October 21, 2004

Medicare Judicial, Administrative, and Legislative Update

1. Quality Improvement Organizations (QIOs) and Centers for Medicare and Medicaid Services (CMS) are negotiating the 8th Statement of Work. The negotiations on behalf of CMS are being handled by the Office of Clinical Standards and Quality. The 8th Scope of Work (SOW)\(^1\) comprises a three-year contract cycle of QIO activities beginning in August 2005. The theme is “transformational change and breakthrough priorities.” The focus is on providing assistance to providers, practitioners, Medicare Advantage (MA) organizations, beneficiaries, and other stakeholders in support of quality improvement.

2. Pay for Performance advocated as a Quality Improvement Measure. The notion here is that there needs to be strong financial incentives that promote the pursuit of improved quality in health care; that the Medicare program, as the largest payer for health care, should take the lead in this area; that the Agency for Healthcare Research and Quality (AHRQ)\(^2\) has established itself as an honest broker of evidence-based treatment

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2 See, “Health Affairs,” AHRQ’s mission is to support research designed to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. It was created as in December 1989 as the Agency for Health Care Policy and Research (AHCPR), a Public Health Service agency in the Department of Health and Human Services (HHS). Reporting to the HHS Secretary, the Agency was reauthorized on December 6, 1999, as the Agency for Healthcare Research and Quality. Its current budget is $269.9 million. Nearly 80 percent of AHRQ’s budget is awarded as grants and contracts to researchers at universities and other research institutions across the country. It has a staff of 294. See, [http://content.healthaffairs.org/cgi/content/full/22/6/8](http://content.healthaffairs.org/cgi/content/full/22/6/8).
standards; that the CMS has taken significant steps toward a quality strategy based on quality measurement and incentives; that even with current quality measures being less than perfect, pay for performance should become a top national priority and that Medicare payments should lead in this effort, with an immediate priority for hospital care.

It is significant that this movement is being advocated by many of the economists who put forward managed care as a way to address cost and access to services for Medicare beneficiaries. Advocates will do well to watch the emergence of this approach and to add the necessary critique from our experiences over time.

3. CMS to implement certain quality assurance mechanisms as required by the Medicare Modernization Act (MMA).

A. Quality Assurance Measures and Systems

Under the Prescription Drug Plan (PDP) sponsor provisions of the MMA, providers must develop quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use, including developing cost and utilization management and medication therapy management programs, provide beneficiaries with comparative information about qualified prescription drug coverage, plan benefits, monthly benefit premium information, quality and performance information, beneficiary cost-sharing, and make available the results of consumer satisfaction surveys regarding plan conduct pursuant to §1860D-4(d) of the Social Security Act.

Proposed implementing regulations require a PDP sponsor, or MA organization offering an MA-PD plan, to disclose required information, including information about its quality assurance program. The Quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use and is to establish a process for (1) drug utilization review; (2) patient counseling; and (3) patient information record-keeping.

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4 42 U.S.C. §1395w-104(c).


Under contracts with the Secretary of HHS, Quality Improvement Organizations (QIOs) are to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to healthcare services, including those related to prescription drug therapy. For purposes of the proposed regulations, MA organizations and PDP sponsors are included in the definition of "health care facility." It should be noted, however, that the proposed QIO responsibilities do not include the review of disputes about services or quality of services. Rather, the emphasis on offering providers, practitioners, MA organizations, and PDP sponsors assistance in obtaining and maintaining compliance with the quality assurance requirements of reducing medication errors and adverse drug interactions and improving medication use as called for in proposed 42 CFR §423.153(c). Note, however, under current law, the QIO function includes the review of quality of care complaints and questions about premature discharge and access to patient requested services and procedures.

B. Deemed Status

The proposed regulations provide, under proposed 42 CFR §423.165(a)(1)-(2), that a PDP sponsor, or MA organization offering an MA-PD plan, is deemed to meet all of the requirements of the proposed regulation if it is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by CMS, and the accrediting organization uses standards approved by CMS.

