Governmental Affairs & Public Policy

Statement to the PPAC Regarding Y2K Readiness and the HCFA's New Medicare Coverage Process

June 14, 1999

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM), representing the nation's largest medical specialty with over 115,000 members, is pleased to provide the following testimony to the Practicing Physicians Advisory Council (PPAC) regarding Physicians' Readiness for the Year 2000 (Y2K) and the Health Care Financing Administration's (HCFA) New Medicare Coverage Process.

Physicians' Readiness For Y2K

ACP-ASIM commends HCFA for its efforts to engage physicians on preparing their office computer systems for Y2K by maintaining a Y2K web site on the Internet, establishing a toll free telephone number for providers to call for Y2K assistance, holding a series of Y2K awareness conferences around the country, and contacting physicians and other health care professionals regarding Y2K preparedness.

ACP-ASIM developed paper and electronic materials to assist its members in preparing for Y2K, launched a public information campaign, and created an Internet web page to better inform members about Y2K actions they should take. ACP-ASIM's "Y2K Toolkit" provides information regarding: general background information and other resources; immediate actions to take; medical practice computer system compliance; medical devices compliance; support systems and outside vendor compliance; and information on selecting a software system. Paper copies of ACP-ASIM's Y2K Toolkit are available at this PPAC meeting.

Additionally, ACP-ASIM's makesY2K-related information available on its Internet site at www.acponline.org/y2k/

HCFA's New Medicare Coverage Process

ACP-ASIM generally supports the HCFA process for making national coverage decisions that was outlined in a April 27, 1999 *Federal Register* notice. We are encouraged that HCFA will tap the expertise of the medical community through its Medicare Coverage Advisory Committee (MCAC). ACP-ASIM's immediate past-president Harold Sox, MD has been selected to serve on the MCAC, and we look forward to providing input as the MCAC process unfolds. However, we have several concerns regarding the process for making national coverage decisions.

HCFA may fail to use the MCAC efficiently and to its full potential. The notice states that HCFA has sole discretion as to whether a request for a national coverage decision requires input from the MCAC. HCFA staff should solicit input from the MCAC, possibly through a MCAC steering committee, when determining which coverage determination requests warrant an MCAC referral or which require a technology assessment first. This would streamline the process for making referrals and requesting technology assessments. It would also assure

that HCFA and the MCAC agree up front as to how each individual coverage request will be handled. Our intent is not to over-extend the committee or require it to hold additional meetings, but rather to ensure that it is effectively and appropriately utilized. Involving the MCAC in referral decisions would be beneficial for HCFA, the coverage determination requestor, and ultimately beneficiaries.

The formality of the process for requesting a national coverage decision may create problems for individual physicians, small group practices, and beneficiaries. Typically, physicians and their patients lack experience in navigating such a process. Requiring individuals and small groups to meet the same requirements as large entities that have the resources and experience necessary to facilitate a formal request is likely to hinder national acceptance of local level innovations. Further, determinations on requests for decisions submitted by small entities are at a competitive disadvantage as they are more likely to be delayed while the necessary information—scientific and otherwise—is compiled and prepared for submission. Perhaps HCFA should appoint members of its staff to serve as ombudsman who will assist those requesting national coverage decisions in preparing those requests.

Including "program integrity" in the list of issues/circumstances that can cause HCFA to initiate the national coverage process suggests that coverage decisions may be driven more by cost savings considerations than by scientific evidence. HCFA's April 27, 1999 Federal Register notice states that HCFA may initiate its review process if there are "program integrity issues surrounding significant underutilization or overutilization..." of a service. We are concerned that HCFA is more likely to focus on overutilization—or perceived overutilization—than when physicians and other health professionals fail to provide the service with the optimal frequency or intensity. The development and implementation of coverage policy at the local level supports this concern. Medicare carriers develop local medical review policies (LMRPs) that restrict coverage because of perceived overutilization or the potential for overutilization. Carrier attempts to increase beneficiary access to needed services is less common. Equally troubling is the fact that HCFA's Program Integrity department maintains oversight of LMRPs. Coverage decisions should be based on scientific evidence and not on program integrity-oriented efforts designed to save the Medicare program money.

The notice establishing the national coverage process fails to address the problems with coverage decisions issued at the local level through LMRPs. This concern is especially noteworthy since HCFA recently confirmed that approximately 90 percent of all coverage decisions are made at the local Medicare carrier level. HCFA currently allows its carriers broad latitude in making local coverage decisions. While HCFA touts its national coverage process as more "open, understandable, and predictable," the current process for making local coverage decisions continues to be somewhat closed, ambiguous, and unpredictable. ACP-ASIM believes that the process by which Medicare carriers make local coverage decisions needs to be reformed. The following pages describe ACP-ASIM's recommendations for reforming the LMRP process. ACP-ASIM will continue to closely monitor the national coverage process and make recommendations for improvement when appropriate.

