

HIPAA and Patient Privacy Issues Raised by the New Medicare Prescription Drug Program

National Medicare Prescription Drug Congress

February 25-27, 2004

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- Creation of New Covered Functions by Medicare Prescription Drug Legislation
- Business Associate Considerations
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Entities Covered by HIPAA

- Privacy Rule applies only to covered entities:
 - Health Plans
 - Healthcare clearinghouses
 - Healthcare providers that engage in electronic transactions such as electronic billing for services

Creation of New Covered Entities by Medicare Prescription Drug Legislation

- Legislation names “Prescription Drug Card Sponsors” as covered entities for HIPAA purposes
- Legislation defines prescription drug card sponsor as:
 - a pharmaceutical benefit management company (PBM)
 - a wholesale or retail pharmacy delivery system
 - an insurer
 - a Medicare + Choice organization
 - any combination of these entities
- Although endorsed sponsors are not by definition “health plans” under the HIPAA Privacy Rule, commentary to the Medicare prescription drug legislation (MPDL) indicates that they are to comply with the Privacy Rule in the same way as health plans are required to

Effective Dates for MPDL

- The MPDL requires that the comprehensive prescription drug benefit be implemented on January 1, 2006
- The MPDL also creates an interim prescription discount drug card available in June of 2004. These cards are intended primarily for individuals that do not have outpatient prescription drug insurance. This interim plan will end upon the January 1, 2006 commencement of the comprehensive plan
- Entities electing to participate in the interim prescription drug card plan must be in compliance with the HIPAA privacy regulations in order to participate
- Only those entities not participating in a prescription drug card plan until January 1, 2006 can postpone HIPAA compliance until such date

Covered Functions Under HIPAA

- Under the HIPAA privacy regulations covered functions are those that make an entity a covered entity (e.g. providing medical care and billing electronically for the care provided are covered functions)
- Some entities perform both covered and non-covered functions. In these cases entities can choose to act as a covered entity or elect to function as a hybrid entity
- Hybrid entities are single legal entities that engage in covered and non-covered functions and have formally designated healthcare components

Covered Functions Under HIPAA (cont'd)

- If an entity elects to declare itself a “hybrid entity,” all components of the entity that perform covered functions must be included as part of the hybrid entity’s healthcare component
- Healthcare components can include non-covered functions if the hybrid entity chooses to include them in the designated healthcare component

Creation of New Covered Functions by the Medicare Prescription Drug Legislation

- By virtue of the creation of new covered entities, the MPDL creates new covered functions as well
- Functions of endorsed sponsors that are directly related to, or necessary for the operations of an endorsed discount card program are covered functions that have been newly created by the MPDL
- Only the endorsed sponsor's operations of an endorsed program are covered functions
- Consequently, activities performed by an endorsed sponsor outside of the scope of its endorsement under the Medicare discount drug program are not made covered functions by the legislation

Creation of New Covered Functions by the Medicare Prescription Drug Legislation (cont'd)

- Entities that perform covered functions and non-covered functions can decide whether to operate as a hybrid entity
- This option is likely to be faced by many prescription drug card sponsors
- Ease of administration may cause a number of prescription drug card sponsors to designate the whole entity as a covered entity, such as when the entity's sole business is the provision of prescription drug cards
- Larger entities participating in prescription drug card programs as well as various other functions may prefer to designate themselves as a hybrid entity

Creation of New Covered Functions by the Medicare Prescription Drug Legislation (cont'd)

- There are a number of implications associated with designating an entity as a hybrid entity as well as with designating an entity as a covered entity when covered as well as non-covered functions are performed
- Entities that designate themselves as hybrid entities must implement measures to restrict access to health information by departments or units that are not designated as part of the covered healthcare component
- Hybrid entities will likely have different policies and procedures for covered and non-covered components and must take this into account when incorporating HIPAA compliance into their operations

Creation of New Covered Functions by the Medicare Prescription Drug Legislation (cont'd)

- Currently, existing prescription drug card programs may have limited exposure to HIPAA, depending on whether they have access to protected health information as part of their functions
- Other entities effected by the MPDL, such as wholesale and retail pharmacies, should already be in compliance with HIPAA
- As a result, the impact of HIPAA compliance initiatives will vary greatly among entities soon to be considered covered entities under the MPDL

Creation of New Covered Functions by the Medicare Prescription Drug Legislation (cont'd)

- A number of entities that will become covered entities under the MPDL are familiar with HIPAA compliance requirements in their capacity as business associates
- The HIPAA privacy regulations require covered entities to enter into business associate agreements with their business associates to ensure that business associates safeguard the confidentiality of the protected health information they create or access on behalf of the covered entity
- Any entity that is currently a business associate will likely have some confidentiality measures required by the HIPAA privacy regulations in place in order to comply with the requirements of their business associate agreements

Business Associate Considerations

- Prescription drug card sponsors that are not currently covered entities will have to ensure (in order to comply with the MPDL's provisions regarding HIPAA) that they identify their own business associates and enter into business associates agreements
- Again, entities participating in prescription drug card plans either during the interim period or later, must be in compliance with the HIPAA privacy regulations prior to participation. This includes compliance with the business associate requirements

Business Associate Considerations (cont'd)

- Depending on the number of contracts that will be subjected to the business associate requirements, this could be a major undertaking and consideration of this issue should be contemplated in advance
- Identification of business associates and implementing tracking systems for maintaining contracts with business associates will be an important component of compliance

Business Associate Considerations (cont'd)

- Since covered entities can also be the business associate of another covered entity, it is important to note that “covered entity” status will have no effect on business associate agreements in effect between prescription drug card sponsors and other covered entities
- Within hybrid entities, business associate agreements are not required between covered and non-covered components

Creation of the Council for Technology and Innovation

- The Medicare Prescription Drug Legislation proposes to establish a new Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (“CMS”) and staffed by senior CMS personnel
- Part of the MPDL’s initiative to increase access to new technologies, the Council for Technology and Innovation will act to better coordinate coverage, coding and payment decisions
- There is tremendous support for the creation of the Council for Technology and Innovation since it is hoped that it will expedite and improve access to new medical advances

Creation of the Council for Technology and Innovation (cont'd)

- The Council for Technology and Innovation should be able to help remove regulatory burdens which currently make the process for obtaining access to new advances cumbersome
- In addition, the Council for Technology and Innovation should also help decrease obstacles to patient care that currently exist. This could bring significant new treatment options to patients
- The Council for Technology and Innovation will likely seek to establish better channels of communication between HHS and providers and beneficiaries which will facilitate the process for making new technology available

Creation of the Council for Technology and Innovation (cont'd)

- Seniors stand to benefit from the Council for Technology and Innovation if it succeeds in decreasing the amount of time CMS takes to make new medical technologies available
- New drug therapies should also become available more expeditiously with the involvement of the Council for Technology and Innovation.