340B ESP AND HIPAA

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OVERVIEW

- 340B Contract Pharmacy
- Manufacturer restrictions
- 340B ESP
- Data submission requirements
- Health Insurance Portability and Accountability Act (“HIPAA”) Analysis

340B CONTRACT PHARMACY

- 340B covered entities may dispense 340B drugs directly or through contractual arrangements with third party pharmacies (“contract pharmacies”)
- Contract pharmacy model typically operates under a “replenishment” or “virtual” inventory model
  - Drugs are dispensed to patients from common drug stock and drugs eligible for 340B pricing are purchased to restock the inventory
- Claims for 340B drugs are generally identical to claims for all other drugs
  - Eligibility for 340B pricing is typically determined after dispensing

MANUFACTURER RESTRICTIONS

- Drug manufacturers are not required to provide a 340B discount and a Medicaid drug rebate on the same drug
  - Providing both is called a “duplicate discount” and covered entities are prohibited from causing duplicate discounts from occurring[1]
- Duplicate discounts are typically prevented from occurring by excluding Medicaid claims from 340B replenishment
- 340B Program does not prohibit contractual duplicate discounts
  - Rebates that are voluntarily offered by manufacturers under commercial payor and Pharmacy Benefit Manager (“PBM”) agreements

Sources:
1. https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion

MANUFACTURER RESTRICTIONS

- Beginning in mid-2020, certain manufacturers began restricting access to 340B drugs dispensed through contract pharmacy arrangements
- Purported reason is to monitor duplicate discounts
- Currently 18 manufacturers are restricting access to 340B pricing on drugs dispensed through contract pharmacy arrangements[1]
  - 16 require submission of contract pharmacy dispensing data
  - 13 allow for exception of designation of a single contract pharmacy
  - 12 allow for exception of designation of covered entity/system owned retail pharmacy

Sources:
1. https://www.340besp.com/resources

340B ESP

- Technology platform to collect claim-level data on 340B drugs dispensed through contract pharmacies[1]
- Collects data and transmits it to participating drug manufacturers
- Drug manufacturers use the data to identify potential Medicaid and commercial duplicate discounts

Sources:

1. https://340besp.com/

DATA SUBMISSION REQUIREMENTS

- Covered entities register to submit claims data for drugs of participating manufacturers
- Covered entities are expected to upload data twice a month[1]
  - 9 specific data elements
    - Rx Number*
    - Prescribed date*
    - Fill date*
    - National Drug Code (“NDC”)
    - Quantity
    - Pharmacy ID
    - Prescriber ID
    - Wholesaler invoice number
    - 340B covered entity ID