The deemable requirements include the cost and utilization management, quality assurance, and medication therapy management programs called for in 42 CFR §423.153. In addition, PDPs, and MA organizations offering MA-PD plans must submit to surveys by CMS to validate its accreditation organization’s accreditation process, and authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

CMS proposes to retain its enforcement authority to initiate enforcement action against any PDP sponsor or MA organization offering an MA-PD plan where CMS determines, on the basis of its own surveys or the results of an accreditation survey, that PDP sponsor or MA organization offering an MA-PD plan no longer meets the Medicare requirements for which deemed status was granted. Without a more defined process and procedure, which identifies and describes the "triggering" mechanisms for initiating its own oversight functions, it is doubtful that this provision will have significant practicable meaning and application.

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9 See, proposed 42 CFR §423.162(c), 68 Federal Register 46821 (August 3, 2004).

10 See, 42 CFR §§ 412.42(hospitals), 478.32 (Skilled nursing facilities).

4. Changes to the Administrative Appeals Process

A. Transfer of Administrative Law Judges (ALJs) from SSA to HHS

Report to Congress: On March 26, 2004, The Secretary of Health and Human Services (HHS) and the Commissioner of Social Security (SSA) submitted to Congress their Plan for the Transfer of Responsibility for Medicare Appeals. The report to Congress was developed under the MMA, which authorized the transfer of administrative law judges (ALJs) from SSA to HHS.

As a result of efforts by the Center for Medicare Advocacy and other advocates to assure the continued independence of ALJs, the MMA requires HHS to establish an office of ALJs that is organizationally and functionally separate from CMS. ALJs are to report directly to the Secretary of HHS and cannot be under the supervision of any other officer of the Department.

According to the report, HHS intends to establish a central office for ALJs that is responsible for direction, liaison, budget support and human resource management of the hearing function. The office will be located in the Baltimore/Washington area. By the end of 2004 HHS will make determinations about the location of its ALJs in field offices. HHS and SSA will look for opportunities to share resources, including videoconferencing (VTC) capabilities.

HHS and SSA project that HHS will need to hire 50 ALJs initially, four more than the 46 ALJs per month SSA currently assigns to handle Medicare cases. The projected need for more ALJs is based on two changes to the Medicare appeals process that have yet to be implemented: the ability to escalate cases to an ALJ hearing when a reconsideration decision is not issued within 60 days, and the establishment of a 90-day time limit for conducting ALJ appeals. The report anticipates that HHS will need more than 50 ALJs in the future, but notes that the addition of a Medicare prescription drug benefit and the expected increase in managed care plan enrollment make it difficult to predict how many more ALJs will be needed. HHS intends to begin soliciting ALJ applicants at the end of 2004 and to begin hiring and training during the first part of 2005.

The report calls for a phased in transition of responsibility for Medicare ALJ appeals:

- HHS ALJs will hear Part A and Part B appeals received on or after July 1, 2005.
- HHS ALJs will hear Medicare Part C appeals received on or after September 1, 2005.

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13 MMA Section 931.
SSA will continue to process all Medicare appeals received before the transition dates; with the goal to complete backlogged cases by September 30, 2005.

Medicare contractors will be instructed to submit appeals to HHS, and HHS will begin tracking appeals received after those dates.

The report refers to initiatives SSA and HHS will undertake to increase the efficiency of the appeals process, including uniform file organization and improved case preparation by Medicare contractors; full screening of Medicare receipts by a centralized unit of SSA and HHS Medicare expert staff for potential dismissals and on the record decisions; increased specialization of ALJs and support staff handling Medicare cases; and maximum use of VTC hearings and expert testimony by phone.

_GAO Report:_ The Government Accountability Office (GAO), as required by MMA, reviewed the transfer plan, and determined that, while the report addresses each of 13 elements specified in the statute, it lacks important information on how the elements are to be implemented.\(^{14}\)

Among the findings of most relevance to beneficiaries:

- The plan contains few milestones for completing tasks, such as developing training materials for ALJs, and does not assign responsibility to any group or office to oversee the tasks. In addition, failure to specify details about key elements, such as geographic location of ALJs, makes it difficult to determine when tasks such as renting and furnishing office space will be completed.

- The plan lacks a contingency component to be used if the transfer cannot occur as scheduled. Although SSA and HHS commented that HHS would continue to use SSA ALJs, they did not provide details to the GAO about how this would occur.

