SEC. 7102. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.

(a) INTEGRITY IMPROVEMENTS.—Subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended to read as follows:

"(d) IMPROVEMENTS IN PROGRAM INTEGRITY.—

"(1) MANUFACTURER COMPLIANCE.—

"(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

"(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

"(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

"(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

"(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

"(III) Performing spot checks of sales transactions by covered entities.

"(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

"(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

"(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

"(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs.

"(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

"(iv) The development of a mechanism by which—

"(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; and

"(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

"(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

"(vi) The imposition of sanctions in the form of civil monetary penalties, which—

"(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

"(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

"(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

"(2) COVERED ENTITY COMPLIANCE.—

"(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

"(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

"(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

"(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

"(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

"(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

"(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(E), through one or more of the following actions:

"(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

"(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

"(III) Referring matters to appropriate Federal authorities within the Food and Drug Admin-

istration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

"(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

"(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

"(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

"(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

"(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

"(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(D) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

"(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

"(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of

overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

"(C) FINALITY OF ADMINISTRATIVE RESOLUTION.—The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

"(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.".

(b) CONFORMING AMENDMENTS.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended—

(1) in subsection (a)(1), by adding at the end the following: "Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."; and

(2) in the first sentence of subsection (a)(5)(E), as redesignated by section 7101(c), by inserting "after audit as described in subparagraph (D) and" after "finds,".