AMA AMERICAN MEDICAL ASSOCIATION

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

March 6, 2009

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

Dear Acting Administrator Frizzera:

On behalf of the physician and student members of the American Medical Association (AMA), I am submitting comments regarding the Centers for Medicare and Medicaid Services (CMS) *Re-Issuance of the 2010 Draft Call Letter to Medicare Advantage Organizations, Medicare Advantage-Prescription Drug Organizations, Cost-Based Contractors, Prescription Drug Plan Sponsors, Employer/Union-Sponsored Group Health Plans, and Programs of All-Inclusive Care for the Elderly Organizations (draft Call Letter).* We support and applaud a number of the provisions in the draft Call Letter, but also have identified areas where we urge CMS to reconsider and modify its proposals when the Final 2010 Call Letter is issued. Nonetheless, we believe that the re-issued draft Call Letter represents an important step toward protecting the interests of beneficiaries and helping physicians meet the health care needs of their patients.

Health Insurance Plan Transparency

Although CMS does not currently publicize health plans' medical loss ratios, the AMA supports the agency doing so in order to provide much needed transparency. There is a vital need for beneficiaries to have a clear understanding of how health care premiums are allocated by health insurance companies, and particularly how much of their premium dollars are spent on health care services as opposed to administration, profit, or for other purposes. Full transparency of how health care insurance premiums are spent will empower beneficiaries to make more informed decisions, and reward plans that minimize administrative waste. According to the Commonwealth Fund, the fastest rising component of health care spending is administrative overhead. Between 2000 and 2005, the net insurance

administrative overhead, including both administrative expenses and insurance industry profits, increased by 12 percent per year. This increase is 3.4 percent points faster than the average health expenditure growth of 8.6 percent. A minimum medical expense threshold is necessary to maximize the value of health insurance premiums, and an important step toward controlling spiraling health care costs, which are due, in part, to the dramatic rise in administrative costs and insurer profits.

CMS has requested comments on how the medical loss ratio should be calculated. In order to calculate the medical loss ratio a number of key terms should be defined in the following manner. First, "medical expense" should be defined as the amount of money that the insurer spends on direct medical care services for enrollees during a calendar year. This should include the insurer's total financial obligation for physician services, non-physician health care professional services, hospital and other health facility services, drugs and medical devices, and other health care services that the health insurer incurs on behalf of its enrollees, and must include amounts paid to health care providers for pay-for-performance or other quality or efficiency enhancing initiatives. Medical expense should not include amounts which are the financial responsibility of the enrollee, the insurer's administrative costs, or expenditures for which the insurer is reimbursed by an enrollee's other insurance coverage or other third party liability. Second, "premiums" should be defined as the amount of money that the insurer earns in a calendar year from the sale of health insurance, excluding dividends or credits applicable to prior years. Third, "administrative costs" should be defined as all expenditures associated with the administration of health benefit coverage, including but not limited to, costs associated with claims processing, collection of premiums, marketing, operations, taxes, general overhead, salaries and benefits, quality assurance, utilization review and management, pharmacy and other benefit management, network contracting and management, and state and federal regulatory compliance. Finally, the "medical expense threshold" should be defined as the quotient, to the nearest one percent, of the total medical expenses divided by the total premiums. In order to promote transparency the foregoing information should be made available by the insurance plans regardless of whether it is provided as a "medical loss ratio." Beneficiaries and their advocates must have adequate information in order to elect the plan that will provide the services that they will need.

Multiple and Low Enrollment Plan Offerings by MAOs

The AMA strongly concurs with the statement that the current multitude of plan offerings is causing widespread confusion for beneficiaries and their advocates in choosing a plan which best suits their health care needs and financial resources. Reducing the number of plans offered by the same Medicare Advantage organization (MAO) would be an enormous help. It compounds the confusion when the same MAO offers multiple versions of the same type of plan, such as multiple MA private-fee-for-service (PFFS) plans. This is potentially misleading and exacerbates the confusion not only for beneficiaries, but also for their advocates, their physicians, and coordinating case managers. It also makes it extremely difficult, if not impossible, for beneficiaries to check with their physician(s), as they should do before they enroll in any plan, and find out if the physician accepts that plan.

Dual Eligibles and Cost-Sharing

For MA plans, the draft Call Letter discusses new requirements for Special Needs Plans (SNPs) under the Medicare Improvements for Patients and Providers Act of 2008. By 2010, SNPs must have developed evidence-based models of care and adequate networks for providers and specialists for covered services. The draft Call Letter also defines what CMS considers to be specific attributes for chronic condition SNPs (C-SNPs), including specially designed benefit packages that provide levels of care beyond the basic care Medicare Part A and Part B provide. These requirements are effective January 1, 2010. The AMA generally supports these requirements.

