.....

(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. __

To strengthen the 340B drug discount program.

IN THE HOUSE OF REPRESENTATIVES

Mr. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To strengthen the 340B drug discount program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act" or the "SECURE 340B Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Confidential to Victoria Knight

Sec. 2. Establishing a clear patient definition.
Sec. 3. Allowable use and robust oversight of contract pharmacies.
Sec. 4. Eligibility for child sites.
Sec. 5. Improving patient affordability and protections.
Sec. 6. Data reporting for transparency.
Sec. 7. Enhancing program integrity.
Sec. 8. Facilitating data exchange to improve program integrity.
Sec. 9. Prohibition on discriminatory practices and contracting.
Sec. 10. Ensuring HRSA has adequate resources to oversee the program.
Sec. 11. Studies and reports.
Sec. 12. Meanings.
Sec. 13. Requirements for nonhospital covered entities and subgrantees.
Sec. 14. Effective date.

SEC. 2. ESTABLISHING A CLEAR PATIENT DEFINITION.

(a) IN GENERAL.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended by adding at the end the following:

"(11) PATIENT DEFINED.—

"(A) IN GENERAL.—In this section, the term 'patient' means an individual who—

"(i) has received an outpatient health care service from a prescribing provider at a covered entity within the preceding 24 months, and such health care service—

"(I) is a service that was reimbursable under title XVIII of the Social Security Act when furnished by a prescribing provider or, in the case of an individual who is not eligible for benefits under such title, would have been so reimbursable had the individual been so eligible; a service shall be considered reimbursable if it is of a type eligible for reimbursement under title XVIII; and

"(II) in the case of a covered entity described in subparagraphs (A) through (K) of subsection (a)(4),

Confidential to Victoria Knight

is a service that is within the scope of the grant or designation described in such subparagraph.

"(ii) received the prescription or order for the covered outpatient drug related to the service described in clause (i); and

"(iii) has a relationship with the covered entity such that the covered entity creates and maintains auditable health care records which demonstrate that—

"(I) the covered entity maintains a provider-to-patient relationship with the individual for the healthcare service related to the covered outpatient prescription or order;

"(II) the prescribing provider has clinical responsibility and oversight for the individual's health care service related to the prescription or order for the covered outpatient drug with the covered entity; and

"(III) any other information specified by the Secretary through notice and comment rulemaking.

"(B) APPLICATION.—For each prescription or order for a covered outpatient drug, an individual shall qualify as a patient under subparagraph (A) only if the requirements of such subparagraph are independently satisfied with respect to that prescription or order.

"(C) RECORD RETENTION AND AUDITING.—A covered entity shall—

"(i) retain auditable health care records in a form and manner specified by the Secretary through notice and comment rulemaking which demonstrate the existence of a patient relationship in accordance with this paragraph for each prescription or order for a covered outpatient drug for a period of the greater of 5 years or such period as required under applicable state

Confidential to Victoria Knight

and federal laws governing medical or pharmacy records; and

"(ii) no more than one time annually, in accordance with subsection (a)(5)(C), permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection, to audit, at the Secretary's or the manufacturer's expense, the records of the entity which demonstrate the existence of a patient relationship in accordance with this paragraph and which directly pertain to the entity's compliance with the requirements of subsection (a)(5)(B).".

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

(1) in subsection (a), by adding at the end the following:

"(12) PRESCRIBING PROVIDER.—In this section, the term 'prescribing provider' means a health care provider who, at the time the health care provider orders or prescribes a covered outpatient drug—

"(A) (i) is an employee or independent contractor of the covered entity such that the covered entity bills for services furnished by the health care provider and is responsible for the care furnished by such provider; or

"(ii) is an employee or independent contractor of a physician organization affiliate of the covered entity, has assigned their right to bill and collect for professional services to such physician organization affiliate, and furnishes outpatient health care services to patients of the covered entity.

