The new law provides a vehicle for expedited judicial review in certain situations, to allow providers to bypass the (sometimes painfully slow) administrative process and go directly to court. This expedited route applies to appeals filed on or after October 1, 2004 where it is determined that the ALJ or the Departmental Appeals Board does not have the authority to decide a question of law, and where the material facts are not in dispute. In order to take advantage of this provision, a provider must submit a written request to a CMS "review entity," which must determine within 60 days of receipt of the request whether expedited judicial review is appropriate.. Expedited judicial review is also available to a provider when CMS terminates or decides not to renew the Medicare provider agreement.

Presentation of evidence

Despite these modifications, providers may find appeals more burdensome after the MMA due to a new prohibition on introducing evidence in any appeal that was not presented at the reconsideration level of appeal, unless there is good cause that precluded the introduction of evidence at the reconsideration level. Previously, providers generally were allowed to introduce new evidence at any point in the appeals process. The new provision is effective October 1, 2004.

MISCELLANEOUS REGULATORY AND ADMINISTRATIVE CHANGES

The MMA is a lengthy law that addresses nearly every aspect of the Medicare program. Given its breadth and complexity, a full discussion of its many provisions is beyond the scope of this Advisory. A few additional provisions merit mention. They require CMS to:

- Adopt procedures setting deadlines for applications for enrollment or renewal of enrollment as a Medicare provider, and establishing a mechanism for providers to appeal denials of applications to enroll or renew enrollment (effective June 8, 2004). CMS also must consult with providers before it changes the provider enrollment forms (effective January 1, 2004).
- Establish a prior determination process that allows a physician or a beneficiary to request a coverage determination for a service that has not yet been provided. The determination will be binding, as long as there was no fraud or misrepresentation of the facts provided to the contractor (effective June 8, 2004 and "sunsets" five years later). If a physician is providing a service for which coverage is questionable, utilizing this process can help clarify whether Medicare or the patient will be responsible for the bill.

CONCLUSION

The new law signifies a sweeping overhaul in the way the Medicare program is administered, and many of the changes will benefit providers. Much of the substance and particulars remain to be developed by rule-making, however, and Congress already is considering a number of bills that modify or scale back the new law. Watch for communications from your fiscal intermediary or carrier as various provisions of the new law are implemented, and check CMS's Medicare Modernization Update Website at http://www.cms.hhs.gov/mmu/. If you have questions about how any of these provisions apply to your organization or would like further details about the new Medicare law, please contact Maureen Weaver 203-498-4384/mweaver@wiggin.com or Jennifer Willcox 203-498-4396/jwillcox@wiggin.com, or any other member of Wiggin and Dana's health care department.

Nothing in this Client Advisory constitutes legal advice, which can only be obtained as a result of personal consultation with an attorney. The information published here is believed to be accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.

One Century Tower
P.O. Box 1832
New Haven CT
06508-1832
Telephone 203.498.4400
Telefax 203.782.2889

400 Atlantic Street
P.O. Box 110325
Stamford CT
06911-0325
Telephone 203.363.7600
Telefax 203.363.7676

450 Lexington Avenue
Suite 3800
New York NY
10017-3913
Telephone 212.490.1700
Telefax 212.490.0536

One CityPlace
185 Asylum Street
Hartford CT
06103-3402
Telephone 860.297.3700
Telefax 860.525.9380

Quaker Park
1001 Hector Street, Ste. 240
Conshohocken PA
19428-2395
Telephone 610.834.2400
Telefax 610.834.3055

The Medicare Prescription Drug, Improvement and Modernization Act:

Regulatory Changes Beyond the Prescription Drug Benefit

WIGGIN AND DANA

Counsellors at Law

Health Care Department

Maureen Weaver, Chair
203.498.4384/ mweaver@wiggin.com

Melinda A. Agsten
203.498.4326/ magsten@wiggin.com

Bennett J. Bernblum
203.498.4336/bbernblum@wiggin.com

Michelle Wilcox DeBarge
860.297.3702/mdebarge@wiggin.com

Gates Garrity-Rokous
203.498.4310/ggarrity_rokous@wiggin.com

Merton G. Gollaher, Jr.
203.498.4362/mgollaher@wiggin.com

Paul A. Hughes
203.498.4321/phughes@wiggin.com

Jeanette C. Schreiber
203.498.4334/jschreiber@wiggin.com

David E. Ormstedt
860.297.3739/dormstedt@wiggin.com

Catherine P. Baatz
860.297.3748/cbaatz@wiggin.com

Amanda Littell
203.498.4529/alittell@wiggin.com

Jennifer N. Willcox
203.498.4396/jwillcox@wiggin.com

The new Medicare Prescription Drug, Improvement and Modernization Act (MMA), signed by President Bush on December 8, 2003, has been described as the most significant restructuring of the Medicare program since Medicare's enactment in 1965. Although attention has focused on the prescription drug benefit authorized by this law (the new "Part D" of Medicare), other lesser-known provisions in the MMA will affect the day-to-day operations of health care providers. This Advisory highlights a few of these important changes.