Local Coverage Decisions

Local coverage decisions take the form of LMRPs. HCFA requires that LMRPs be developed in consultation with a local carrier advisory committee (CAC). Each state maintains a CAC that is comprised of one physician representative per each major medical specialty. A Medicare carrier medical director (CMD) must distribute a proposed LMRP to the CAC before implementing it as carrier policy. CAC representatives have a minimum of 45 days to gather comments from their respective specialties. The CMD has full discretion in determining how

to incorporate comments received from the CAC during the comment period. The LMRP takes effect 30 days after being published by the carrier.

The focus of LMPRs varies. A CMD can use an LMRP to determine whether an item/service is a covered benefit by the Medicare program. Further, an LMRP can determine the clinical conditions under which a covered service will be paid for by the Medicare program.

Problems with the LMRP Process

In reality, it is extremely difficult for physicians to keep track of LMRPs. Requirements are communicated to physicians in a disjointed and ineffective way. CMDs update LMRPs that determine the conditions under which a covered service is paid for by periodically publishing additions and deletions to the list of acceptable clinical conditions, usually in the form of diagnosis codes. Typically, only the changes are listed. The original policy is rarely updated and published in its entirety. The result is that individual practices have to update the original policies in their files to maintain accurate information, which makes it virtually impossible for physicians to learn LMRPs. Even the most well-informed physicians have difficulty keeping apprised of changing LMRPs.

ACP-ASIM is not arguing that all coverage decisions and policies should be national. The College supports local physician input into LMRPs. CMDs, in conjunction with CACs, play a key role in ensuring that local Medicare policies are fundamentally related to what the local medical community views as appropriate standards of medical practice. The LMRP process should be reformed, however. This could be accomplished through structural improvements to the CAC process and by identifying "best practices" of the existing State CACs.

Recommendations

1. *HCFA Should Separate Local Coverage Decisions From Program Integrity functions. HCFA's Office of Clinical Standards and Quality should oversee carrier LMRP issues.*

   Section 7501.2 of the MCM states that "LMRP(s) is primarily a program integrity tool" and that " it is generally developed to specify criteria that describes whether the item/service is covered and under what clinical circumstances it is considered to be reasonable, necessary, and appropriate." Further confirmation that LMRPs focus on program integrity is that Section 7503 of the MCM, which pertains to CACs, instructs the CAC co-chair to send copies of CAC meeting minutes to HCFA's Program Integrity Group/Contractor Management Group with the Office of Financial Management at the agency's central office.

   It is inappropriate for coverage decisions to be made principally on whether they save money. Denying a item/service as a covered benefit or restricting it's a coverage to a limited number of clinical conditions because of cost considerations and/or because of perceived or potential overutilization is unfair to beneficiaries. It is problematic that CMDs are primarily accountable to the Program Integrity Group within HCFA's Office of Financial Management when making coverage decisions. Beneficiaries' interests would be best serviced if the office within HCFA that focuses on quality of care was the one that decides which items/services are reasonable, necessary, and appropriate.

2. *Carriers should provide a 60-day public comment period for all proposed policy changes instead of the*

current 45-day comment period.

The current comment period is too short for medical societies to make informed judgments and comments on policy changes. This is a problem particularly in rural states where the size of the medical society staff may be limited.

3. *At the conclusion of the comment period, the carrier should state, in writing, its reasons for accepting or rejecting the comments in framing the final policy.*

   All CAC members should receive the carriers rationale for adopting policy changes, and the public should receive this information on request. Just as the Administrative Procedures Act requires HCFA and other federal agencies to respond to comments made on its proposed rules, so too should carriers have to provide an explanation of why they have adopted a particular policy. In this way, the medical and patient community will know why the carrier is pursuing a particular course of action. In addition, educating physicians and their staffs about the policy change would further the goal of adopting correct policy and relieve carriers of administrative burdens that result from physicians misunderstanding policy changes.

4. *HCFA should provide "best practices" guidelines to CMDs so they can incorporate them into their CAC process.*

   ACP-ASIM is encouraged that HCFA has contracted with the consulting firm of PricewaterhouseCoopers (PwC) to make recommendations to improve the effectiveness and the efficiency of the LMRP development process. As a part of its contract, PwC is to identify "best practices" that could be used to improve local policy development as HCFA attempts to standardize the process nationwide.

