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Part D Provisions in Medicare Bill

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The Medicare Improvements for Patients and Providers Act, 2008 (the Act), enacted by Congress on July 15, 2008 contains several provisions that impact Part D. We have advised under separate newsletter as to the electronic prescription provisions, and we are separately providing a more detailed assessment of those provisions. This newsletter reviews the key other Part D provisions included in the Act. All provisions are effective for benefit years beginning on or after January 1, 2010, unless otherwise specified. All references to Part D plans include both stand alone plans and those offered through Medicare Advantage organizations.

Formulary Requirements for Protected Classes

The Act requires the Secretary to identify categories and classes of drugs which meet both of the following criteria:

- Restricted access would have major life threatening clinical consequences for individuals who have a disease or disorder.
- There is a significant clinical need for access to multiple drugs within a category or class due to unique chemical action and pharmacological effects of the dosing (e.g. drugs used to treat cancer).

Part D plans are required to include coverage of all Part D drugs in the identified categories and classes, but exceptions are permitted under a process that:

- Ensures exceptions are based on scientific evidence and medical stands of practice.
- For antiretroviral medications, is consistent with specified DHHS guidelines.
- Includes public notice and comment.

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The interpretation and implementation of this provision is likely to be very contested. Some view the provision as merely meant to codify the current CMS policy on the six protected classes. However, other than the mention of cancer, there is no reference to the other protected classes or of grandfathering. In order to have the rules finalized prior to the formulary submissions due in April of 2009 for the 2010 benefit year, CMS will need to issue a proposed rule very quickly.

Use of Part D Data

The Act requires that Part D data that the Secretary determines is necessary and appropriate for the organization to provide under a Part D contract:

- May be used to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services.
- Shall be made available to Congressional support agencies for purposes of conducting congressional oversight, monitoring, and making recommendations on Medicare.

This provision, which is effective upon enactment, basically reinforces CMS' authority underlying the final Part D claims data rule which took effect in June, 2008. However, there are no express limits on the scope of Part D claims data that could be disclosed.

Prescription Drug Pricing Standards

Part D plans that use a standard of reimbursement of pharmacies based on the cost of a drug (e.g. AWP) must update the drug pricing standards used for pharmacy reimbursement on at least a weekly basis, with an initial update on January 1 each year. This is effective for benefit years beginning January 1, 2009.

Barbiturates and Benzodiazepines

Beginning in 2012, Part D plans may cover barbiturates (for certain conditions) and benzodiazepines.

Designation of Compendia

The Act revises the definition of a "medically accepted indication" for which an off-label use of a Part D drug could be covered to:

- Establish a definition effective upon enactment applicable to a Covered Part D drug used as an anti-cancer chemotherapeutic regimen that is consistent with definition applicable to such drugs under the Part B

program. There is no change for off-label uses for non cancer drugs, which retains the existing definition which is consistent with the Medicaid program.

- Provide for updating the compendia used in defining "medically accepted indication" under the Part D program using a process consistent with that under Part B, which allows the Secretary to update the list rather than requiring a statutory change, effective for 2009 budget year.
- Require compendia used to identify medically accepted indications have a publicly transparent process for evaluating therapies and identifying potential conflicts of interest (as of January 2010).

These provisions would be expected to expand the sources that could be used as a basis for establishing coverage of off-label cancer treatments under Part D.

Low-Income Provisions

The Act includes several protections for Low-Income Subsidy (LIS) population, including ones that:

- Eliminate the application of Part D late enrollment penalties to LIS individuals, effective January 1, 2009.
- Exempt the value of life insurance policies from the assets and resource test to determine eligibility for Part D LIS, effective January 1, 2010, for eligibility determinations for months beginning on that date.
- Provide an opportunity for judicial review of final LIS eligibility decisions retroactive to enactment of MMA.
- Expand eligibility for the Medicare Savings Programs (means-tested programs that pay Medicare cost-sharing) by increasing the asset limits. Individuals who enroll in the MSPs automatically receive low income subsidies under Part D, so the provision can be expected to increase enrollment in LIS.