- The plan does not adequately explain its workload, staffing, and cost estimates or consider the future impact of changes made to the appeals process by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)\(^ {15}\) that have not yet been implemented. For example, ALJs averaged 327 days to complete a Medicare appeal in fiscal year 2003, but BIPA requires ALJS to issue decisions within 90 days.

- The plan bases its estimate of the costs for processing appeals on the amount SSA is paid; however, the actual costs exceed this amount. The plan contains no criteria or other measures to justify future requests for increased funding.

- The plan discusses electronic filing of appeals and the use of video-conferences instead of in-person hearings. However, it does not discuss an anticipated time

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\(^{15}\) Pub. L. No. 106-554, section 521.
frame for issuing regulations to implement these new procedures. Without regulations, the GAO states, "...it is not clear how appellants will be assured of having sufficient access to ALJs.....what forum will be used to provide information to beneficiaries and providers, how access to this information will be provided, and what will be used as the basis for this information."

- BIPA created a new level of review before the ALJ level, the Qualified Independent Contractor (QIC). According to the GAO, CMS says they will have to delay implementation of the QIC level of review if final appeals regulations to implement BIPA are not issued by November 2004. As a result, the GAO believes that HHS ALJs might operate under different regulations and processing systems, one following current rules and one following BIPA, depending on whether the claim under review has gone through the QIC process.

- The GAO states that the plan’s lack of specificity of geographic distribution of ALJs by itself threatens to undermine the timely transfer of ALJs. Appellants cannot be assured of timely access to ALJs across the country without a geographic distribution plan. The location and size of offices affects hiring staff, including the transfer to HHS from SSA of current ALJs with Medicare expertise.

- SSA and HHS have not done any analysis concerning the use and establishment of videoconference sites, including whether HHS will follow SSA guidance that beneficiaries should not travel more than 75 miles to a hearing. It is unlikely that videoconference sites will be available within that radius in remote areas. While ALJs told the GAO that beneficiaries prefer face-to-face hearings over videoconferences or teleconferences, HHS and SSA have not analyzed what proportion of appellants would be willing to use the new mechanisms. The GAO acknowledges that "hearing by ALJs will provide an appellant’s sole opportunity to be heard in person, making access to them all the more important."

- The plan lacks details concerning the content of training for new Medicare ALJs. It also does not discuss who will be responsible for developing the materials or for presenting the training, or include steps to ensure the objectivity of ALJ training. The GAO questions whether the time frame for hiring and training ALJs will be sufficient to allow HHS ALJs to begin hearing appeals in July 2005.

- The plan provides no specifics concerning how independence of ALJs will be maintained, and merely repeats the statutory requirements. It contains no information about organization structure, management, or standards to evaluate whether independence is achieved.

The GAO recommends that SSA and HHS provide a more substantive and detailed transfer plan that includes milestones for implementation, identifies geographic distribution for both offices and videoconferencing sites, develops strategies for handling two separate processing systems if BIPA regulations are not implemented, and define the relationship of HHS ALJs to other organizations in HHS to ensure decisional independence.

**Final regulations:** In the fall of 2002 CMS issued two Federal Register notices concerning changes made to the Medicare Parts A and B appeals process by BIPA. First, CMS announced it was delaying all but two of the changes until final regulations were promulgated.\(^\text{16}\) Then CMS issued proposed implementing BIPA regulations.\(^\text{17}\) CMS has yet to issue the final regulations, although rumors exist that they will be issued imminently. As noted above, CMS believes issuance of final BIPA regulations is critical to implementation of the new QIC level of review, which the GAO believes is critical to implementation of the ALJ transfer plan.\(^\text{18}\) The Center for Medicare Advocacy, Inc., will post information about final regulations on its web site and through its *Weekly Alert* as soon as the regulations are issued.

**QICs:** CMS issued a press release on Monday, October 18, 2004, announcing that eight entities had been chosen to serve as QICs and to perform reconsiderations of determinations of Medicare Part A and Part B claims.\(^\text{19}\) The press release states that CMS is "...working toward completing our overhaul of the Medicare claims appeals system by October 1, 2005...." Several of the entities chosen, such as IPRO and Maximus, already review some Medicare claims.