"(B) has clinical responsibility over the care related to the order or prescription for the covered outpatient drug, as demonstrated by the provider's signature on the relevant order or prescription for the covered outpatient drug;

Confidential to Victoria Knight

"(C) is enrolled as a provider in the Medicare program under title XVIII of the Social Security Act, or the Medicaid program under title XIX of the Social Security Act; and

"(D) is not excluded by the Secretary from participation in Medicare and State health care programs pursuant to section 1128 of the Social Security Act (42 U.S.C. 1320a-7).

(2) in subsection (b), by adding at the end the following:

"(3) PHYSICIAN ORGANIZATION AFFILIATE DEFINED.—For purposes of subparagraph (A)(ii), the term 'physician organization affiliate' means an entity that—

"(A) is lawfully organized for the purpose of employing or contracting with licensed professionals to furnish clinical services;

"(B) has an ongoing, legally binding agreement with the covered entity to provide health care services to patients of the covered entity at the covered entity's locations; and

"(C) the outpatient healthcare services are provided such that responsibility for the care provided remains with the covered entity and meets the other requirements in this paragraph.".

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

"(f) REFERRAL QUALIFICATIONS.—

"(1) IN GENERAL.—Subject to the requirements of this subsection, in the case of a patient of an eligible covered entity who is referred by such covered entity to a provider outside such covered entity, and such non-covered entity provider prescribes a covered outpatient drug within 24 months of the date of such referral, the eligible covered entity may provide such drug to such patient as a covered outpatient drug pursuant to the drug

Confidential to VictoriaKnight

discount program under this section, in the same manner and under the same conditions as the covered entity would provide such drug had such drug been prescribed by a prescribing provider of such covered entity.

"(2) COVERED ENTITY ELIGIBILITY.—For purposes of this subsection the covered entity that dispenses or administers the covered outpatient drug must be—

"(A) a federally qualified health center, as described in subsection (a)(4)(A), that is also a comprehensive primary care medical home, certified as a Patient-Centered Medical Home by a national accrediting organization;

"(B) a critical access hospital, as described in subsection (a)(4)(N); or

"(C) a sole community hospital, as described in subsection (a)(4)(O).

"(3) PATIENT ELIGIBILITY.—For purposes of this subsection—

"(A) the individual to whom a covered outpatient drug is dispensed or administered must be a patient of the covered entity meeting the requirements under (a)(11);

"(B) the individual must have received direct care from the covered entity within 24 months prior to the date on which the individual was referred to receive care by the prescribing entity;

"(C) the care furnished to the individual by the covered entity that resulted in the referral must be—

"(i) in the case of a federally qualified health center described in paragraph (2)(A), within the scope of the grant application made to the Secretary under section 330(k)(1);

Confidential to Victoria Knight

"(ii) in the case of a critical access hospital described in paragraph (2)(B), within the scope of the agreement with the state under section 1820(c)(2) of the Social Security Act; and

"(iii) in the case of a sole community hospital described in paragraph (2)(C), within the scope of the request made to the Secretary for such classification under section 1886(d)(5)(C)(iii) of the Social Security Act; and

"(D) the covered entity must have—

"(i) Referred the individual to the prescribing entity;

"(ii) Consulted with a clinician at the prescribing entity regarding the individual's care; and

"(iii) Provided care to the individual after dispensing or administering the prescription, as appropriate.

"(E) in the case of a federally qualified health center described in paragraph (2)(A), a prescription generated as a direct result of an emergency department visit or hospital discharge.

"(4) EXCLUSIONS.—The following categories of drugs shall not be eligible for discounts under this subsection—

"(A) orphan-designated drugs; or

"(B) in the case of a prescription written by a federally-qualified health center described in paragraph (2)(A), a drug that is infused or that requires a clinician to administer, except for those entities providing infusions as of the date of enactment of this Act and subject to the limitation described in paragraph (5).

