

42 C.F.R. § 403.902

Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

- (1) Operates in the United States; and
- (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

- (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.
- (2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Certified nurse midwife means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Certified registered nurse anesthetist means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

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