CMS has also indicated that it will be implementing a 60-day decision deadline, meaning Medicare contractors will have to inform beneficiaries of their decision within 60 days of receipt of the claim or appeal. Of course, the 60 day deadline, added by MMA, is an extension of the original 30-day deadline included in BIPA. Although CMS touts the new deadline as an improvement in its press release, it actually gives contractors more time than some currently take to issue decisions.

5. **Coverage for new Medicare preventive benefits begins January 1, 2005.**

The following sections of the MMA added coverage for new preventive benefits for Medicare beneficiaries, to become effective on January 1, 2005:

- §611- coverage of an initial physical exam (it does not cover lab tests) performed within 6 months of a beneficiary enrolling in Part B. If a beneficiary never enrolls in Part B (and many don't because they have other duplicative coverage) they

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\(^{16}\) 67 Fed. Reg. 62478 (Oct. 7, 2002). CMS implemented the revised deadlines for requesting review and the reduction in the jurisdictional amount for filing a request for an ALJ hearing of a Part B claim.

\(^{17}\) 67 Fed. Reg. 69312 (Nov. 15, 2002).

\(^{18}\) ALJ hearings currently are conducted according to the same rules as social security claims; the proposed rules established Medicare-specific procedures for ALJ hearings and for subsequent review by the Departmental Appeals Board (DAB). The ALJ Transfer Report emphasizes the importance of having Medicare-specific rules because the BIPA changes, apply to Medicare claims but not to Social Security disability claims.

never get this exam. Because this provision is not applied retroactively, only people who enroll in Medicare Part B after that date will get the exam.

- §612- coverage of cardiovascular screening blood tests. The benefit covers a cholesterol (lipids and triglycerides) test once every two years at most. It does provide for the addition of other tests within the Secretary's approval but may be limited to only certain individuals and only with the recommendation of the U.S. Preventive Services Task Force.

- §613 - coverage of diabetes screening tests. This benefit provides coverage for a fasting plasma glucose test (other tests as the Secretary deems appropriate) and is limited to individuals at high risk for diabetes. This is defined as having any of the following risk factors - htn, dyslipidemia, obesity (BMI>30), previous identified impaired glucose tolerance, OR at least two of the following: overweight (BMI 25 - 30), family history of DM, history of gestational DM or delivery of baby > 9 lbs., age 65 or older. Frequency covered is no more than twice per year.

6. Increased Part B deductible20: The MMA increased the Part B deductible to $110 starting in January 2005. In subsequent years the Part B deductible will be increased by the annual percentage increase in the monthly actuarial value of benefits payable under Part B.

7. CMS announces 2.3 percent increase in Medicare home health payment rates for Calendar year 2005.21 According to CMS, the increase will bring an extra $250 million in payments to home health agencies next year. Home health agencies are paid on the basis of a prospective payment system (PPS). Providers receive a higher rate for patients with greater needs. Payment rates are based on relevant data from patient assessments. Home health rates are updated annually by either the full home health market basket percentage, or by the home health market basket, adjusted by Congress. CMS establishes the home health market basket index, which measures inflation in the prices of an appropriate mix of goods and services includes in home health services.

A February 2004 Government Accounting Office (GAO) report finds that the total amount the Medicare agency paid freestanding Home Health Agencies (HHAs) as a group more than covered the overall costs of caring for their Medicare home patients; that this was true for both HHAs that served exclusively rural patients and those that served exclusively urban patients. The GAO report noted, however, that financially weak-performing HHAs had higher overhead costs, spending twice as much on overhead and almost 40 percent more on direct patient care. Patients of the weak-performing HHAs needed slightly less intensive care as measured by Medicare's system of classifying patients according to their expected care needs.22

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20 MMA Section 629, amending 42 U.S.C. § 1395l (b).

21 See, CMS Open Door Forum Announcements, Oct. 18, 2004. HOMEHEALTH_HOSPICE_DMEOPFL@CMS.HHS.GOV.
8. CMS's promotion of disease management is becoming a major financial investment opportunity, and is spawning a growth industry. CMS and Congress continue to promote disease management as the vehicle for providing services to Medicare beneficiaries with chronic conditions. The report cited in this section indicates that disease management firms represent a growth industry and a major financial investment opportunity. As a public policy matter, however, advocates should explore to what extent disease specific approaches to chronic care negate a broader chronic care benefit, including care coordination across diseases and illnesses.

