

regulations as set forth in parts 160, 162, and 164 will still govern the performance of those functions which make it a health plan, health care clearinghouse, or covered health care provider.

c. HIPAA Privacy Rule

As covered entities, endorsed sponsors are responsible for complying with the HIPAA Privacy Rule. The Privacy Rule limits the uses and disclosures a covered entity may make with individually identifiable health information (known as protected health information), requires that safeguards be applied to the information to protect it, and gives individuals rights with respect to the protected health information about them, including rights to access and correct the information. Thus, endorsed sponsors are responsible for safeguarding the protected health information of beneficiaries of the program, and must limit the uses and disclosures made with the information to only those permitted by the Privacy Rule and these regulations. In addition, under the program, beneficiaries have certain rights to be informed of the uses and disclosures the endorsed sponsor is permitted or required to make with their protected health information, to access their records, and to have corrections made to their records, among other rights. See 45 CFR part 160 and subparts A and E of part 164 for the full set of standards, implementation specifications, and requirements of the Privacy Rule.

1. Endorsed Sponsors To Be Treated in Same Manner as Health Plans

The standards, implementation specifications, and requirements in the HIPAA privacy regulations do not apply uniformly to all covered entities; rather, certain provisions apply only to one or two of the different types of covered entities. We believe we have the discretion to prescribe the manner in which the regulations will apply to endorsed sponsors, as section 1860D-31(h)(6)(A) is silent on this issue. Although endorsed sponsors are not by definition health plans under HIPAA, we believe that the HIPAA privacy regulations should apply to endorsed sponsors in the same manner as applicable to health plans because endorsed sponsors' operations more closely resemble those of health plans than health care clearinghouses or providers.

Health plans are organizations that provide, or pay the cost of, "medical care," which is defined in section 2791(a)(2) of the Public Health Service

Act (42 U.S.C. 300gg-91(a)(2)) as amounts paid for (1) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; (2) amounts paid for transportation primarily for and essential to such medical care; or (3) amounts paid for insurance covering such medical care or transportation. As endorsed sponsors do not themselves provide or pay the cost of medical care, they are not by this definition health plans under HIPAA. However, endorsed sponsors resemble health plans in several respects.

Whereas health plans typically negotiate discount rates for health care products and services, endorsed sponsors similarly will negotiate discounted prices for covered discount card drugs. In addition, health plans coordinate health care for its enrollees, in part by assessing the interaction of various modalities of treatment, which endorsed sponsors also provide albeit on a more limited basis by assessing and avoiding adverse drug interactions and providing educational activities that resemble some of a health plan's care coordination activities. Endorsed sponsors' processing payment for covered discount card drugs provided to transitional assistance enrollees is also somewhat similar to a health plan's payment infrastructure and processes, although unlike health plans, generally speaking, endorsed sponsors would not be bearing capitated risk under this program.

In contrast, the functions performed by endorsed sponsors do not resemble the functions performed by health care providers or health care clearinghouses. A health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), or any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. Under the Medicare discount drug card program, endorsed sponsors will not provide medical or health services to beneficiaries, but instead will arrange for discount card enrollees to have access to negotiated prices and related products and services. A health care clearinghouse is a public or private entity that processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction or receives a standard transaction from another entity and processes or facilitates the

processing of health information into nonstandard format or nonstandard data content for the receiving entity. Endorsed sponsors, however, will not be required to perform such services. Accordingly, except as otherwise provided and discussed below, § 403.812(b) of our regulations provide that the HIPAA privacy regulations will apply to endorsed sponsors in the same manner as they apply to health plans.

2. Waiver by the Secretary

Section 1860D-31(h)(6)(B) provides that, in order to promote participation of endorsed sponsors in the Medicare drug discount card program, the Secretary may waive portions of the HIPAA Privacy Rule for a limited period of time as the Secretary deems appropriate. While the Secretary expects endorsed sponsors to be able to comply with the Privacy Rule and, therefore, does not at this time anticipate a need to exercise his waiver authority, the Secretary reserves the right to do so at a later time, if such waiver is deemed necessary to promote participation of endorsed sponsors in the Medicare drug discount card program.

3. Administering the Drug Card Program

The Privacy Rule permits covered entities to use or disclose protected health information without individual authorization for health care treatment and payment activities, as well as for certain legal, financial, and administrative functions—known as health care operations—that support treatment and payment activities. To carry out their obligations under the Medicare drug discount card program, endorsed sponsors will have to conduct a number of activities pertaining to products and services offered under the endorsement that may involve the use or disclosure of beneficiary information. These activities and services will include processing beneficiary applications and enrollment in the program, reducing the likelihood of medication errors and adverse drug interactions, providing customer service and information and outreach materials, and administering transitional assistance. (For a description of the services required as part of the endorsement, see section II.C.5 of this document.) The use or disclosure of beneficiary protected health information for these activities are encompassed within the Privacy Rule's definition's of "payment" and "health care operations" and, thus, may be conducted without beneficiary authorization.