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CMS WITHDRAWS CONTROVERSIAL CHANGES TO MEDICARE PART D

EXECUTIVE SUMMARY

On March 10, 2014, CMS announced in a letter to Congress that it plans to withdraw certain controversial provisions of its omnibus-type proposed rule on policy and technical changes to the Medicare Advantage Program ("Part C") and Medicare Prescription Drug Benefit Program ("Part D"). Following the proposed rule's publication on January 10, 2014, CMS received numerous comments from members of Congress and health care industry stakeholders expressing concern that the proposed rule would result in unnecessary changes to Part D and impede beneficiaries' access to affordable health care. Although CMS has elected not to finalize certain provisions of the proposed rule at this time, entities such as pharmacies, pharmacy benefit managers ("PBMs"), health insurers and providers involved in providing prescription drug benefits under Parts C and D should be aware of the potential impact of portions of the proposed rule that remain in place.

DETAILED ANALYSIS

Among other changes outlined in the proposed rule, CMS initially recommended proposals to lift the protected class definition on three drug classes, set standards on Part D plans' requirements to participate in preferred pharmacy networks, reduce the number of Part D plans a sponsor may offer and clarify the non-interference provisions of the Social Security Act. Due to an outpouring of concern from industry stakeholders during the proposed rule's comment period, CMS Administrator Marilyn Tavenner stated on March 10 that CMS will not be taking steps to finalize the following proposed changes at this time:

- Removing three drug classes (immunosuppressants for the treatment of drug rejection, antidepressants and antipsychotics) from a protected class of drugs. This proposal would have resulted in Part D plan sponsors no longer being required to include all or substantially all drugs in these three drug classes on their Part D formularies.
- Implementing a formal interpretation of the so-called "non-interference provision" of the Social Security Act, which is intended to promote competition and generally prohibits the government from interfering with negotiations between drug manufacturers, pharmacies and Part D plan sponsors. In the proposed rule, CMS took the position that it does not interpret the non-interference provision as applying to negotiations between Part D plan sponsors and pharmacies, although CMS clarified that it would not interfere with contractual disputes between sponsors and pharmacies unless the matter implicated CMS requirements.
- Setting standards related to Part D plan sponsors' use of preferred pharmacy networks. Citing concerns that preferred pharmacy networks can result in some beneficiaries not having access to preferred pharmacies, CMS proposed requiring all Part D plan sponsors to offer pharmacies the opportunity to offer "preferred cost sharing" if the pharmacy met certain "any willing provider" requirements.
- Proposing to limit the number of plans stand-alone prescription drug plan sponsors may offer in a region.

CMS's announcement that it does not currently plan to finalize the proposed provisions described above does not mean that such changes are completely dead. In its letter to Congress, CMS explained that it plans to engage in future stakeholder input "before advancing some or all of the changes in these areas in future years." More importantly, stakeholders should be aware that many key portions of the proposed rule have not been withdrawn. Specifically, CMS stated in the letter that it intends to finalize the following proposals at this time:

- Proposals related to consumer protections and business continuity for Medicare Advantage ("MA") organizations and Part D plan sponsors. These proposals include requiring MA organizations and Part D sponsors to develop and maintain business continuity plans for use during natural disasters. CMS also plans to mandate that essential functions, including benefit authorization, claim adjudication, call center and supporting operations, be restored within 24 hours after such functions fail or are disrupted during a disaster. Such proposals will require the cooperation of pharmacies and PBMs with which MA organizations and Part D sponsors contract.
- Strengthening standards for prescribers of prescription drugs under Part D. To help ensure that Part D drugs are prescribed only by qualified prescribers, CMS has proposed that physicians and eligible professionals enroll in the Medicare program by January 1, 2015 in order to prescribe covered Part D drugs. This will require Part D sponsors or their designated PBMs to check a prescriber's individual NPI to determine whether the prescriber is validly enrolled in Medicare before paying a claim from a network pharmacy or a request for

reimbursement from a beneficiary. Additionally, CMS has proposed granting itself authority to deny a physician or eligible professional's Medicare enrollment application if the professional's DEA certificate or ability to prescribe drugs under his or her state license is revoked or suspended.

- Expanding the release of Part D data, including unencrypted prescriber, pharmacy and plan identifiers contained in prescription drug event ("PDE") records, to external researchers in order to assist CMS in evaluating the Part D program and improve the clinical care of beneficiaries. Beneficiary identifiable data and commercially sensitive data of Part D sponsors (such as data on bids, rebates and other price concessions) will not be subject to release, although this proposal would provide external researchers such as HHS entities and Congressional oversight agencies access to prescriber-identified claims to study prescribing trends.

PRACTICAL TAKEAWAYS

Although CMS has withdrawn certain controversial changes in the proposed rule, pharmacies, PBMs, health insurers and providers should be aware that many other provisions of the lengthy proposed rule still stand. CMS's letter did not rescind or otherwise address other provisions in the proposed rule, such as provisions related to mail order pharmacies, medication therapy management ("MTM") programs, application of prescription drug pricing standards and the expansion of CMS's audit, evaluation and inspection authority. Due to the large volume of comments received on the proposed rule, industry stakeholders will have to wait to see how CMS addresses such comments in the final rule.

If you have any questions or would like additional information about this topic, please contact Julie K. Lappas at 317-977-1490 or jlappas@hallrender.com or your regular Hall Render attorney.

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