may encourage those non-participating surgeons to change their enrollment status.

Sincerely,

Jay P. Malmquist, DMD
President

Jeffrey D. Stone, DDS, MD
Chairman, Committee on Healthcare and Advocacy

cc: Committee on Healthcare and Advocacy
Robert C. Rinaldi, Ph.D., CAE, executive director
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October 31, 2005

Centers for Medicare & Medicaid Services
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Submitted electronically

To Whom It May Concern:

The Center for Medicare Advocacy, Inc., on behalf of the undersigned organizations, submits the following comments concerning the proposed rule to establish a process for prior determinations for certain items and services covered by Medicare. 70 Fed. Reg. 51321 (August 30, 2005). The organizations represent low-income older people and people with disabilities to ensure access to quality health care.

Comment on Background

The Background section of the proposed regulation describes the use of ABNs by physicians "in cases where the physician believes that the services may not be covered. . ." However, it is our experience that a significant number of physicians use ABNs in a non-selective way to protect themselves from perceived risk of liability. The instructions for using ABNs do not allow this blanket use of ABNs, but that does not seem to deter physicians' staff. Further, ABNs are presented to patients shortly before treatments are scheduled to begin, so that patients have no real choice but to sign them. CMS is urged to do a better job of monitoring physicians to assure that they give their patients ABNs only when they have analyzed a particular procedure at hand and have formed a reasonable belief that it may not be covered.

Comments on Provisions of the Proposed Rule

General Comments:

Overall, we believe that the regulations lack the specificity needed for the public to comment on how well the procedures will operate. We are concerned that CMS' reliance on postings on the individual contractor web sites and on processes described only in manuals will make it difficult for both beneficiaries and physicians to understand and use the new prior determination process. In addition, we are concerned that the definition of the services for which the process will be available contains a loop-hole that may make the process ineffective.

Comments on Section 410.20(d)(2)

1. By including the procedures for requesting a prior determination in a manual provision and not in these proposed regulations, CMS has denied the public the opportunity to comment on the procedures. Since physicians and beneficiaries will be the primary users of the process, it is imperative that their needs be taken into consideration when developing the procedures. A process that is convenient for a Medicare contractor may not necessarily be convenient or easy for a beneficiary or physician to use. In addition, manual provisions do not have the same legal effect as do regulations, and they are much easier to change. If the process changes too frequently, no one will be sure of how to request a prior determination.

2. We object to the provision in this subsection that the services eligible for a prior determination will be made public only through publication on a contractor's web site. The majority of Medicare beneficiaries do not use the Internet, and Internet usage decreases as income decreases. Thus, most beneficiaries will have no way of knowing whether an expensive service recommended for them may be subject to the new process. Without such knowledge, they may choose to forgo the process out of concern for their potential liability, and the new process will not have solved the problem it was designed to eliminate.

A much more effective way to inform beneficiaries of the availability of the prior determination process than publication in the manuals and on the web, as proposed by CMS, would be to include a description of the process for requesting prior determinations on the ABN form. Such a description would give beneficiaries timely notice of the availability of the prior determination process in a manner directly linked to the warning of non-coverage in the ABN.

In addition, Medicare contractors are obligated to provide educational information to the beneficiaries and providers they serve. We recommend that contractors be required, on an annual basis, to include the list of services for which a prior determination may be available in a regular mailing to both providers and beneficiaries.

3. The proposed regulation limits too severely the kinds of services for which prior determinations will be provided. Although CMS cites cost as a reason for limiting the availability of prior determinations, nothing in the legislation authorizing "reasonable limits"

suggests that such a drastic limitation was intended by Congress. See SSA § 1869(h)(2). Further, the time estimated by CMS for preparing prior determinations – 1,250 hours annually – is quite modest. It does not support the limitation on availability of prior determinations proposed by CMS.

4. We appreciate CMS' decision to include separately plastic and dental surgeries with an average allowed charge of $1,000. We have represented many clients who have appealed denied claims involving those processes, and spoken with others who have rejected the services because they were not sure whether Medicare would cover them.