Prompt Payment by Part D Plans

The Act requires Part D plans to transmit payment to pharmacies (other than mail order or long term care pharmacies) for clean claims within 14 days of receipt for claims submitted electronically or 30 days for all other clean claims.

- Claims are deemed to be clean if the Part D plan does not notify claimant of deficiency within required time frames.
- For claims that are not clean, timely notice must include all deficiencies.
- Interest payments at a specified rate are required if payment is not made within the required time frame.

- Interest payments can not be included in Part D plan administrative costs or allowable risk corridor costs.
- Part D plans are prohibited from retaliating against providers that exercise their rights.
- Part D plans must pay all clean claims submitted electronically by electronic transfer of funds upon request by the pharmacy.
- Pharmacies located in or contracting with long term care facilities have at least 30, and up to 90 days to submit claims to Part D plans.

The Act appears to require that these provisions be included in all contracts between Part D plans and pharmacies.

Marketing Prohibitions and Limitations

The Act includes several new provisions expanding the scope of CMS oversight of Part C and Part D plan marketing activities.

Prohibited activities as of January 1, 2009 now include:

- No cash, gifts or monetary rebates except as specifically permitted
- No unsolicited means of direct contact including door to door and outbound telephone contact
- No cross-selling of non-health related products
- No meals regardless of value at promotional or sales events
- No marketing in health care settings (except in common areas) and at educational events

Certain activities are now limited and further regulated (as provided by the Secretary but no later than November 15, 2008):

- Scope of the marketing appointment needs to be spelled out in advance
- Co-branding (e.g. the name and logo of network providers on plan materials) will be limited
- Promotional items and gifts can not exceed nominal value
- Compensation can only be under guidelines that ensure the use of incentives to enroll beneficiaries in plans that best meet their needs

New provisions also now address HHS/State collaboration to address fraudulent or inappropriate marketing practices for contract years beginning January 1, 2009:

- Plans must only use licensed agents and brokers,

comply with state appointment laws, and report reasons for terminations to states under applicable state law

- Plans must also comply with state requests for information about licensed agents, brokers or other third parties as part of a state investigation

The Act goes about as far as Congress can to strengthen Medicare jurisdiction over marketing without turning it over to states. The interesting regulatory issue is how these changes will comport with the rules proposed in May by CMS that were an attempt to stave off additional statutory mandates on marketing. CMS now faces the daunting task of issuing new rules so they can be in effect for the marketing activities that begin October, 2008 for the 2009 plan year.

Other Provisions

There are numerous other provisions relevant to stakeholders in the prescription drug arena, including regarding clinical trials, comparative effectiveness studies, coverage of preventive services, studies on racial and ethnic disparities, etc. Please let us know if you would like any more information on those – or any other – aspect of the Act.

back to top

FOR ADDITIONAL INFORMATION ON THIS ISSUE, CONTACT:

Wendy L. Krasner Ms. Krasner has extensive expertise in federal healthcare programs in areas including Medicare coverage, pharmaceutical reimbursement, and Medicare and Medicaid managed care arrangements. In particular she has a unique expertise with regard to the legal, regulatory and policy implications of the new prescription drug benefit now offered under Medicare and how the new benefit interacts with the many other facets of our healthcare system.

Andrea G. Cohen Ms. Cohen provides advice on legal issues, policy, advocacy and strategy to healthcare and not-for-profit clients. Before joining Manatt, she served as Health and Oversight Counsel to the U.S. Senate Finance Committee, where she advised Senator Max Baucus (D-MT) and other members of the Finance Committee on legislative and investigative matters relating to Medicaid, Medicare, and the Children's Health Insurance Program. In that role, she participated actively in negotiating and drafting the Medicare Modernization Act of 2003. She also served as Senior Policy Counsel at the Medicare Rights Center from

2004-2005, where she represented consumers' interests in implementation of the new Medicare legislation.