

Food and Drug Administration, HHS

§ 203.3

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AUTHORITY: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

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Subpart A—General Provisions

§ 203.1 Scope.

This part sets forth procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Blood and blood

components intended for transfusion are excluded from the restrictions in and the requirements of the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

§ 203.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see part 205 of this chapter), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.

§ 203.3 Definitions.

(a) *The act* means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*).

(b) *Authorized distributor of record* means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(c) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(d) *Blood component* means that part of a single-donor unit of blood separated by physical or mechanical means.

(e) *Bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) *Charitable institution or charitable organization* means a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(g) *Common control* means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership

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of stock, voting rights, by contract, or otherwise.

(h) *Distribute* means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term “distribute” does not include:

(1) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(2) Providing of a drug sample to a patient by:

(i) A practitioner licensed to prescribe such drug;

(ii) A health care professional acting at the direction and under the supervision of such a practitioner; or

(iii) The pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the act and regulations.

(i) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(j) *Drug coupon* means a form that may be redeemed, at no cost or at reduced cost, for a drug that is prescribed in accordance with section 503(b) of the act.

(k) *Electronic record* means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(l) *Electronic signature* means any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.

(m) *Emergency medical reasons* include, but are not limited to, transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of

acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage; but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

(n) *FDA* means the U.S. Food and Drug Administration.

(o) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

(p) *Handwritten signature* means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(q) *Health care entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in §203.22(h) and (i), a person cannot simultaneously be a “health care entity” and a retail pharmacy or wholesale distributor.

(r) *Licensed practitioner* means any person licensed or authorized by State law to prescribe drugs.

(s) *Manufacturer* means any person who is a manufacturer as defined by §201.1 of this chapter.

(t) *Nonprofit affiliate* means any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954.

(u) *Ongoing relationship* means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

(v) *PDA* means the Prescription Drug Amendments of 1992.

(w) *PDMA* means the Prescription Drug Marketing Act of 1987.

(x) *Person* includes any individual, partnership, corporation, or association.

(y) *Prescription drug* means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

(z) *Representative* means an employee or agent of a drug manufacturer or distributor who promotes the sale of prescription drugs to licensed practitioners and who may solicit or receive written requests for the delivery of drug samples. A detailer is a representative.

(aa) *Sample unit* means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or distributor to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.

(bb) *Unauthorized distributor* means a distributor who does not have an ongoing relationship with a manufacturer to sell or distribute its products.

(cc) *Wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing or-

ganization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with section 503(b) of the act;

(7) The distribution of drug samples by manufacturers' and authorized distributors' representatives;

(8) The sale, purchase, or trade of blood or blood components intended for transfusion;

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with § 203.23; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(dd) *Wholesale distributor* means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

[64 FR 67756, Dec. 3, 1999, as amended at 73 FR 59500, Oct. 9, 2008]

Subpart B—Reimportation

§ 203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that