Allowing plans to choose the best method for conveying information to providers about cost-sharing rules is a recipe for disaster in general, but particularly with regard to dual eligibles. CMS Regional Offices must assume a measure of responsibility for conveying this information to physicians in their regions. Physicians cannot make any sense of different information provided to them by the hundreds of different plans in their states.

Cost Sharing Guidance

The AMA strongly urges CMS to require MAOs to provide beneficiaries and physicians with a side-by-side chart comparing co-insurance, copayments, deductibles, and out-of-pocket limits under the MA plan to co-insurance, copayments, deductibles, and out-of-pockets limits under regular Medicare. It also should be made clear that Medicare supplemental or Medigap policies cannot be used to help with MA plan cost-sharing requirements.

The practice of plans offering lower cost-sharing for prior notification should be prohibited. It simply adds to the confusion and complexity that physicians and patients face in trying to understand these plans. Typically, patients, physicians, case managers, and their advocates have difficultly in securing this information even after a patient elects a plan. This underscores how the lack of an apples-to-apples comparison between regular Medicare and the large number of plan offerings effectively precludes beneficiaries and their advocates from making informed decisions and may compromise the coordination of care even after a plan is selected.

Preventive Services Incentives

The AMA supports guidance that promotes the provision of incentives to patients to utilize Medicare preventive benefits or obtain health education. This program should be evaluated to determine its effectiveness in improving utilization of preventive services and to assess which strategies worked best. Successful strategies should be replicated in the regular Medicare program and not limited to MA. We strongly agree that there is no place for these types of incentives in pre-enrollment marketing.

Audits

Beginning in 2010, CMS plans to conduct "more targeted, data-driven and risk-based audits," instead of focusing on routine plan audits. To conduct these more focused audits, CMS plans to use existing data to create "performance profiles" of plan sponsors and to identify poorly performing plans. The audits will also focus on what CMS considers the highest risk areas for beneficiary harm (e.g., enrollment operations, appeals & grievances). The AMA generally supports these provisions that will ensure greater oversight and accountability.

As part of its new audit strategy, CMS said that it may require MA and Part D plan sponsors to perform self-audits and report the results back to CMS. In addition, plans will be required in 2010 to audit the data that they are required to report to CMS, using audit technical specifications that CMS plans to publish in late 2009. The AMA generally supports this requirement.

The AMA supports audits to ensure MA and Part D plans are in compliance with all federal requirements. Over the past year, however, physician offices have made numerous complaints to the AMA about extremely burdensome audits of their patients' charts that are conducted by MA plans. In many cases, the correspondence that MAOs send to physician offices implies that the chart reviews are mandated by CMS. Given the very small percentage of charts that are actually included in CMS-required risk validation audits, it appears that the great majority of the chart reviews that are the subject of these complaints are self-initiated by the plans and not required by CMS. The correspondence is misleading in this respect. In addition, it appears that the purpose of the audits is less to assure compliance with MA regulatory requirements and more of a fishing expedition to find data that would support increased risk scores and attendant increased payments to the plan. Finally, many MAOs utilize third parties to obtain the information from medical practices and the physician office has no idea what plan is doing the audit.

As CMS contemplates increasing its oversight of MA plans, we urge the agency to take into account the potential impacts of more aggressive program integrity efforts on the medical practices that provide care to the plan's subscribers. At a minimum, office staff time required to pull, review, copy, and re-file medical records should be compensated. Methods should be employed to ensure that physicians can identify the entity that is requesting information, the reason for the request, the reason for any deadline that is given for responding to the request, and that the same practices are not required to comply with audit demands from a multitude of plans.

PQRI Bonuses and E-Prescribing Incentives

The AMA strongly agrees with the guidance indicating that, as PFFS plans are required to pay the same rates as Medicare to physicians, they also must pay PQRI and electronic prescribing (e-prescribing) incentive payments to eligible physicians. Beyond PFFS plans, however,

there are many other MA plans that link their physician payment rates to the Medicare Fee Schedule and have rates that are advertised as being equal to or a percentage of the Medicare Fee Schedule rates. Any MA plan that utilizes the Medicare Fee Schedule as the basis for its physician payment rates should be required to pay PQRI and e-prescribing incentive payments to eligible physicians.