Comments on § 410.20(d)(3)

The exclusion from the prior determination process of services for which NCDs and LCDs are applicable is a grave error. These are generally the services for which patients most need to be able to obtain prior determinations because:

1. They are services that Medicare is very likely not to cover;

2. Many times the NCDs and LCDs list circumstances in which there will be coverage, and other circumstances in which there will not be coverage. We see many cases in which the contractor has denied coverage based on a NCD or LCD that actually provides for coverage in the beneficiary's particular circumstances. It is thus crucial for patients to know the circumstances and/or the evidence needed to support coverage under the relevant NCD or LCD so that they can supply the designated information.

3. The CMS rationale for excluding NCDs and LCDs from the prior determination process is factually incorrect. CMS states in the proposed rule that beneficiaries and providers already have access to the NCDs and LCDs, but this is not true, especially for beneficiaries. Almost none of them know about the existence of these coverage rules, or about any particular rule that might affect coverage of a particular service. Even physicians, in our experience, are often unaware of particular NCDs and LCDs.

4. The legislation itself clearly instructs CMS to provide prior determinations when NCD or LCD is the basis for a denial of coverage, "including on what national or local coverage determination (if any) the determination if based and a description of any applicable rights under subsection (a)." SSA § 1869(h)(B)(i). The exclusion of services affected by NCDs or LCDs violates this provision of the authorizing statute.

When and how will CMS review the NCDs and LCDs/LMRPs? Most importantly, why would CMS leave in place an NCD that is not clear? Why would CMS allow a contractor to rely on an LCD or LMRP, especially one that interprets an NCD, which is not clear? We fear a time when CMS, determining that all of its policies are crystal clear, determines that no service is subject to the prior determination process. Such a decision would defeat the purpose of the statutory provision.

Comments on § 410.20(d)(4)

1. We renew our objections to the use of manual provisions to increase the services included on the list. The process for including additional services should be subject to public comment to assure that the process works well for those who will use it. For example, there needs to be some way for a physician who identifies, based on his or her own experience, a service that meets the requirements in §410.20(d)(2)(i) to request that the service be added to the list.

2. The regulation also needs to include information on how frequently CMS and contractors will be required to update the list. If the list is only going to be updated yearly, then physicians can download the list once a year and be assured they have the correct information. If the list will be updated randomly, then physicians will be required to check the list every time they recommend a procedure they believe may be covered, which will create an unnecessary burden. Similarly, beneficiaries need to understand the accuracy of the information they are provided by the contractor. Once the frequency with which the list must be updated is established, Medicare contractors should be required to provide written updates to beneficiaries of any changes to the list.

Having accurate information about services subject to the prior determination process is critical since the regulations require that only services included on the list as of the date of the request will be eligible for the prior determination process.

Comments on §410.20(d)(5)(ii)(A)

1. The regulations should specify that the notice must be written.

2. The provisions should also include the recourse available to a beneficiary and the consequence to a provider when a provider fails or refuses to submit accompanying documentation. The beneficiary should not be deprived of access to the process simply because a provider disagrees with the beneficiary's decision to seek a prior determination.

Comments on §410.20(d)(5)(ii)(B)(1)

1. If a NCD or LCD is the basis for a prior determination that a service will not be covered, the notice of non-coverage should include a copy of the NCD or LCD so that the beneficiary can determine what circumstances and/or evidence are required to establish coverage.

2. The notice of noncoverage should also be required to explain that someone who receives a notice of noncoverage may still obtain the service, submit a bill to Medicare, and then appeal if the bill for services is denied.

We thank you for the opportunity to submit comments and look forward to working with you to implement the new prior determination process.

Sincerely,

Vicki Gottlich
Center for Medicare Advocacy, Inc.

