[DISCUSSION DRAFT]

SEC. __. STRENGTHENING THE OUTPATIENT DRUG DISCOUNT PROGRAM.

(a) RENAMING.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by striking the section heading and inserting "**OUTPATIENT DRUG DISCOUNT PROGRAM**".

(b) PURPOSE.—

(1) IN GENERAL.—Section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)(1)) is amended—

(A) by striking "The Secretary shall enter into" and inserting the following:

"(A) ESTABLISHMENT OF DRUG DISCOUNT PROGRAM.—The Secretary shall enter into"; and

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

"(B) PURPOSE.—The purpose of the drug discount program under this section is to enable covered entities who serve as safety net providers for uninsured, underinsured, underserved, and medically vulnerable patients to utilize scarce resources to the maximum extent practicable for purposes of increasing such patients' access to, and receipt of, health care services.".

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1)(B) shall be construed as limiting the provision of covered outpatient drugs (as defined in section 340B of the Public Health Service Act (42 U.S.C. 256b)) subject to an agreement under such section to individuals who are considered uninsured, underinsured, underserved, and medically vulnerable.

(c) PROVIDING CEILING PRICES TO STATE MEDICAID AGENCIES.—

(1) IN GENERAL.—Section 340B(a)(3) of the Public Health Service Act (42 U.S.C. 256b(a)(3)) is amended—

(A) in the paragraph heading, by striking "DRUGS PROVIDED UNDER" and inserting "COORDINATION WITH";

(B) by striking "Drugs described in" and inserting the following:

"(A) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.—Drugs described in"; and

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

"(B) PROVIDING CEILING PRICES TO STATE MEDICAID AGENCIES.—Beginning one year after the date of the enactment of this legislation, the Secretary shall provide to State Medicaid agencies access to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner that limits such access to State Medicaid agencies and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.".

(2) RULE OF CONSTRUCTION.— Nothing in the amendment made by paragraph (1)(C) shall be construed as limiting the ability of a covered entity (as defined in subsection (a)(4) of section 340B of the Public Health Service Act (42 U.S.C. 256b)) to choose when to apply, with respect to drugs purchased by the entity, discounts under the drug discount program under such section or other discounts or rebates for which such purchases are eligible under other provisions of Federal law.

(d) DEFINITION OF PATIENT.—Section 340B(a)(5)(B) of the Public Health Service Act (42 U.S.C. 256b(a)(5)(B)) is amended—

(1) by striking "With respect to any" and inserting the following:

"(i) IN GENERAL.—With respect to any"; and

(2) by adding at the end the following new clauses:

"(ii) PATIENT DEFINED.—For purposes of clause (i), the term 'patient' means, with respect to a covered entity, an individual—

"(I) with whom a covered entity has established a clinical or medical relationship, such that the individual has had an in-person clinical or medical visit at the covered entity and the covered entity maintains records of the individual's health care;

"(II) who receives a health care service from the covered entity, which results in the ordering or prescribing of a covered outpatient drug;

"(III) who receives health care services from a health care professional who is either employed by the covered entity or provides such services under contractual or other arrangements such that responsibility for the care provided remains with the covered entity; and

"(IV) who receives a health care service or range of services from the covered entity (other than an entity described in subparagraphs (L) through (O) of paragraph (4)) which is consistent with the service or range of services for which grant funding has been provided to the entity by the Federal Government or the provision of which satisfies the condition described in clause (iii) of section 1905(l)(2)(B) of the Social Security Act.

"(iii) INCLUSION.—For purposes of clause (i), an individual registered with a covered entity specified in paragraph (4)(E) shall be considered a patient of such entity, if the individual is registered and determined to be eligible by the entity.

"(iv) EXCLUSIONS.—For purposes of clause (i), an individual shall not be considered a patient of a covered entity if—

"(I) the only health care service received by the individual from the covered entity is or through the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.".