*Data elements hashed via SHA-3 process

Sources:
1. https://340besp.com/faqs#section2

HIPAA ANALYSIS

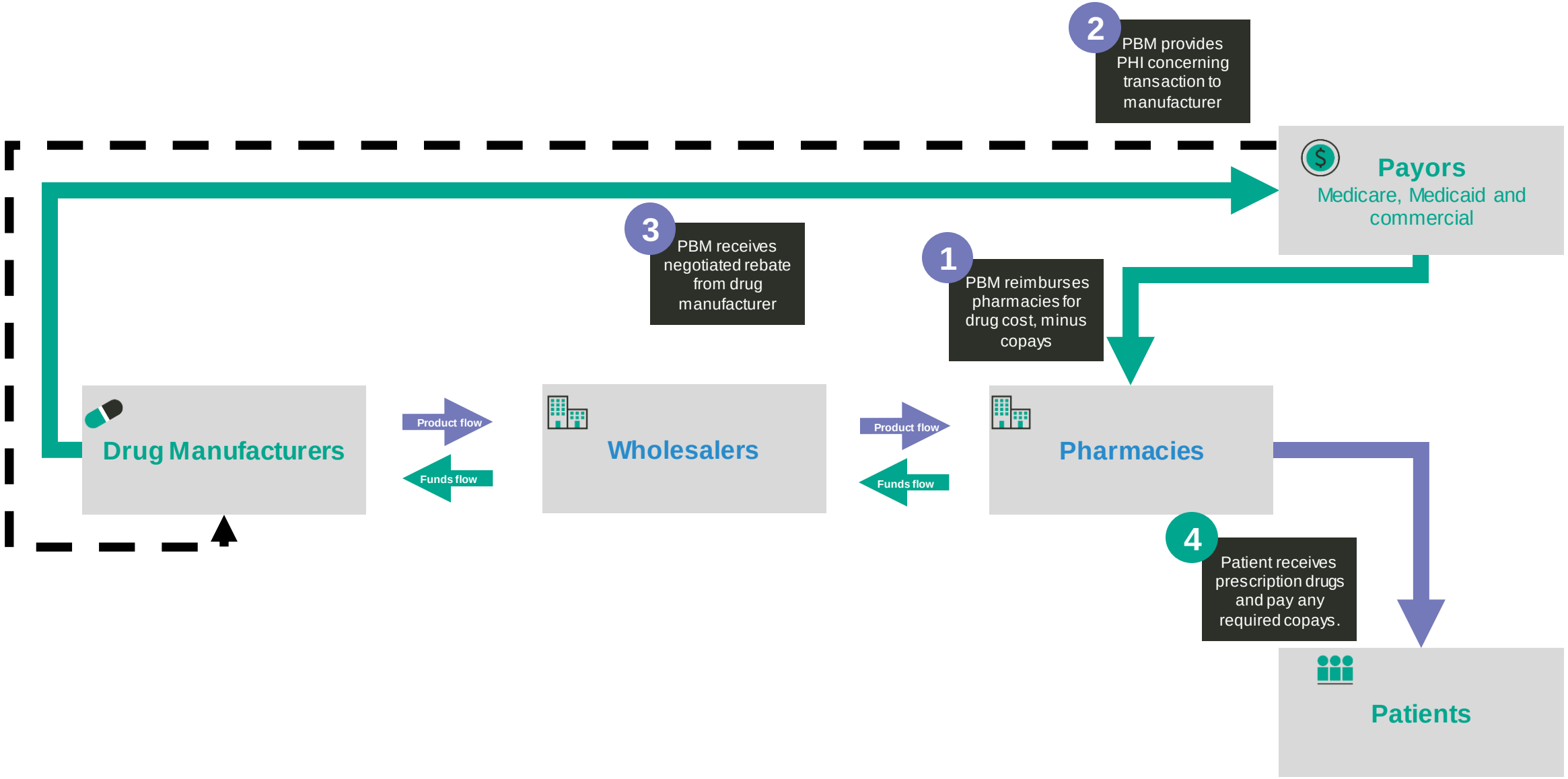
HIPAA permits the following uses and disclosures of Protected Health Information ("PHI") for payment purposes:

- A covered entity may use or disclose PHI for **its own** treatment, **payment**, or health care operations[1]

- A covered entity may disclose PHI **to another covered entity or a health care provider** for the **payment** activities of the entity that receives the information[1]

Sources:
1. https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html

MODEL OF PRESCRIPTION DRUG REBATE FLOW



PERMITTED DISCLOSURE OF PHI TO MANUFACTURER

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

Answer:

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.

