Frequently Asked Questions

Health Insurance Portability and Accountability Act (“HIPAA”) Frequently Asked Questions for Data Associated with 340B Drug Pricing Program

The purpose of this document is to help address questions specific to HIPAA’s application to prescription-related data relevant to the 340B Program.

Why does Kalderos obtain certain data from providers in connection with the 340B Program?

Kalderos works with stakeholders across the pharmaceutical supply chain to ensure the integrity of drug discount programs. In this instance, Kalderos is retained by drug manufacturers to work on the manufacturer's behalf to verify 340B discounts to 340B Program covered entity providers. Kalderos acts on behalf of the manufacturer to analyze 340B discounts to these providers and to provide information to manufacturers to allow them to determine whether a 340B discount to a provider is consistent with 340B Program rules and whether a prohibited duplicate discount scenario exists.

What data does Kalderos require to verify the provider's 340B discount?

Kalderos uses the minimum necessary data to review the 340B discount. Specifically, Kalderos uses the prescription ID, national drug code ("NDC"), units, date of service, national provider identifier ("NPI"), 340B covered entity ID, and certain drug information from the entity's historical drug purchasing data to analyze the discount. If necessary, manufacturers may define additional required fields for the purpose of fulfilling the financial transaction. This data is required in order to verify whether the discounts are consistent with 340B Program rules and whether a prohibited duplicate discount scenario exists.

Is it Kalderos's view that HIPAA requires a business associate agreement ("BAA") between Kalderos and a provider for Kalderos to receive the data necessary to verify the provider's 340B discount?

No. Kalderos works with stakeholders throughout the pharmaceutical supply chain on behalf of the drug manufacturer that provides the 340B discount. HIPAA permits health care providers that are "covered entities" to disclose information covered by HIPAA (i.e., Protected Health Information) for their own payment purposes without a BAA as part of their payment activities, among other purposes. See 45 C.F.R. § 164.501. The U.S. Department of Health and Human Services' Office for Civil Rights ("OCR") has explained that HIPAA covered entities (e.g., health plans) can disclose information to manufacturers consistent with HIPAA and without a BAA for purposes of adjudicating claims in the following two FAQs:

FAQ 455: Does the Privacy Rule permit health plans to disclose protected health information to pharmaceutical manufacturers for the adjudication of drug rebate contracts?

Yes. The Privacy Rule permits a health plan to disclose protected health information, such as prescription numbers, to a pharmaceutical manufacturer for purposes of adjudicating claims submitted under a drug rebate contract. Because the amount of the rebate is based on drug utilization by individual enrollees, such disclosures are permitted as part of a covered entity's payment activities. See 45 CFR 164.502(a)(1)(ii) and the definition of "payment" at 45 CFR 164.501.

A business associate agreement is not required to make these disclosures. However, a health plan must make reasonable efforts to limit the information disclosed to that which is the minimum necessary to adjudicate claims under the contract. See 45 CFR 164.502(b) and 164.514(d) for more information on the minimum necessary standard.

HHS, OCR, FAQ, June 5, 2003, https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html.

FAQ 456: Does the Privacy Rule permit state Medicaid agencies to disclose protected health information to pharmaceutical manufacturers and third party data vendors for purposes of validating claims under the Medicaid Drug Rebate program?

Yes. The Privacy Rule permits State Medicaid agencies to disclose protected health information, such as prescription numbers, to pharmaceutical manufacturers and third party data vendors that assist the pharmaceutical manufacturers, for purposes of validating claims submitted under the Medicaid Drug Rebate program. Because the amount of the rebate is based on drug utilization by individual enrollees, such disclosures are permitted as part of a State Medicaid agency's payment activities. See 45 CFR 164.502(a)(1)(ii) and the definition of "payment" at 45 CFR 164.501.

A business associate agreement is not required to make these disclosures. State Medicaid agencies are required by law to disclose certain information to drug manufacturers as part of the drug rebate program. To the extent that the law requires a disclosure, the minimum necessary standard does not apply. (See 45 CFR 164.512(a) for further information and limitations on disclosures required by law.) To the extent that protected health information is disclosed for payment purposes but not pursuant to a legal requirement, the State Medicaid agency must make reasonable efforts to limit that information to that which is the minimum necessary to adjudicate the rebate claims. See 45 CFR 164.502(b) and 164.514(d) for more information on the minimum necessary standard.

HHS, OCR, FAQ, June 5, 2003, https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html.

In accordance with this guidance from OCR on permissible payment-related disclosures, it is Kalderos' view that the disclosure of such information by providers, or their business associates acting on their behalf, to a manufacturer, or an entity acting on the manufacturer's behalf, for the purposes of evaluating the propriety of discounts associated with 340B utilization is permitted under HIPAA without a BAA. Similar to OCR's claims adjudication FAQ – where OCR has made clear that a BAA is not required – here, it is our view that a BAA is not required for a provider to disclose information to a manufacturer (or its contractor) for purposes of the manufacturer's determination of whether a discount is consistent with 340B Program rules and whether a prohibited duplicate discount scenario exists in connection with a drug dispensed by a provider. This disclosure is subject to the minimum necessary standard.

As noted in the previous FAQ, in order to verify the 340B discount, the manufacturers on whose behalf Kalderos operates need the following information about each patient for whom a provider seeks a discount: prescription ID, NDC, units, date of service, NPI, 340B covered entity ID, and certain drug information. These data elements are each necessary for the manufacturers to validate whether discounts are consistent with 340B Program rules and whether a prohibited duplicate discount scenario exists.

Please note that this FAQ addresses questions specific to HIPAA's application to prescription-related data relevant to the 340B Program. Other laws may apply that are not covered by this FAQ. This information is provided for informational purposes only, and is not intended to be legal advice.