"(5) DOCUMENTATION REQUIREMENTS.—

Confidential to Victoria Knight

"(A) IN GENERAL.—In association with any covered outpatient drug receiving a discount under this subsection, the individual's medical record must include documentation to demonstrate compliance with the requirements of paragraph (3), including—

"(i) documentation of the direct care provided to the individual by the covered entity prior to the referral to the prescribing entity;

"(ii) documentation of the referral from the covered entity to the prescribing entity;

"(iii) documentation of direct care received by the individual from the covered entity that resulted in the referral and that occurred within 24 months prior to the initial referral;

"(iv) documentation of care received by the individual from the prescribing entity within 24 months of the covered entity referral, which may take the form of receipt of consult notes or documentation of a discussion between the covered entity and prescribing entity regarding the care furnished by the prescribing entity;

"(v) documentation of ongoing consultation between the covered entity and the prescribing entity as appropriate for the covered entity's ongoing responsibility of the individual's care, consistent with the scope of care described in paragraph (3)(C); and

"(vi) documentation of the prescribing entity's prescription to be dispensed or administered by the covered entity and updated through the qualified entity's medication list for the patient.

"(B) DOCUMENT RETENTION.—All documentation described under this paragraph shall be maintained for a period of the greater of 5 years or such period as required

Confidential to Victoria Knight

under applicable state and federal laws governing medical or pharmacy records as auditable records that demonstrate compliance with the requirements of this subsection.

"(6) REFERRAL AUDITS BASED ON VOLUME.—

"(A) IN GENERAL.—The Secretary shall conduct audits of any eligible covered entity that meets the following conditions in a given year—

"(i) referral prescriptions described in paragraph (1) exceed 25 percent of the total number of covered outpatient drugs purchased and dispensed by the covered entity for the year;

"(ii) referral prescriptions described in paragraph (1) are in the 75th percentile of all reporting covered entities by covered entity classification; or

"(iii) referral prescriptions exceeding the average annual percentage for that covered entity classification over the most recent 3-year period, of the total number of covered outpatient drugs purchased and dispensed by the qualified referral covered entity.

"(B) TRANSPARENCY OF INFORMATION.—The Secretary shall make public aggregate information on eligible covered entities audited under subparagraph (A) available on a website of the Health Resources and Services Administration, in such form and manner that the Secretary determines appropriate.

"(7) ADDITIONAL AUDITS.—

"(A) In addition to audits conducted under paragraph (6), the Secretary shall audit any covered entity receiving discounts under this subsection for compliance with requirements of this subsection every four years and, in the case of covered entities receiving abnormal volumes of discounts as compared to such covered entity's discounts

Confidential to Victoria Knight

over the previous three year period, more frequently (but no more than one time annually).

"(B) The Secretary shall through notice and comment rulemaking establish a process for manufacturers to request audits of discounts provided under this subsection at any time the manufacturer provides documentation to the Secretary of suspected non-compliance with the requirements of this subsection, with information received by the manufacturer from the clearinghouse established under section 1150D of the Social Security Act that provides credible evidence of non-compliance serving as acceptable documentation for this purpose.

"(8) ENFORCEMENT.—

"(A) LOSS OF REFERRAL AUTHORIZATION.—

"(i) A covered entity for which the Secretary determines through an audit conducted pursuant to or otherwise authorized under this section that the share of referral prescriptions during the previous calendar year exceeds 35 percent of the covered entity's total number of covered outpatient drugs purchased and dispensed by the covered entity in the applicable year, may be subject to a Corrective Action Plan in accordance with the corrective action plan process established under subsection (d)(2)(B)(vii).

"(ii) A covered entity that fails to implement a Corrective Action Plan required under clause (i) and comply with the timeline for correction set forth in such Corrective Action Plan shall immediately lose eligibility under this subsection for a period determined by the Secretary through notice and comment rulemaking, but no more than 1 year.

"(iii) The Secretary and the Administrator of the Health Resources and Services Administration shall develop a process through notice and comment

Confidential to Victoria Knight

rulemaking for covered entities that lose eligibility for discounts under this section pursuant to clause (ii) to complete the Corrective Action Plan and resume referrals under the program.

"(B) MONETARY PENALTIES.—The Secretary may impose civil monetary penalties on covered entities for any discounts under this section later deemed ineligible on the grounds the covered entity is found to be noncompliant with the requirements of this subsection with respect to the relevant prescription. The amount of such civil monetary penalties shall be paid to the affected manufacturer.".