   ACP-ASIM informally polled its members involved in State CACs to and came up with the following examples of effective CAC processes:

   - The Wisconsin carrier continues to work with the CAC member representing the specialty or specialties most affected by a proposed LMRP after the conclusion of the 45-day comment period and before implementing it by publishing it in its Medicare Bulletin. This additional step in the decision-making process enables the carrier to improve the proposed LMRP by allowing further input from relevant specialties, without occupying the time of the entire CAC. This type of increased interaction results in more thoughtful LMRPs and is consistent with the intent of the CAC process. Further, the carrier-physician relationship is enhanced by carrier efforts to work collaboratively with the physician community.
   - The CMD that co-chairs the California CAC extended the comment period for 45 to 60 days.
   - The Rhode Island CMD sends draft LMRPs to CAC members before the meeting but begins the 45-day comment period on the meeting date (HCFA requires CACs to provide a 45-day comment period that begins when the draft LMRPs are sent out to CAC members).

   At a minimum, each of these practices should be adopted nationwide.

5. *There needs to be a process for fine tuning LMRPs after they are implemented. The lack of an*

established process to modify existing LMRPs forces physicians to seek changes in a disjointed manner.

There is no standard way for physicians to appeal LMRP coverage decisions, both those that determine whether an item/service is covered and those that indicate the clinical circumstances in which an item/service is considered reasonable and medical necessary. There needs to be a way to correct misguided LMRPs that are hurried through a process that is not conducive to broad input.

There should be a formal mechanism that allows physicians (for themselves and on behalf of their patients) to recommend changes to LMRPs—whether appealing a coverage decision or altering an LMRP that restricts the conditions in which a covered service will be paid. Recommended changes should go back to the CAC. If the LMRP is further disputed, HCFA's Office of Clinical Standards and Quality should intervene to ensure that beneficiaries are not being denied medically necessary services or being inappropriately forced to pay for them out-of-pocket because of an incorrect LMRP.

Beneficiaries are often saddled with additional out-of-pocket costs for items/services that are not covered and when coverage is inappropriately restricted to a limited number of clinical conditions. In cases were the item/service is covered for only a specific conditions, the physician must find a condition, indicated by a diagnosis code(s), that fits the patient and will be covered. Physicians can currently ask the CMD to expand the list of conditions that merit coverage. Acceptance or rejection of these recommended policy changes is left solely to the discretion of the CMD. The HCFA central office generally stays out of this area. However, the Program Integrity Group within the Office of Financial Management, and not the physicians on the Office of Clinical Standards and Quality staff, would intervene if HCFA got involved. Clearly, the latter would be a more appropriate arbiter of these issues.

6. *Carriers need to assess the financial/cost-benefit impact of the LMRPs that they choose to implement in a systemic way*.

   Although LMRPs are generally implemented to restrict the situations in which covered services are paid, carriers should be able to determine the overall financial impact of an LMRP. A carrier should collect data on the number of claims pertaining to a denied service covered by an LMRP that are appealed and how often denials are overturned on appeal. It is wasteful to implement a restrictive LMRP that is to save money when the cost of manually reviewing appealed claims outweighs any savings generated by initial denials.

   For example, Transamerica Occidental Life Insurance Co., the Medicare carrier for Southern California, maintains LMRPs that limit coverage of laboratory tests such as blood counts, blood glucose, and serum magnesium to a specific list of conditions, indicated by diagnosis codes. Limiting coverage of tests whose use is widely indicated and clinically accepted for the purpose of program integrity is disruptive for physicians and their patients. Adjudicating claims that are appealed after originally being denied because of restrictive LMRPs is likely to actually increase costs if a significant number of denials are overturned on appeal.

7. *HCFA has a responsibility to inform beneficiaries that LMRPs that deny coverage of an item/service or restrict coverage to specific patient conditions will cause their out-of-pocket medical expenses to*

increase.

LMRPs with a program integrity bent have financial implications for beneficiaries. Physicians are forced to strike a balance between ensuring that their patients receive all items/services that are medically necessary and minimizing their patients' out-of-pocket costs.

The simple presence of a LMRP limiting coverage increases the likelihood that patients will refuse items/services. Physicians must ask patients to sign an advanced beneficiary notification form (ABN), in which the patient agrees to pay for the item/service if Medicare denies payment, if they are uncertain as to whether Medicare will pay for the item/service under the circumstances. Difficult-to-learn LMRPs frequently prevent physicians from knowing when Medicare will cover an item/service. Patients are further disadvantaged as those who cannot afford to pay for an item/service out of pocket may forgo the treatment.