9. CBO reports that there is insufficient evidence to conclude that disease management programs produce cost savings. In response to an inquiry by Senator Don Nickles, Chairman of the Committee on Budget, the Congressional Budget Office (CBO) analyzed peer-reviewed studies of disease management programs for congestive heart failure, coronary artery disease, and diabetes, as well as other articles in medical journals. CBO determined that these studies do not provide sufficient evidence to find that disease management programs reduce overall health care costs by paying for themselves. CBO admits that the findings may reflect the fact that the studies did not focus on cost issues. CBO will continue to monitor such studies and reports as CMS develops its disease management demonstration projects being developed by CMS.

10. Advocates continue to work on getting CMS to count all time in the hospital toward meeting the Medicare-covered skilled nursing facility (SNF) 3-day prior hospitalization requirement. This issue will be discussed in greater detail in the "Medicare Time Limits" workshop. Advocates have been working with CMS to obtain a clarification that all time spend in the hospital, following an admission, including emergency room time, and time in observation status, would count toward meeting the 3-day prior hospitalization requirement. This issue has grown in intensity as lengths of hospital stays have decreased to approximately 5.8 days in 2001, according to the CDC's April 2003 data. The problem persists in spite of the favorable ruling in Jenkel v. Shalala, 845 F. Supp. 69, 70 (D. Conn. 1993), finding that a beneficiary's inpatient stay began when the beneficiary was taken to the emergency room and then later admitted to the hospital.

In our latest discussions with CMS, we have been informed that the agency is inclined toward counting the time spent in observation status at a hospital as time that counts toward the 3-day prior hospitalization requirement. We have not gotten movement on

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23 See, Disease Management Investment Opportunities, October 15, 2004, prepared by Cochran, Caronia Securities, LLC. www.cochran-caronia.com. Click on research and sales, then research reports.


25 The 3-day prior hospitalization requirement is found at 42 U.S.C §1395x(i); 42 C.F.R. §409.30(a)(1).
counting emergency room time, in spite of Jenkel. This policy change will be reflected in an omnibus proposed rule making notice to be issued sometime in the spring of 2005.

11. Trends and notions emergent in legislative proposals to "fix" the Medicare Modernization Act (MMA).\textsuperscript{26} It should be noted that we are in the final year of the second legislative session for the 108\textsuperscript{th} Congress. All bills will have to be reintroduced. Generally, the best resource for obtaining the status of federal legislation is the Library of Congress website, http://thomas.loc.gov.

Given the up-coming presidential election, it is not likely that controversial legislation will pass this year. Nonetheless, there is likely to be some omnibus budget package passed. It most probably will not take on major new legislative initiatives.

Of the many bills introduced thus far in this Congress, they can be grouped generally as follows: (a) to lower the Medicare Part B premium or to keep it at its pre MMA level; (b) to end the 24 month waiting period for persons with a disability; to end cost-sharing for the Part B premium; (c) to authorize and require CMS to negotiate drug prices; (d) to eliminate special subsidies for HMOs and repeal health savings accounts (HSAs); (e) to create a federal national prescription drug card program; (f) to require greater CMS accountability of Joint Commission on Accreditation of Healthcare Organizations and deemed accreditation; (g) to increase home health care funding in rural areas; (h) to improve benefits related to kidney disease; (i) to require geriatric assessments and chronic care management; (j) to provide incentives for furnishing of quality care under Medicare Advantage plans; (k) to allow for drug re-importation; (l) to provide for automatic enrollment and eligibility for low-income subsidies under the Medicare transitional and permanent prescription drug programs; (m) to provide that all US citizens are allowed to purchase the same health care insurance as available to members of Congress; (n) to eliminate privatization of the Medicare program; (o) to improve health care disparities based on race and ethnicity; (p) to require the federal reimbursement of emergency health services furnished to undocumented aliens.

\textsuperscript{26} Public Law No. 108-173, signed into law December 8, 2003.