SEC. 3. ALLOWABLE USE AND ROBUST OVERSIGHT OF CONTRACT PHARMACIES.

(a) USE OF CONTRACT PHARMACIES.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is further amended by adding at the end the following:

"(13) CONTRACT PHARMACIES.—

"(A) IN GENERAL.—In the case of a covered entity that elects to contract with a pharmacy or pharmacies to dispense covered outpatient drugs purchased by a covered entity at or below the applicable ceiling price described in paragraph (1) to patients of the covered entity, a manufacturer of a covered outpatient drug that is subject to an agreement with the Secretary under paragraph (1) shall—

"(i) offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price described in paragraph (1) regardless of whether the drug is dispensed directly by the covered entity or via a contract pharmacy arrangement;

"(ii) deliver or allow the delivery of covered outpatient drugs purchased by covered entity sites to pharmacy locations as requested by a covered entity, in

Confidential to Victoria Knight

accordance with the covered entity's contract pharmacy agreements;

"(iii) not place any of the following conditions on the ability of a covered entity to purchase a covered outpatient drug at or below the applicable ceiling price described in paragraph (1) for dispensing according to its written contract pharmacy arrangements:

"(I) Restricting distribution options only with respect to covered outpatient drugs, covered entities, or contract pharmacies.

"(II) Requiring the submission of claims data directly to the manufacturer out of submissions to the entity receiving the contract to maintain the clearinghouse under section 1150D of the Social Security Act.

"(III) Conditioning, restricting, or refusing participation in such an arrangement solely on the basis that the covered entity elected to use a contract pharmacy.

"(IV) Any such other conditions specified by the Secretary through notice and comment rulemaking.

"(B) REGISTRATION OF CONTRACT.—Each covered entity shall register with the Secretary any contract described in subparagraph (A), in accordance with such registration requirements established by the Secretary through notice and comment rulemaking. Such registration requirements shall include requiring covered entities to—

"(i) submit all contract pharmacy agreements to the Secretary in a timely manner;

"(ii) register each contract pharmacy arrangement with the Secretary, as applicable, prior to implementing the contract pharmacy agreement; and

Confidential to Victoria Knight

"(iii) attest to their compliance with the requirements under this subsection at the time of contract pharmacy registration and annually thereafter.

"(C) CONTRACT REVIEW PROCESS.—The Secretary shall establish through notice and comment rulemaking a process to review all written agreements between a covered entity and each of its contract pharmacies, as described in subparagraph (A), to ensure compliance with the requirements under this subsection. In connection with such review process, there shall be no limitation on the number of contract pharmacies a covered entity may contract with nor any geographic limitation on the location of such contract pharmacies.

"(D) TRANSPARENCY.—The Secretary shall make the following information about contract pharmacy arrangements that have been approved under subparagraphs (A) and (B) available on the public Internet website of the Department of Health and Human Services:

"(i) Name(s) of each covered entity, including the name of its child site(s) that uses contract pharmacy(ies).

"(ii) Name(s) and address(es) of each contract pharmacy location to which the contract pharmacy arrangement applies.

"(iii) Effective date(s) of the contract pharmacy arrangement(s).

"(iv) The last year a drug was dispensed under the contract pharmacy arrangement(s) from each location.

"(v) The volume of dispensed drugs under this section per reporting period.

"(vi) The geographic distance between the covered entity reported under (i) and each contract pharmacy reported under (ii).

Confidential © Victoria Knight

"(vii) Information on the contract pharmacy's status as a mail-order or specialty pharmacy.

"(viii) Details on the location of the contract pharmacy, including whether the contract pharmacy is located in—

"(I) an urban area (under Census definition);

"(II) a rural area (under Census definition);

"(III) a frontier county or frontier state (as defined in Section 1886(d)(3)(E)(iii)(II) of the Social Security Act);

"(IV) a medically underserved area (MUA) as defined in section 295p(6);

"(V) a Healthcare Provider Shortage Area (HPSA) as defined in section 254e; or

"(VI) an area classified as one for a medically underserved population (MUP) as defined in section 254b(b)(3).

