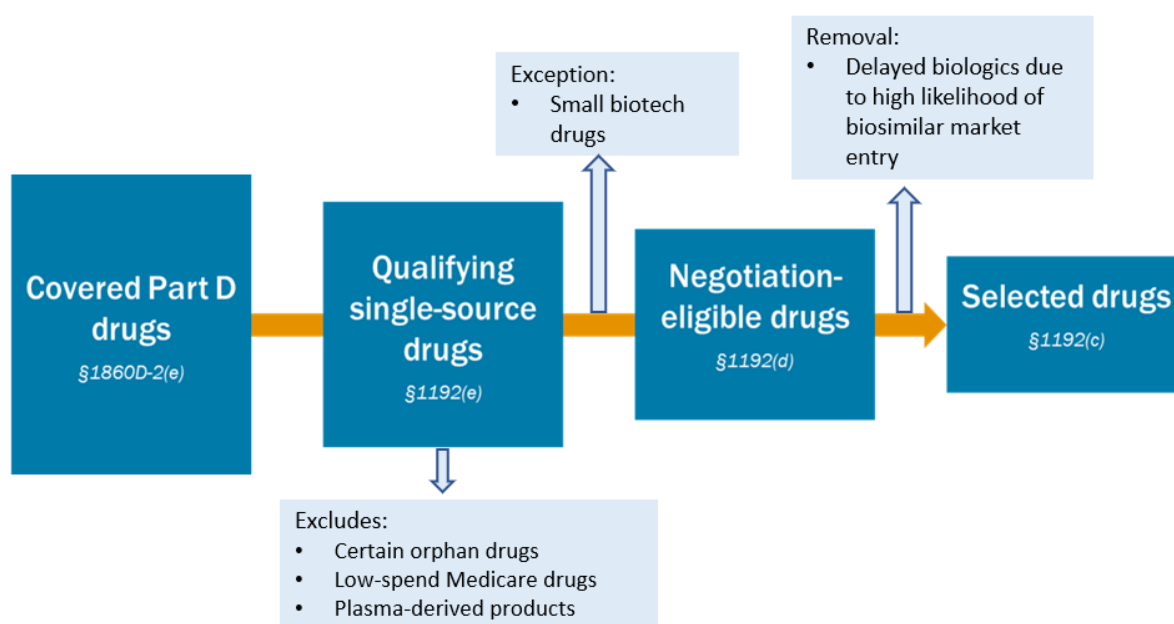


2026 as described in section 30.2 of this revised guidance (in this step, CMS will also exclude certain drugs in accordance with section 1192(d)(2) and (3) of the Act).

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2026 according to the Total Expenditures for such drugs under Part D of Title XVIII for the 12-month period described above (described in section 30.3 of this revised guidance). In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry described in section 1192(f) of the Act, CMS will select the 10 negotiation-eligible drugs with the highest Total Expenditures under Part D of Title XVIII for negotiation for initial price applicability year 2026 (described in section 30.3 of this revised guidance) and publish a list of those ten selected drugs not later than September 1, 2023 (described in section 30.4 of this revised guidance). Figure 1 provides a visual depiction of this process, and detailed guidance pertaining to this process for initial price applicability year 2026 is included below.

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026

For initial price applicability year 2026, in accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) that meets the following criteria:

- For drug products, a qualifying single source drug is a drug (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the