(e) MAINTENANCE OF AUDITABLE RECORDS.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by adding at the end the following new subparagraph:

"(E) AUDITABLE RECORDS REQUIRED.—Beginning with 2016, a covered entity shall maintain, for a period of not less than 5 years, auditable records, with respect to covered outpatient drugs dispensed by the entity under this section.".

[( ) LIMITATION ON AMOUNT CHARGED TO UNINSURED LOW-INCOME PATIENTS. Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by adding at the end the following new subparagraphs:

"(F) LIMITATION ON AMOUNT CHARGED TO UNINSURED LOW-INCOME PATIENTS.—With respect to patients (as defined in subparagraph (B)(ii))of a covered entity who are not entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, or to assistance for medical expenses under any other public assistance program or private health insurance program, the covered entity may collect fees for providing covered outpatient drugs to low income patients according to such methodology as determined appropriate by the Secretary."]

[( ) INTERACTION WITH CORRECTIONAL FACILITIES. Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by adding at the end the following new subparagraphs:

"(G) EXCLUSION OF CORRECTIONAL FACILITIES.—A covered entity shall not be a correctional facility, prison, jail, reformatory, detention center, or any other similar facility maintained by either Federal, State or local authorities for the purpose of confinement or rehabilitation of adult or juvenile criminal offenders."

"(H) PROHIBITING REVENUE SHARING WITH CORRECTIONAL FACILITIES.-- With respect to any covered outpatient drug that is subject to an agreement under this section, a covered entity shall not share or otherwise transfer revenue from the

purchase or dispensing of the drug to a correctional facility, prison, jail, reformatory, detention center, or any other similar facility maintained by either Federal, State or local authorities for the purpose of confinement or rehabilitation of adult or juvenile criminal offenders."|

(f) TREATMENT OF CONTRACT PHARMACY SERVICES.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended by adding at the end the following new paragraph:

"(11) CONTRACT PHARMACY SERVICES.—In the case of a covered entity that elects to dispense covered outpatient drugs subject to an agreement under this section to patients (as defined in paragraph (5)(B)(ii)) of the covered entity through the use of contract pharmacy services, such covered entity shall—

"(A) have a contractual agreement in place between the entity and each contract pharmacy used by the entity to dispense such drugs;

"(B) register each such agreement with the Secretary and include in such registration the distance of the contract pharmacy from the covered entity;

"(C) ensure the compliance of any such agreement with the requirements of this section to prevent drug diversion in violation of subsection (a)(5)(B) and to prevent duplicate discounts in violation of subsection (a)(5)(A), including by—

"(i) developing, with each contract pharmacy subject to such an agreement, a system to verify patient eligibility;

"(ii) developing, with each contract pharmacy, a mechanism for tracking that is suitable to prevent the diversion of drugs subject to an agreement under this section to individuals who are not patients of the covered entity;

"(iii) establishing an arrangement with each such contract pharmacy and the State Medicaid agency involved to prevent duplicate discounts; and

"(iv) developing, with each such contract pharmacy, a mechanisms tracking the income of patients of the covered entity and the amount such patients pay to receive covered outpatient drugs from such pharmacy;

"(D) maintain, and ensure that each such contract pharmacy maintains, auditable records;

"(E) establish a process for, and conduct, periodic comparisons of the entity's prescribing records with each such contract pharmacy's dispensing records to detect potential irregularities; and

"(F) provide for annual audits of each such contract pharmacy to be conducted by an independent outside auditor.".

(g) MANUFACTURER REQUIREMENTS.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), as amended by subsection (f), is further amended by adding at the end the following new paragraph:

"(12) AUDITABLE RECORDS MAINTAINED BY MANUFACTURERS.—Beginning with 2016, a manufacturer subject to an agreement under this section shall maintain, for a period of not less than 5 years, auditable records, with respect to covered outpatient drugs of such manufacturer.".

