



**Bill Text**  
**108th Congress (2003-2004)**  
**H.R.1.ENR**

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## H.R.1

**Medicare Prescription Drug, Improvement, and Modernization Act of 2003**  
**(Enrolled Bill [Final as Passed Both House and Senate] - ENR)**

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### **SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.**

(a) IN GENERAL- Section 1128B(b)(3) (42 U.S.C. 1320a-7(b)(3)), as amended by section 101(e)(2), is amended--

(1) in subparagraph (F), by striking `and' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting ` ; and'; and

(3) by adding at the end the following new subparagraph:

`(H) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.'

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS-

(1) ESTABLISHMENT-

(A) IN GENERAL- The Secretary shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER- The Secretary shall consider the following factors, among others, in establishing standards relating to the

exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits an individual's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) DEADLINE- Not later than 1 year after the date of the enactment of this Act the Secretary shall publish final regulations establishing the standards described in paragraph (1).