
42 U.S. Code § 1320a-7i

Reporting of information relating to drug samples

(a) In general

Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized distributor of record of an applicable drug shall submit to the Secretary (in a form and manner specified by the Secretary) the following information with respect to the preceding year:

(1) In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier under subsection (d)(2) of section 353 of title 21, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

(B) any other category of information determined appropriate by the Secretary.

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