REGULATORY CHANGES AND OTHER GUIDANCE

Timely regulations

The Centers for Medicare and Medicaid Services (CMS) is infamous for delays in finalizing regulations. The MMA attempts to solve this problem by requiring the Secretary of HHS to establish regular time-frames for publishing final regulations. Except under "exceptional circumstances," the interval between a proposed regulation and the final rule cannot exceed three years. The new law also provides that if CMS incorporates into a final rule new measures that are not a "logical outgrowth" of what was proposed, then the provision must be treated as a proposed regulation with opportunity for public comment. These provisions took effect on December 8, 2003.

Retroactive application of regulations, manuals, rules

The MMA also bars CMS from retroactively applying any substantive changes in regulations, manual instructions, interpretive rules, statements of policy or guidelines of general applicability, unless necessary for the public interest or to comply with a statutory mandate. Under the law, no "substantive" change in the Medicare program may take effect until 30 days after the change is issued or published. The practical effect of this provision may be limited, however. Retroactive application generally is disfavored as a matter of administrative law, and so government agencies often take the position that a new position is *not* a "substantive" change but is instead an "interpretation" or "clarification" of *existing law*. The prohibition on retroactivity applies to compliance actions taken after the MMA's effective date (December 8, 2003).

Reliance on written guidance from contractors

Importantly, the new law protects providers from the imposition of fines or sanctions (including interest imposed as part of a repayment plan) if the provider relied on written guidance from CMS or a Medicare contractor when providing services or submitting a claim. This provision only applies to written guidance received on or after July 24, 2003. Previously in its Compliance Program Guidance, the Office of Inspector General (OIG) suggested that reliance on written advice from a government agency or Medicare contractor can be sufficient to demonstrate compliance, and so the new law provides helpful statutory support of what appeared to be existing policy. Moreover, another provision in the Medicare law gives this "reliance on written guidance" defense some teeth. Beginning October 1, 2004,

as part of the new outreach and education initiatives discussed below, Medicare contractors must provide "clear, concise and accurate" written responses within 45 days of receiving a written inquiry from a provider (or beneficiary). Providers that take advantage of this requirement by writing to request guidance about a billing practice and receive the required written response may rely on the written response, even if it later turns out that the contractor's guidance was incorrect (providers would still be liable for repaying any overpayments, however).

PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

In addition to the requirement discussed above that Medicare contractors respond to written inquiries within 45 days, the new law requires CMS to undertake a number of provider education initiatives:

- CMS must devise incentive payments to reward Medicare contractors for successful provider education, measured by specific claims payment error rates or other methodology.
- Contractors must maintain a toll-free number where providers and beneficiaries can obtain information regarding billing, coding, claims, coverage and other Medicare information, and must establish internet sites that answer frequently-asked questions and provide access to the contractors' printed materials.
- Contractors must have a system for identifying the individual that supplies the information in response to written inquiries or on the toll-free number.
- CMS must establish standards for accuracy, consistency and timeliness of the information that Medicare contractors give to providers and beneficiaries, and evaluate contractors with respect to these standards.
- Medicare contractors may not use a record of attendance (or failure to attend) educational activities for providers or suppliers or use other information gathered during such educational activities to conduct an audit or prepayment review.

Except for the internet site requirement (effective October 1, 2004), all of these provisions went into effect on December 8, 2003. Starting October 1, 2004, CMS must also provide education programs and technical assistance tailored for small providers (defined as health care providers with fewer than 25 full-time equivalent employees).

PAYMENT REVIEWS

Limitation on prepayment audits

Prepayment audits can slow down reimbursement to a provider, and the MMA imposes some important limits on the practice. Effective December 8, 2004, Medicare contractors can conduct random prepayment reviews (meaning a demand for the production of records or documentation absent any cause with respect to a claim) only to develop general (program-wide or contractor-wide) payment error rates, and only according to standard protocols set by CMS. If a health care provider or supplier voluntarily identifies an improper billing practice, the Medicare contractor may not initiate a "nonrandom" prepayment review unless there is a likelihood of a sustained or high level of payment error (the same standard limiting the use of extrapolation, discussed below).

New standards for postpayment audits

For postpayment audits initiated after December 8, 2003, the Medicare contractor must give the provider written notice of the intent to conduct the audit. The contractor further is required to give the provider a full review and understandable explanation of the audit findings that permits the development of an appropriate corrective action plan, inform the provider about any appeal rights and consent settlement options, and give the provider the opportunity to submit additional information (which the contractor must take into account). The statute excepts situations where giving notice or providing the findings would compromise any law enforcement activities.