"(E) IMPROVEMENTS IN CONTRACT PHARMACY ARRANGEMENT INTEGRITY.—To ensure the integrity of contract pharmacy arrangements described in subparagraph (A), including to prevent diversion and duplicate discounts described in paragraph (5)(A), the Secretary shall promulgate rules to carry out the following:

"(i) Require a written agreement between a covered entity and any pharmacy with which the covered entity has a contract pharmacy arrangement. Each such agreement shall—

"(I) list the address of each contract pharmacy location that will dispense drugs on behalf of the

Confidential to Victoria Knight

covered entity, including all covered entity sites that plan to use the contract pharmacy;

"(II) be signed and in effect not later than the day before the contract pharmacy begins dispensing covered outpatient drugs purchased under this section on behalf of the covered entity; and

"(III) include the standard contract provisions established under clause (ii).

"(ii) Develop standard contract provisions that are required to be included in each written agreement described in clause (i), including provisions providing that—

"(I) the covered entity will purchase the drug and maintain title to the drug pursuant to the terms of the award or designation from the Department of Health and Human Services that qualifies such entity as a covered entity and any applicable Federal, State, or local law;

"(II) the contract pharmacy is responsible for providing pharmacy services and providing data to covered entities to support their submission of covered outpatient drug data to a clearinghouse contracted entity described in section 1150D of the Social Security Act;

"(III) the covered entity will not interfere with patient choice of their pharmacy provider nor require patients to use a certain pharmacy, including to obtain a prescription from the covered entity and obtain the drug from the pharmacy provider of his or her choice;

"(IV) the contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity, such as home care, delivery, and reimbursement services;

Confidential to Victoria Knight

"(V) regardless of the services provided by the contract pharmacy, access to covered outpatient drugs purchased under this section will be restricted to patients of the covered entity;

"(VI) the covered entity and the contract pharmacy will adhere to all Federal, State, and local laws and requirements;

"(VII) the contract pharmacy will provide the covered entity with any information requested consistent with customary business practices, such as quarterly billing statements, status reports of collections, receiving and dispensing records, and information required for audits under subsection (a)(5)(C);

"(VIII) the covered entity and the contract pharmacy will utilize the clearinghouse to verify patient eligibility, as defined by the Secretary, and will establish and maintain safeguards to prevent diversion of covered outpatient drugs purchased under this section;

"(IX) the contract pharmacy may not use covered outpatient drugs purchased under this section to dispense prescriptions that are reimbursed under the Medicaid program under title XIX of the Social Security Act, unless the covered entity, the contract pharmacy, and the State Medicaid agency have established, in writing and made available to pharmaceutical manufacturers upon request, an arrangement to prevent duplicate discounts, consistent with paragraph (5)(A);

"(X) both the covered entity and the contract pharmacy shall be subject to audits, by the Secretary and drug manufacturers, of records that pertain to the covered entity's compliance with

Confidential to victoriaKnight

paragraph (5), to prevent diversion and violations of the duplicate discount prohibition; and

"(XI) the contract pharmacy is required to submit to the covered entity all data elements the covered entity is required to report to the clearinghouse pursuant to section 1150D of the Social Security Act.

"(iii) Review written agreements, at the time of registration or recertification, or more frequently if the Secretary determines necessary, between covered entities and contract pharmacies to ensure compliance with the requirements under this section, to analyze program operations, and to provide program oversight.

"(iv) Provide specific guidance to covered entities regarding the needed practices and procedures for contract pharmacy oversight, including the scope and frequency of such oversight.

"(v) Establish a retention period of the greater of 5 years or such period as required under applicable state and federal laws governing medical or pharmacy records during which covered entities and contract pharmacies are required to maintain all relevant auditable records in relation to contract pharmacy arrangements, including records relating to transactions of drugs purchased pursuant to an agreement under paragraph (1), sufficient to demonstrate compliance with the requirements to prevent diversion and violations of the duplicate discount prohibition.".