(h) MANUFACTURER REPORTING OF SALES DATA.—Section 340B(d)(1)(B)(iv) of the Public Health Service Act (42 U.S.C. 256b(d)(1)(B)(iv)) is amended—

(1) by redesignating subclauses (I) and (II) as subclauses (II) and (III), respectively; and

(2) by inserting before subclause (II) (as so redesignated) the following new subclause:

"(I) beginning with 2016, manufacturers submit to the Secretary data with respect to sales of covered outpatient drugs to each covered entity made by the manufacturer on an annual basis;".

(i) INDEPENDENT AUDIT REQUIRED.—Section 340B(d)(2) of the Public Health Service Act (42 U.S.C. 256b(d)(2)) is amended—

(1) in subparagraph (B)(i)—

(A) by striking "(I) The development of procedures" and inserting "(I)(I) The development of procedures"; and

(B) adding at the end the following new subclause:

"(II) Beginning not later than 180 days after the date of the enactment of this subclause and annually thereafter, as a condition of recertification pursuant to this clause, the Secretary shall require that a covered entity with a high volume of purchases of covered outpatient drugs subject to an agreement under this section conduct an independent audit of the entity's compliance with the requirements of this section and submit the results of such audit to the Secretary."; and

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

"(C) HIGH VOLUME OF PURCHASES.—For purposes of subparagraph (B)(i)(II), the Secretary shall determine whether a covered entity has a high volume of purchases of covered outpatient drugs subject to an agreement under this section. In making such determination, the Secretary shall include, at a minimum, the covered entities whose volume of purchases of such drugs in a year are in the top ten percent of the volume of purchases of such drugs by all covered entities in the year.".

(j) ADDITIONAL PENALTIES FOR VIOLATIONS.—Section 340B(d)(2)(B)(v) of the Public Health Service Act (42 U.S.C. 256b(d)(2)(B)(v)) is amended—

(1) in subclause (I), by striking "subsection (a)(5)(B)" and inserting "subparagraph (A) or (B) of subsection (a)(5)";

(2) in subclause (II)—

(A) by striking "subsection (a)(5)(B) was systematic and egregious" and inserting "subparagraph (A) or (B) of subsection (a)(5) was systematic"; and

(B) by striking "a reasonable period of time to be determined by the Secretary" and inserting "a period of not less than 5 years";

(3) by redesignating subclause (III) as subclause (VI); and

(4) by inserting after subclause (II) the following new subclauses:

"(III) Where the Secretary determines a violation of subsection (e) was systematic and routine, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a period of not less than 5 years.

"(IV) Where a covered entity intentionally violates subsection (e), the imposition of civil monetary penalties in an amount determined appropriate by the Secretary.

"(V) Where the Secretary determines a covered entity fails to take corrective action with respect to a violation of this section in a timely manner, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a period of not less than 5 years.".

(k) AUDITS BY SECRETARY.—Section 340B(d)(2)(B) of the Public Health Service Act (42 U.S.C. 256b(d)(2)(B)) is amended by adding at the end the following new clause:

"(vi) The conduct of an audit of certain covered entities. In selecting the covered entities to be audited, the Secretary shall give priority to covered entities that—

"(I) have a high volume of purchases of covered outpatient drugs subject to an agreement under this section;

"(II) have identified or reported vulnerabilities;

"(III) have not met the reporting requirements under subsection (e) or have not submitted reports under such subsection within the period specified in such subsection; or

"(IV) are not otherwise subject to oversight by the Secretary as grant recipients under other Federal grant programs administered by the Secretary.".