RECOVERY OF OVERPAYMENTS

Repayment plans authorized

The MMA provides some relief to providers that experience financial difficulties in repaying Medicare overpayment amounts. Prior to the MMA's enactment, CMS was not obligated to negotiate a repayment schedule for providers unable to make a lump sum payment. Sometimes CMS would negotiate payment plans, but there were no uniform standards. The MMA establishes consistent parameters for when CMS must enter into repayment agreements, and some of the terms that should be included in the agreements. The MMA requires that CMS enter into an extended repayment plan upon request in cases where it would be a "hardship" for a provider to repay a Medicare overpayment within 30 days. A "hardship" occurs when the amount of the overpayment exceeds 10% of Medicare payments to the provider as reported in the most recent cost report, or (for providers who do not file cost reports, 10% of the provider's aggregate Medicare payments in the last calendar year). A repayment plan can range from six months to three years, or five years in the case of extreme hardship, and interest will accrue on the balance through the period of repayment. CMS can refuse to enter into a repayment plan if there is reason to believe the provider will file for bankruptcy or cease participating in Medicare, or if there are indications of fraud or abuse. This provision applies to requests for repayment plans after December 8, 2003.

Recoupment stayed pending reconsideration

Beginning December 8, 2003, CMS is prohibited from recouping overpayments from providers that have requested reconsideration of an overpayment determination. CMS may not initiate any recoupment action until after the reconsideration decision is rendered.

Extrapolation limitations

The new law imposes an important limitation on the use of extrapolation to determine overpayment amounts. Specifically, Medicare contractors can utilize extrapolation only in cases where there is a "sustained or high level of payment error," or where "documented educational intervention" has failed to correct the problem. While providers may see some relief from widespread use of extrapolation as an audit technique, the reach of this provision is sharply curtailed by an express statement prohibiting any judicial or administrative review of a decision that extrapolation is appropriate. In other words, if CMS determines that there is a "sustained level of payment error," it can use extrapolation in its audit, and the provider will have no recourse or right to appeal that decision. The limitations on extrapolation go into effect for samples initiated one year after the MMA's enactment (December 8, 2004).

Consent settlements formalized

The MMA formalizes CMS's current administrative practice of offering consent settlements to providers in lieu of a full-scale audit process involving a statistically valid random sample (SVRS). Before offering such a consent settlement, CMS must do the following:

- inform the provider that a preliminary review indicates there may be overpayment;
- explain the nature of the problems identified and the steps the provider should take; and
- provide a 45-day period for the provider to submit additional information.

Based on this additional information, CMS must determine whether or not an overpayment exists. If so, CMS must give notice of the determination to the provider, and may offer a choice between a consent settlement to settle the projected overpayment or a full SVRS audit.

Overutilization of billing codes

By December 8, 2004, CMS must establish a process to give notice to certain classes of providers in cases where particular billing codes may be overutilized by that class of providers. CMS must collaborate with professional organizations representing various providers in the development of this process.

APPEALS*

** This section addresses appeals by Medicare beneficiaries, providers and suppliers, not appeals before the Provider Reimbursement Review Board (PRRB).*

HHS Administrative Law Judges established

The MMA makes important changes to the Medicare appeal process. Most significantly, by April 1, 2004 the Secretary of HHS was to develop a plan transferring responsibility for Medicare appeals from Administrative Law Judges (ALJs) at the Social Security Administration to the Department of Health and Human Services (the Social Security Administration used to be a division of HHS, but became an independent government agency in 1995). HHS met this deadline by submitting a report to Congress on March 26, 2004 that describes the transition process and sets a phased timetable, culminating in a transfer of responsibility for all Medicare appeals to HHS by October 1, 2005. A copy of the report can be reviewed at http://www.hhs.gov/medicare/appealsrpt.html.

Some commentators have expressed concern that this transfer will compromise the independence of ALJs, who currently reverse Medicare contractors in a high proportion of cases. Perhaps alert to this possibility, Congress included provisions in the new law requiring that HHS assure the independence of ALJs by placing the judges in an office that is "organizationally and functionally separate" from CMS. HHS's report to Congress addresses the issue, representing that HHS will take steps to maintain the independence of ALJs upon their transfer to HHS, and will have all ALJs report to the Secretary of HHS, rather than any officers at CMS.

Appeal time-frames for contractors

The Medicare Benefit Improvement and Protection Act of 2000, or "BIPA," reformed the appeals process by consolidating both Part A and Part B appeals into a uniform process, introducing a new level of appeal and a new appeals entity (the "qualified independent contractor" or QIC), and revising the time frames for all levels of appeal. Citing a lack of funding, CMS has delayed the implementation of much of BIPA. Nonetheless, the MMA makes numerous changes to the BIPA-required appeals system that is not yet in place:

- When BIPA is implemented, a decision on both the first and second level of appeal (the "redetermination" level and the "reconsideration" level) must be rendered in 60 days, rather than the 30 days originally provided by BIPA.
- Effective December 8, 2003, beneficiaries' medical records may be used in appeals reconsiderations by QICs.
- Beginning in 2005, the "amount in controversy" necessary to trigger the various appeal levels (currently $100) now will increase each year in accordance with the consumer price index.

Expedited judicial review