On behalf of

Arizona Center on Disability Law
Medicare Advocacy Project of Greater Boston Legal Services on behalf of its eligible clients
Medicare Rights Center

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AdvaMed
Advanced Medical Technology Association

October 31, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Prior Determination for Certain Items and Services [CMS-6024-P]

To whom it may concern:

I am writing on behalf of the Advanced Medical Technology Association (AdvaMed) regarding the Medicare proposed rule on "Prior Determination for Certain Items and Services," which was published in the Federal Register at 70 Fed. Reg. 51321 (August 30, 2005). We appreciate the opportunity to comment on this proposed rule.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

Background

As you may know, AdvaMed has taken an active interest in Medicare coverage issues, at both the national and the local levels. We are supportive of the intent underlying section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which is to ensure that physicians and beneficiaries have a means to find out whether a given item or service is considered reasonable and necessary for a given beneficiary before incurring financial liability. Over the years, AdvaMed has consistently pressed for a clear, predictable, and timely national coverage process, as well as for the opportunity for the public to participate actively in it. Likewise, we support the development of a clear process for physicians and patients to obtain advance information about coverage from Medicare contractors. This process has the potential to eliminate barriers to patient access that may stem from patient or physician uncertainty as to whether an item or service is covered by Medicare.

Provisions of the Proposed Rule

However, we are concerned that CMS has crafted a process that is lengthy and does not adequately address the areas of Medicare coverage that patients and physicians find unclear.

First, CMS proposes to require Medicare contractors to respond within 45 days of prior determination requests. We are concerned that as a practical matter, this timeframe is too lengthy to be useful for beneficiaries and physicians. For physicians and beneficiaries to make use of the process, CMS should respond to requests for prior determinations promptly so that the waiting time for the procedure does not result in worsening a given patient's condition. We recommend that CMS shorten the length of time for issuance of prior determinations to make the process usable for physicians and patients.

Second, CMS proposes initially to limit the physicians' services subject to the prior determination process to "at least 50 services with the highest allowed average charges that are performed at least 50 times annually," and furthermore CMS expects that the final list "may be fewer than 50." (70 Fed. Reg. at 51323) However, CMS has not published either its initial or its final list. We recommend that CMS make the list of services that it proposes to make subject to the prior determination process widely available to the public and subject to notice and comment. Absent the ability to see the particular services that would be subject to this new process, it is difficult to comment fully on whether the list would adequately capture the types of procedures that patients and physicians are likely to be reluctant to undergo or perform due to confusion about coverage.

Third, we are concerned that the criteria CMS proposes to use for the selection of eligible procedures results in a narrow list that may not adequately capture the types of services about which patients and physicians are most likely to have coverage questions. Our preliminary analysis of the types of procedures that CMS might identify using highest allowed average charges and a fifty-procedure threshold for procedures performed resulted in a list of procedures that includes some procedures that are typically performed in emergent circumstances when there would be little time for advance inquiry through the prior determination process. We recommend that CMS consider as a factor whether a given service is elective in order to make the prior determination process useful to patients and physicians as a practical matter.

Fourth, we recommend that CMS start with a larger pool of services and increase that pool as CMS gains experience with the process. We believe that an initial pool of at least 100 services would be appropriate given that services "with adequate national and local coverage determinations" would be excluded from the list.

Fifth, we recommend that CMS take into account denial rates associated with services under the Medicare physician fee schedule in establishing the pool of services that would be eligible for the new process. We believe that this factor may capture the types of procedures about which physicians and patients most often have coverage questions.

Finally, the preamble to the proposed rule states that "where a prior determination is requested but an NCD or LCD/LMRP exists, the contractor will send the beneficiary a copy of that policy along with the explanation of why a prior determination will not be made." We are concerned that physicians and beneficiaries are often confused about whether a given NCD or LCD/LMRP does or does not result in Medicare coverage for their case in particular. Rather than simply explaining why a prior determination would not be made, we recommend that CMS actually explain whether the relevant LMRP or NCD indicates that the service at issue is covered by Medicare or not.

Thank you again for the opportunity to comment. Should you have any questions, please contact Teresa Lee, Associate Vice President for Payment and Policy, at 703/434-7219 or via e-mail at tlee@advamed.org.

