New Proposed Medicare-Endorsed Prescription Drug Card Assistance Program Fails To Protect the Privacy of Medicare Beneficiaries

On March 6, 2002, the federal Centers for Medicare & Medicaid Services (CMS) published a proposed rule creating a prescription drug card assistance program for Medicare beneficiaries. (See 67 Fed. Reg. 10262.) The proposed rule establishes a process through which drug card sponsors (e.g., pharmacy benefit managers) obtain a Medicare endorsement from CMS for their prescription drug card program.

Despite some privacy-related promises made in the preamble to the proposed rule, the only limit in the actual text of the proposed regulation on how sponsors (e.g., pharmacy benefit managers) use and disclose protected health information is that they cannot “send or otherwise direct market to beneficiaries materials unrelated to the Medicare-endorsed prescription drug card program, unless the beneficiary provides prior written consent to receive these materials.” §403.806(c)(6)

- There is no reference to how consent is obtained or what must be included in the consent form (e.g., no ban on burying the consent in the enrollment forms).
- There is no ban on forced consent (requiring that consent be signed in order to enroll in program).

There is no other limit on how sponsors use beneficiary information.

There is no other requirement in the text of the regulation about beneficiary consent or authorization for any use or disclosure.

There is no limit on how sponsors disclose beneficiary information to others.

Sponsors only need to adhere to the following vague requirements:

- “Protect the privacy and confidentiality of beneficiaries and beneficiary-specific information” §403.806(c)(5)
- “Maintain written privacy policies describing how privacy and confidentiality will be protected.” §403.806(c)(7)
• Include in their privacy policies how they will “notify beneficiaries of the expected uses of their personal information.” §403.806(c)(7) [note: doesn’t require that notice be sent/received in advance of enrollment]

• When Medicare beneficiaries are enrolled as a group by a health insurer, the sponsor must “assure . . . [d]isclosure to beneficiaries of all expected uses of their personal information under the endorsed drug discount program” §403.811(b)(1)(iii) [note: doesn’t require that “disclosure” be sent/received in advance of enrollment]

In addition, sponsors share beneficiary information with each other under the rubric of an administrative consortium. (See §403.810.) There are no limits on what beneficiary information goes to the consortium or on how the consortium (or its members) use or disclose it to others.

It is imperative that the regulations governing this prescription drug card program include strong privacy safeguards because it is unclear to what extent the new HIPAA medical privacy regulation would apply. The proposed rule itself does not address the applicability of the HIPAA privacy regulation. Comments on this proposed rule must be received by CMS no later than May 6, 2002.

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