(l) REPORTING REQUIREMENTS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(1) by redesignating subsections (d) (as amended by subsections (i), (j) and (k)) and (e) as subsections (c) and (d), respectively; and

(2) by adding at the end the following new subsection:

"(e) REPORTING REQUIREMENTS FOR COVERED ENTITIES.—

"(1) IN GENERAL.—A covered entity described in subparagraphs (L), (M), and (O) of subsection (a)(4) shall annually submit to the Secretary a report. Such report shall contain, with respect to the year covered by the report, information on—

"(A) the number and percentage of patients (as defined in subsection (a)(5)(B)(ii)) of the covered entity, disaggregated by payor type (including at least the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Children's Health Insurance Program under title XXI of such Act, the TRICARE program under chapter 55 of title 10, United States Code, and private insurance);

"(B) the aggregate amount of reimbursement received by the covered entity (calculated using a methodology developed by the Secretary) for covered outpatient drugs subject to an agreement under this section, disaggregated by payor type;

"(C) the aggregate acquisition cost for covered outpatient drugs subject to an agreement under this section dispensed during the year, disaggregated by payor type;

"(D) how the entity uses revenue generated by the drug discount program under this section and how the entity uses such revenue to, with respect to uninsured, underinsured, underserved, and medically vulnerable patients, increase such patients' access to, and receipt of, health care services;

"(E) how the entity prevents duplicate discounts under subsection (a)(5)(A);

"(F) the number of covered outpatient drugs subject to an agreement under this section dispensed by the covered entity (and in the case of a covered entity described in subsection (a)(11), by each pharmacy with which the entity has a contract to dispense such drugs);

"(G) the amount and percentage of uncompensated care provided to patients by the covered entity;

"(H) the name of any third party, vendor, or other similar entity (if any) that the covered entity retains to administer the covered entity's inventory management system or contract pharmacy arrangement; and

"(I) other such reporting requirements as the Secretary determines is necessary for effective management and oversight of the drug discount program under this section.

"(2) TIMING OF FIRST REPORT.—The first report submitted under paragraph (1) shall be submitted not later than 18 months after the date of the enactment of this subsection.".

(m) USER FEES.—Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by subsection (l), is further amended by adding at the end the following new subsection:

"(f) USER FEES.—

"(1) IN GENERAL.—Subject to paragraph (6), the Secretary shall assess and collect a user fee from covered entities participating in the drug discount program under this section.

"(2) PAYMENT.—Any fee collected under paragraph (1) shall be due upon the later of—

"(A) the certification or recertification of a covered entity, as applicable; or

"(B) 30 calendar days after the date of the enactment of an appropriations Act providing for the collection and obligation of fees under this subsection for a fiscal year.

"(3) AMOUNT OF FEE.—The amount of a fee under paragraph (1) shall be equal to the amount determined by the Secretary under paragraph (4).

"(4) DETERMINATION OF AMOUNT OF FEE.—The Secretary shall, not later than 180 days before the start of each fiscal year that begins after September 30, 2016, establish, for the next fiscal year the amount of the fee payable under this subsection by a covered entity using sales data submitted by the manufacturers of covered outpatient drugs subject to an agreement under this section. Such amount shall not exceed the sum of .1 percent of each purchase of a covered outpatient drug made by the covered entity under the drug discount program under this section during the previous year.

"(5) USE OF FEES.—Fees collected under paragraph (1) shall be used for the general costs of the oversight and administration of this section, including activities conducted for purposes of enhancing program integrity, review, audit, and enforcement actions. Such fees shall be used to supplement and not supplant the amount provided in appropriations Acts to carry out this section.

"(6) AVAILABILITY OF FEES.—Fees authorized under paragraph (1) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.".

(n) DIRECT-HIRE AUTHORITY.—

(1) IN GENERAL.—Notwithstanding section 3304(a)(3) of title 5, United States Code, and without regard to the provisions of sections 3309 through 3318 of such title, the Secretary may, beginning on the date of the enactment of this section, exercise direct-hire authority to appoint not more than ten qualified candidates to permanent positions within the competitive service in order to carry out management and oversight activities under section 340B of the Public Health Service Act (42 U.S.C. 256b).

(2) DURATION OF AUTHORITY.—The direct-hire authority provided under paragraph (1) shall expire on the date that is 2 years after the date of enactment of this Act.