Sincerely,

/s/

David Nexon
Senior Executive Vice President

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OCT 31 2005

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

October 28, 2005

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Re: Medicare Program; *Prior Determination for Certain Items and Services*; Proposed Rule; 70 *Fed. Reg.* 51,321 (Aug. 30, 2005); File Code CMS-6024-P

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates this opportunity to provide our views on the Centers for Medicare and Medicaid Services' (CMS) proposed rule concerning *Prior Determination for Certain Items and Services;* Proposed Rule; 70 *Fed. Reg.* 51,321 (Aug. 30, 2005).

CMS is proposing to implement section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which requires the Secretary to establish a prior determination process as to whether the physicians' service is covered by Medicare. The Secretary is authorized to establish by regulation "reasonable limits" on the physicians' services for which a prior determination may be requested. The Secretary may consider the dollar amount involved with respect to the physician's service, administrative costs and burdens, and other relevant factors.

CMS is proposing to establish an initial pool of eligible physicians' services comprised of at least those 50 services with the highest allowed average charges that are performed at least 50 times annually. CMS will exclude from this pool any services for which a national or local coverage determination exists that, based on CMS' judgment, has sufficiently specific reasonable and necessary criteria to permit the beneficiary or physician to know whether the service is covered without a prior determination. CMS acknowledges that the services on this list, after excluding for services with adequate national and local coverage determinations, may be fewer than 50. CMS may expand the list in the future if the need arises.

The AMA appreciates CMS' implementation of this provision of the MMA, and we have several comments regarding such implementation. **The AMA urges CMS to significantly expand the number of services on the initial prior determination list. An initial list of 50 is too small, particularly since services for which CMS deems there is an adequate national or local coverage determination (NCD or LCD/LMRP) would be excluded from the list.** Thus, it is unclear how many services would even be on a final list after these exclusions are made. Section 938 of the MMA is a somewhat narrow provision that is intended to provide physicians and beneficiaries with regulatory relief from the myriad and confusing coverage rules under Medicare. **We urge CMS not to restrict further this much needed regulatory relief by establishing a list that is too limited.**

In addition, as stated above, CMS proposes that services excluded from the list will be those for which, in CMS' judgment, an NCD or LCD/LMRP "provides the sufficiently specific reasonable and necessary criteria for the specific procedure for which the prior determination is requested." **The AMA urges CMS not to exclude these services from the list.** Although coverage criteria under an NCD or LCD/LMRP may be clear or seem "sufficient" to CMS, the same likely will not be the case for Medicare beneficiaries and physicians. Many NCDs and LCDs contain criteria that is very complex and often confusing. Medicare experts at CMS, especially those who have the unique vantage point of having participated in developing coverage criteria for a certain service or who daily deal with and interpret Medicare rules and regulations, have a much greater understanding of the scope of coverage for a particular procedure. Physicians, however, do not have that expertise and may not be able to easily interpret the complex Medicare language that is often used to describe coverage of a procedure. A Medicare beneficiary likely would have even less understanding of the coverage criteria. Moreover, many physicians may not have immediate access to an NCD or LCD/LMRP and thus will not know if a particular procedure is covered. **Accordingly, we urge CMS to maintain on the prior determination list those NCDs and LCDs/LMRPs that appear to CMS to provide "sufficiently reasonable and necessary criteria" to properly determine coverage.**

Further, CMS will instruct its contractors, in cases where a prior determination is requested, but where an NCD or LCD/LMRP exists, to send the physician or beneficiary a copy of that policy along with an explanation of why a prior determination will not be made. **The AMA urges that CMS instruct the contractor to simply state in its explanation whether or not the procedure is covered. Since the contractor is already sending the policy to the requesting party, it would be a simple task for the contractor to confirm whether or not Medicare covers the procedure in question.** If, however, adding such a statement of coverage confirmation would be difficult for the contractor, perhaps it would be equally difficult for the physician or patient to make a coverage determination as well. **Thus, we urge CMS to both maintain services on the prior determination list for which there is a "sufficient" NCD or LCD/LMRP and instruct its contractors to issue a confirmation of coverage along with the relevant NCD or LCD/LMRP.**

The AMA appreciates the opportunity to provide our views on the foregoing matter and we look forward to working with CMS to ensure that the goals of section 938 of the MMA are achieved.

Sincerely,

Michael D. Maves, MD, MBA