



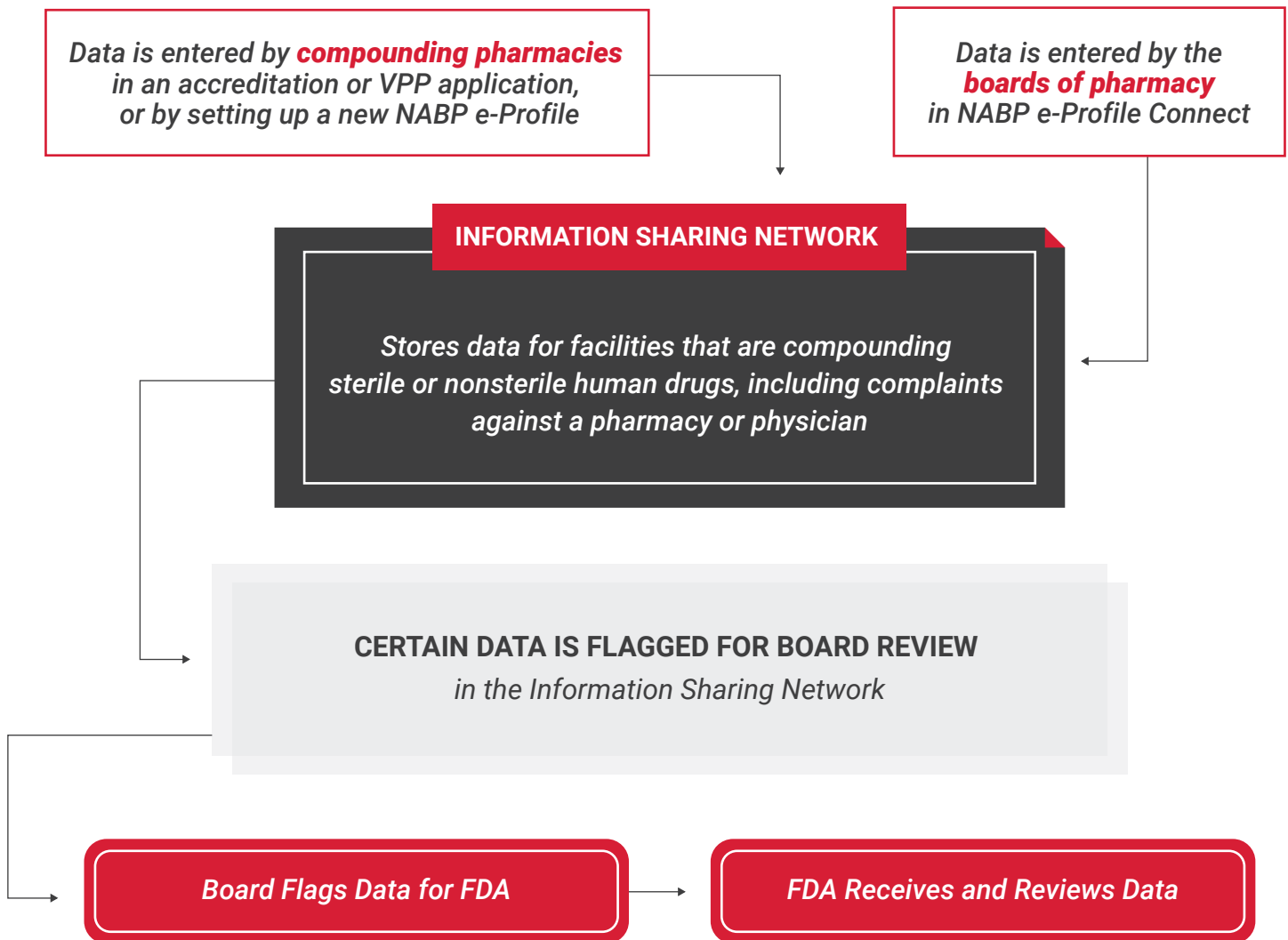
Collect and Share Compounding Data With NABP's Information Sharing Network

NABP's Information Sharing Network helps state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA). Access to the network is free and allows your board to meet the obligations outlined in the memorandum of understanding (MOU) on compounded human drug products.

PATHWAYS FOR DATA ENTRY

& the flow of data through NABP e-Profile Connect

Developed as an expansion of NABP e-Profile Connect, the Information Sharing Network will be available for boards of pharmacy to begin entering data in early 2021.



Visit www.nabp.pharmacy/Compounding-Project for more information on how the Information Sharing Network works or to access the FDA MOU.

Data Collected

The Information Sharing Network collects the following pharmacy and complaint data.

General Pharmacy Information – Entered by the Pharmacy or the Board

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
 - Human drug compounding – sterile or nonsterile
 - Patient-specific or non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, additional data is collected related to licensing, prescription orders, and distribution numbers

Complaint Information – Entered by the Board

Complaints of adverse drug experiences or product quality issues relating to human drug products that are compounded by a physician and distributed interstate are also entered by the board. Data collected includes:

- Name and contact information of the complainant or notifier
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

Complaints of adverse drug experiences, product quality issues, or distribution of human drug products that are compounded by a physician are also entered by the board.

For a complete list of data collected in the Information Sharing Network, visit www.nabp.pharmacy/Compounding-Project.

Data for Board Review

The Information Sharing Network flags data for the boards of pharmacy to review based on certain criteria.

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate.
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate.

By logging in to e-Profile Connect, the boards can review and submit the information to FDA with the click of a button.

Sending Data to FDA

Boards must submit the required information to FDA in accordance with the timelines outlined in the MOU, which can be as little as five days depending on the type of complaint.

A list of the data transmitted to FDA and the associated timelines can be found at www.nabp.pharmacy/Compounding-Project.