Model LMRPs

Ideas for LMRPs are sometimes derived from "model" LMRPs that are developed by working groups of CMDs. CMDs from around the country periodically develop a policy template on an issue(s) that a CMD(s) thinks needs to be addressed. HCFA only reviews these model policies to make sure that they do not contradict national Medicare policy. Individual CMDs can then run the model or a variation of the model through its State CAC for implementation. Currently, national medical specialty societies and other interested parties are generally unable to have input into the development of "model" LMRPs.

Recommendation

National medical societies should have input into "model" LMRPs developed by "working groups" of CMDs for the purpose of being implemented through local CACs.

A working group of CMDs should involve relevant medical societies when formulating a model policy. This type of collaboration will result in more suitable LMRPs and better prepare national medical societies to target educational efforts toward members.

It is a disservice to beneficiaries and providers to allow model LMRPs developed by a regional or national workgroup of CMDs to become de facto regional or national policies. Model LMRPs have the potential to become national policies if they are implemented throughout the country, with the only difference being changes made by the State CAC. It is inappropriate for HCFA to permit model LMRPs that are initiated by a few CMDs whose focus is program integrity become the equivalent of a national policy.

For example, a workgroup(s) of CMDs has drafted at least 15 model LMRPs for clinical laboratory tests. Many of these models were implemented by CMDs through their CACs because of perceived overutilization or because of potential overutilization. As a result, it is likely that a model(s), or a variation of that model(s), has been implemented in many States. We cannot definitively say that every carrier has an LMRP in place for a specific laboratory test or even identify how closely the existing LMRPs track with the model because HCFA currently fails to keep track of the LMRPs maintained by each carrier.

The Balanced Budget Act of 1997 directed HCFA to convene a negotiated rulemaking committee to develop uniform coverage and administrative policies for clinical laboratory tests. HCFA's approach to this committee provides some insight into agency's view of the model LMRPs for laboratory tests. After the negotiated rulemaking committee selected the laboratory tests for which it would develop national coverage policies (now being called "coverage determinations" as they were not derived from the national coverage process that HCFA published in the April 27, 1999 *Federal Register*), some committee members suggested using existing model LMRPs as a starting point. HCFA, a member of the negotiated rulemaking committee, rejected that suggestion stating that national coverage policies (determinations) needed to be held to a higher standard of scientific evidence. If HCFA is not fully comfortable with using CMD workgroup-developed model LMRPs as a template for national policy, it is certainly inappropriate to allow model policies to in effect become national, with only minor tinkering by State CACs.

Conclusion

ACP-ASIM believes that adoption of the recommendations included in this statement, and recapped below, will ensure that beneficiaries receive all medically necessary services that are provided under appropriate clinical conditions

National Coverage Process

1. HCFA should take into account the size and resources of the entity requesting a national coverage determination to avoid hindering national acceptance of local level innovation.
2. Medical and scientific evidence and not program integrity concerns should trigger initiation of the national coverage process.
3. HCFA should use the MCAC efficiently and to its full potential by seeking its input when deciding whether or not to refer a request for a national coverage or to ask for a technical assessment

Local Coverage Decisions

1. HCFA Should Separate Local Coverage Decisions From Program Integrity functions. HCFA's Office of Clinical Standards and Quality should oversee carrier LMRP issues.
2. Carriers should provide a 60-day public comment period for all proposed policy change instead of the current 45-day period.
3. At the conclusion of the comment period, the carrier should state in writing, its reasons for accepting or rejecting the comments in framing the final policy.
4. HCFA should provide "best practices" guidelines to CMDs so they can incorporate them into their CAC process.
5. There needs to be a process for fine tuning LMRPs after they are implemented. The lack of an established process to modify existing LMRPs forces physicians to seek changes in a disjointed manner.
6. Carriers need to assess the financial/cost-benefit impact of the LMRPs that they choose to implement in a systemic way.
7. HCFA has a responsibility to inform beneficiaries that LMRPs that deny coverage of an item/service or restrict coverage to specific patient conditions will cause their out-of-pocket medical expenses to increase.
8. National medical societies should have input into "model" LMRPs developed by "working groups" of

CMDs for the purpose of being implemented through local CACs.

ACP-ASIM thanks PPAC for the opportunity to comment on Physicians' Readiness for Y2K and Medicare's New Coverage Process.