We urge CMS to require MAOs to have transparency in their PQRI bonus payment practices. Specifically, MAOs should be required to provide physicians with advance notice of how and when the MAO will distribute PQRI bonuses to physicians. This will provide physicians with advance notice regarding PQRI bonuses for financial planning purposes and will avoid the massive confusion that may result if an MAO sends a check or electronic payment (i.e., a PQRI bonus) to a physician without any explanation of the purpose for the check.

Significant physician outreach and education regarding the e-prescribing incentive payment program will be critical to encourage and support the utilization of e-prescribing within the Part D program. Part D sponsors should be required to develop and implement a network provider education and outreach plan on the e-prescribing incentive payment program so that physicians are able to take advantage of the incentive program early on.

It is critical that all pharmacies are able to support e-prescribing. Part D sponsors should be required to work with their network pharmacies to ensure that they are able to support e-prescribing. We agree that Part D sponsors should be required to indicate which of their network pharmacies support e-prescribing in their pharmacy directories so that physicians and patients are made aware of the e-prescribing capabilities of network pharmacies. We recommend that this information be readily available, easy to navigate (e.g., ability to locate a pharmacy using a map or zip code), as well as placed in one central, accessible location on CMS' website.

Part D New PDE Edits for NDCs Not Registered and Listed with the FDA

CMS has proposed rejecting prescription drug events (PDE) submissions on January 1, 2010, with national drug codes (NDCs) for which the Food and Drug Administration (FDA) is unable to provide regulatory status determinations through their regular processes. There is no way to determine what impact the withdrawal of Part D coverage for unapproved drugs would have because there has been no comprehensive listing of these drugs or how often they are being used. In some cases a number of these drugs never went through the current FDA approval process because the drug pre-dates the current FDA approval process. We generally believe that these are generics (e.g., Phenobarbital). Phenobarbital is a barbiturate that is the most widely used anticonvulsant worldwide and the oldest still commonly used. The World Health Organization (WHO) recommends its use as first-line for partial and generalized tonic-clonic seizures (those formerly known as Grand Mal) in developing countries. It is a core medicine in the WHO Model List of Essential Medicines, which is a list of minimum medical

needs for a basic health care system. In more affluent countries it is no longer recommended as a first-line medication; however, it is relied on as an alternate when a patient fails to respond to treatment with more modern anti-epileptic drugs. Phenobarbital has never been through the FDA approval process, but it is still a medically necessary drug that Part D plans should continue to cover. The January 2010 withdrawal of Part D coverage for all drugs that have not been through the current FDA's regulatory process would be premature and is too rapid a timeline when so much is still unknown.

Part D Utilization Management Criteria

For utilization management, CMS will now require plans to post all utilization management criteria on their websites by November 15, 2009, when the 2010 open enrollment period begins. This will require plans to disclose to existing and potential enrollees their step therapy and prior authorization requirements. The draft Call Letter also says that CMS will continue to review plans' utilization management strategies as part of their formulary submissions. The AMA strongly supports this provision.

In addition, for 2010, Part D plans will be required to satisfy specific medication therapy management (MTM) program standards. These new requirements, which include more specific enrollment, targeting, intervention, and reporting, are intended to "promote greater consistency and raise the level of the MTM interventions offered to positively impact medication use."

The AMA strongly supports all elements of this section. These requirements will be extremely helpful in ensuring that patients with Part D plans are able to gain appropriate access to the drugs prescribed by their physicians.

Part D Guidance

In its guidance specific to Part D plans, the draft Call Letter warns plan sponsors against sending "substantially inaccurate" submissions to meet application and bid deadlines. CMS said that in the first four years of the Part D program, plan sponsors had made submissions "so lacking in required information or correct detail as to fail to constitute a valid timely submission." Beginning with the 2010 contracting cycle, CMS will consider incomplete and inaccurate submissions as having missed the deadline. The AMA strongly supports this requirement since it will provide beneficiaries, physicians, and others who assist beneficiaries with timely and accurate information.

Another change for the 2010 benefit year is the elimination of "reference-based pricing." This is where enrollees are required to pay additional cost sharing for certain drugs, typically calculated as the difference between the cost of a brand-name drug and its generic equivalent. Reference-based pricing is too complex for beneficiaries to accurately determine expected out-of-pocket costs. The AMA strongly supports the elimination of reference-based pricing.

We appreciate the opportunity to comment on the re-issued draft 2010 Call Letter. The AMA strongly supports CMS efforts to provide regulatory oversight of MA and Part D plans. The need for plan transparency is as great as ever and the steps outlined above will provide beneficiaries, physicians, and others in the health care system with readily accessible information that is comprehensible and will support informed decision-making, promote coordination of care, and ensure the delivery of health care when beneficiaries need it.

Sincerely,

Michael D. Maves, MD, MBA