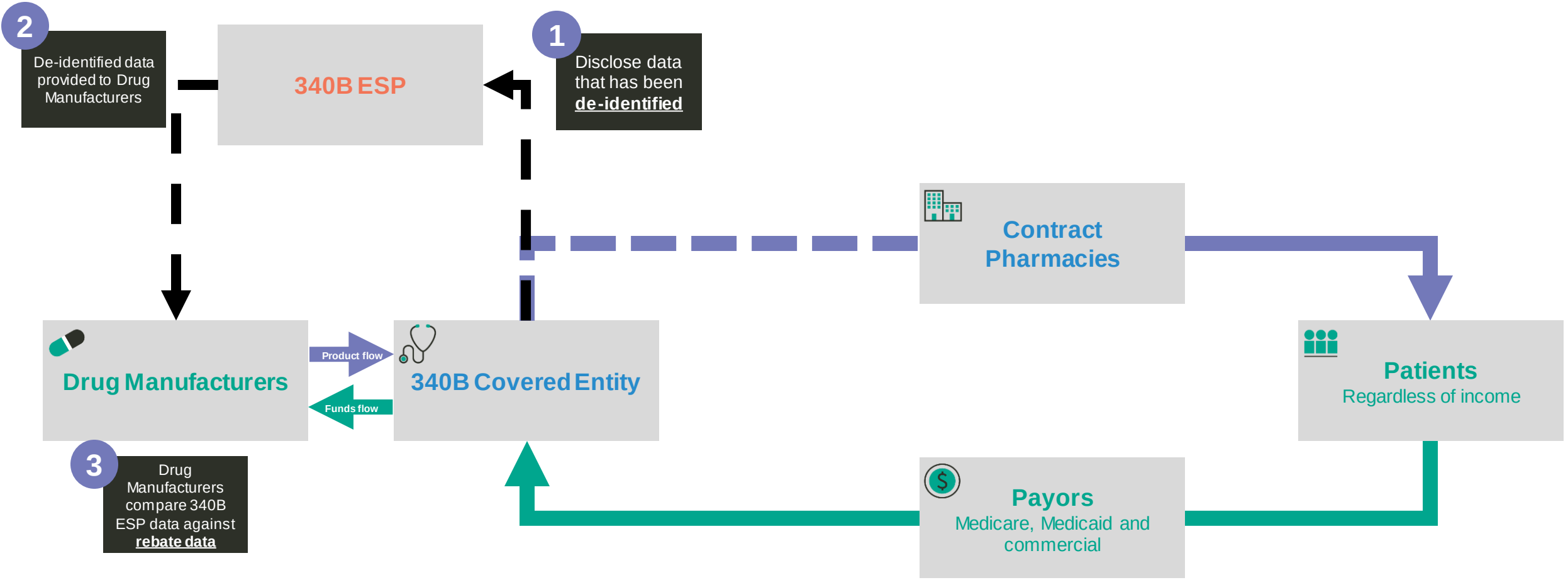
A business associate agreement is not required to make these disclosures. However, a health plan must make reasonable efforts to limit the information disclosed to that which is the minimum necessary to adjudicate claims under the contract. See 45 CFR 164.502(b) and 164.514(d) for more information on the minimum necessary standard.[1]

Sources:
1. https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html

PURPLE6

Above is the NY code, please write it down and enter on the *CLE Affirmation Form/Post-Program CLE Survey* to receive a CLE Certificate.

340B ESP DATA FLOW



DIFFERENCES BETWEEN HIPAA FAQ SCENARIO AND 340B ESP DISCLOSURES

- 340B covered entities do not hold rebate contracts with drug manufacturers
- 340B discounts are separate from, and not directly related to, the rebates that PBMs receive
- Under 340B ESP arrangement, covered entity discloses de-identified data related to transaction *after* covered entity has already received discount from manufacturer
- PBMs provide rebate data to manufacturer as part of process to receive the rebate

ARGUMENTS THAT DISCLOSURE OF PHI TO DRUG MANUFACTURER IS FOR 340B COVERED ENTITY'S OWN "PAYMENT" PURPOSES

- The disclosure is ultimately within the payment "cycle" associated with the 340B program

- The disclosure serves a "payment" purpose by ensuring that the same drugs that are discounted are not inappropriately subject to rebate later on in the "cycle"

ARGUMENTS THAT THE DISCLOSURE OF PHI IS ULTIMATELY A DISCLOSURE TO ANOTHER COVERED ENTITY FOR *ITS* PAYMENT PURPOSES

- Per the logic of the FAQ, a 340B covered entity could disclose the PHI to a PBM if the PBM independently requested the data to fulfill a rebate contract with a drug manufacturer

- The manufacturer is essentially asking the PBM and 340B Covered Entity to skip this step because the PBMs are not incentivized to administrate such data collection and disclosure