(o) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) TECHNICAL AMENDMENTS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by subsections (l) and (m), is further amended—

(A) in subsection (a)(5), by striking "subparagraphs (A) or (B)" each place it appears in subparagraphs (C) and (D) and inserting "subparagraph (A) or (B)"; and

(B) in subsection (b)(2)—

(i) in the paragraph heading, by inserting "OUTPATIENT" after "COVERED"; and

(ii) in the matter preceding subparagraph (A), by inserting "outpatient" after "covered".

(2) CONFORMING AMENDMENTS.—

(A) Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by subsections (l) and (m) and paragraph (1), is further amended—

(i) in subsection (a)(1)(A) (as designated by subsection (a)), by striking "described in paragraph (3)" and inserting "described in paragraph (3)(A)"; and

(ii) in subsection (c) (as redesignated by subsection (l))—

(I) in paragraph (1)(B), by striking "subsection (a)(1)" each place it appears in clause (i) and clause (vi)(III) and inserting "subsection (a)(1)(A)"; and

(II) in paragraph (3)(B)(i), by striking "subsection (a)(1)" and inserting "subsection (a)(1)(A)".

(B) Section 1927(b)(4)(B)(v) of the Social Security Act (42 U.S.C. 1396r–8(b)(4)(B)(v)) is amended by striking "340B(a)(1)" and inserting "340B(a)(1)(A)".

(p) REPORTS TO CONGRESS.—

(1) INFORMATION PROVIDED BY COVERED ENTITIES THAT ARE HOSPITALS.—Not later than two years after the date of the enactment of this section, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report. Such report shall contain—

(A) with respect to covered entities specified in subparagraphs (L), (M), and (O) of subsection (a)(4) of section 340B of the Public Health Service Act (42 U.S.C. 256b), the information contained in the first report submitted under subsection (e) of such section (as added by subsection (l) of this section) by such entities; and

(B) an analysis and description of options, which may include recommendations for possible statutory changes, for replacing the disproportionate share adjustment percentage referred to in subsection (a)(4)(L)(ii) of such section 340B as a measure for qualifying hospitals that provide outpatient treatment to a disproportionate share of uninsured, underinsured and underserved populations.

(2) REPORT BY COMPTROLLER GENERAL.—Not later than one year after the date of the enactment of this section, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the use of contract pharmacies by covered entities (as described in paragraph (11) of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a))), disaggregated by the types of covered entities and the physical distance of the contract pharmacies from the respective covered entity.

(q) REGULATIONS.—

(1) PRIORITY REGULATIONS.—Not later than 180 days after the date of the enactment of this section, the Secretary of Health and Human Services shall issue a notice of proposed rulemaking on—

(A) the eligibility requirements for covered entities specified in subparagraphs (L) through (O) of subsection (a)(4) of section 340B of the Public Health Service Act (42 U.S.C. 256b);

(B) the definition of a patient under subsection (a)(5)(B)(ii) of such section, including considerations on the appropriate frequency of clinical visits necessary to establish a patient relationship;

(C) the requirements for covered entities electing to use contract pharmacies under subsection (a)(11) of such section; and

(D) the reporting requirements for covered entities under subsection (e) of such section.

(2) OTHER REGULATIONS.—Not later than two years after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue regulations on—

(A) the prevention of duplicate discounts under subsection (a)(5)(A) of section 340B of the Public Health Service Act (42 U.S.C. 256b);

(B) the limitations on the amount charged to low-income uninsured patients under subsection (a)(5)(F) of such section;

[(C) the exclusion of correctional facilities under subsection (a)(5)(G) of such section;

(D) the prohibition of revenue sharing with correctional facilities under subsection (a)(5)(H) of such section;]

(E) the penalties applicable for certain violations of such section, specified in section (d)(2)(B)(v) of such section; and

(F) the user fee collected pursuant to subsection (f) of such section.

(r) EFFECTIVE DATE.—Unless otherwise specified, the amendments made by this section shall be effective on the date that is 180 days after the date of the enactment of this section.