(b) PROGRAM INTEGRITY.—Section 340B(d)(1)(B)(vi)(III) of the Public Health Service Act (42 U.S.C. 256b(d)(1)(B)(vi)(III)) is amended—

(1) by striking "intentionally charges a" and inserting the following: "intentionally—

Confidential to Victoria Knight

"(aa) charges a covered entity a price for purchase of a covered outpatient drug that exceeds the maximum applicable price under subsection (a)(1);";

(2) by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

"(bb) refuses to offer a covered outpatient drug for purchase at or below the maximum applicable price under subsection (a)(1) or deliver or allow to be delivered a covered outpatient drug purchased by a covered entity at or below such maximum applicable price; and

"(cc) places conditions on the ability of a covered entity to purchase a covered outpatient drug at or below the maximum applicable price under subsection (a)(1).".

SEC. 4. ELIGIBILITY FOR CHILD SITES.

Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is further amended by adding at the end the following:

"(14) CHILD SITES.—

"(A) IN GENERAL.—A covered entity described in subparagraph (L), (M), (N), or (O) of paragraph (4) that owns and operates a child site that participates in the drug discount program under this section shall maintain documentation of, and annually certify to the Secretary through such certification processes established under the Medicare enrollment and cost reporting rules, that each such child site is wholly-owned by the entity and clinically and financially integrated with the covered entity and providing

Confidential to Victoria Knight

care consistent with the policies of the covered entity, including by—

"(i) registering each child site with the Secretary;

"(ii) applying the same financial assistance policy and patient assistance policy as apply with respect to other sites operated by the covered entity; and

"(iii) ensuring that each child site complies with the Medicare provider-based rules under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations) or meets the requirements of subparagraph (B)(i).

"(B) ELIGIBILITY FOR CHILD SITES.—

"(i) IN GENERAL.—A child site is eligible for participation in the drug discount program under this section, through the eligibility of the covered entity that owns and operates such child site, only if the covered entity demonstrates that the child site meets the following requirements:

"(I) The child site applies the same patient financial assistance policy as the covered entity.

"(II) The child site participates as a provider or supplier in both the Medicare program under title XVIII of the Social Security Act, and the Medicaid program under title XIX of such Act of the State in which the child site is located, without discrimination against patients of such programs at such locations.

"(III) The child site ensures that the providers who order or dispense covered outpatient drugs purchased under this section at the child site have clinical responsibility for health care services that are related to the use of the covered outpatient drug purchased under this section that is dispensed.

Confidential to Victoria Knight

"(IV) The child site provides a clinically meaningful range of services within the scope of the services that prescribing providers employed by or contracted with the child site, covered entity, or a physician organization affiliate of the covered entity are qualified to deliver.

"(V) If the child site is owned by a covered entity described in paragraph (4)(L), the child site shall ensure that the provider who prescribes a covered outpatient drug purchased under this section meets the requirements in paragraph (12).

"(VI) The child site and the covered entity are operated under the same license, except in areas where the State requires a separate license for the child site, or in States where State law does not permit licensure of the child site and the covered entity under a single license. If a State health facilities cost review commission or other agency that has authority to regulate the rates charged by providers in a State finds that a child site is not part of the covered entity, the child site shall not be eligible for the drug discount program under this section.

"(VII) The clinical services of the child site and the covered entity are integrated as evidenced by the following:

"(aa) Professional staff of the child site have clinical privileges at the covered entity.

"(bb) The covered entity maintains the same monitoring and oversight of the child site as for any other owned entity or subsidiary of the covered entity.

"(cc) The medical director of the child site maintains a reporting relationship with the chief medical officer or other similar official of

Confidential to Victoria Knight

the covered entity that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the covered entity and the chief medical officer or other similar official of the covered entity, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the covered entity.

"(dd) Medical staff committees or other professional committees at the covered entity are responsible for medical activities in the child site, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the child site and covered entity.

"(ee) Medical records for patients treated in the child site are integrated into a unified retrieval system, or have the ability to be readily accessed by the covered entity.

"(ff) Inpatient and outpatient services of the child site and the covered entity are integrated, and patients treated at the child site who require further care have full access to all services of the covered entity and are referred where appropriate to the corresponding inpatient or outpatient department or service of the covered entity.

"(VIII) The financial operations of the child site are fully integrated within the financial system of the covered entity, as evidenced by shared income and expenses between the covered entity and the child site. For purposes of the Medicare program under title XVIII of the Social Security Act, the costs of a child site are reported in the

Confidential to Victoria Knight

appropriate cost center or cost centers of the covered entity, and the financial status of any child site is incorporated and readily identified in the covered entity's trial balance.

"(IX) The child site is held out to the public as part of the covered entity. When patients enter the child site, they are aware that they are entering the covered entity.

"(X) The child site is operated under the ownership and control of the covered entity, as evidenced by the following:

"(aa) The business enterprise that constitutes the child site is 100 percent owned by the covered entity; except that a child site may be jointly owned if:

"(AA) the covered entity holds a majority ownership interest of not less than 51 percent;

"(BB) each co-owner is either: (i) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code, or (ii) a State or local governmental entity, including a public university or academic medical center;

"(CC) each co-owner that is not a covered entity has, independent of the joint venture, a bona fide charitable, public health, or governmental mission that includes the direct provision of health care services to low-income, uninsured, or medically underserved individuals;

"(DD) no co-owner is a for-profit entity;

Confidential to Victoria Knight

"(EE) no co-owner that is not a covered entity was formed, reorganized, converted, or materially restructured for the purpose of qualifying as an eligible co-owner under this subparagraph; and

"(FF) the Administrator of the Health Resources and Services Administration has not determined, after notice and an opportunity to respond, that the joint venture structure was constituted for the purpose of obtaining eligibility under the drug discount program under this section or expanding claims for discounts under such program, rather than to further the health care mission of the covered entity and the health care needs of the patient population served by the child site.

"(bb) The covered entity and the child site have the same governing body.

"(cc) The child site is operated under the same organizational documents as the covered entity, and is subject to common bylaws and operating decisions of the governing body of the covered entity.

"(dd) The covered entity has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments at the child site.

"(XI) The reporting relationship between the child site and the covered entity have the same frequency, intensity, and level of accountability that

Confidential to Victoria Knight

exists in the relationship between the covered entity and its other departments, as evidenced by compliance with all of the following requirements:

"(aa) The child site is under the direct supervision of the covered entity.

"(bb) The child site is operated under the same monitoring and oversight by the covered entity as any other department of the covered entity, and is operated as any other department of the covered entity with regard to supervision and accountability. The director or individual responsible for daily operations at the child site—

"(AA) maintains a reporting relationship with a manager at the covered entity that has the same frequency, intensity, and level of accountability that exists in the relationship between the covered entity and its existing departments; and

"(BB) is accountable to the governing body of the covered entity, in the same manner as any department head of the covered entity.

"(XII) The following administrative functions of the child site are integrated with the functions of the covered entity: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle such administrative functions for the child site and the covered entity, or the administrative functions for both the child site and the covered entity are—

"(aa) contracted out under the same contract agreement; or

Confidential to Victoria Knight

"(bb) handled under different contract agreements, with the contract of the child site being managed by the covered entity.

"(XIII) The child site is listed on the covered entity's most recently filed Medicare cost report on a line that is reimbursable under the Medicare program (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the site would be correctly included on a reimbursable line of a Medicare cost report if the covered entity filed a cost report). Such cost report demonstrates that the services provided at the child site have associated costs and charges for covered entity outpatient department services under title XVIII of the Social Security Act (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the services provided at the child site include or consist solely of outpatient services).

"(ii) HRSA DEEMING.—

"(I) IN GENERAL.—If the Administrator of the Centers for Medicare & Medicaid Services has determined a site to be qualified as a provider-based entity and in compliance with the provider-based requirements under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations), the Secretary shall deem the site to have met the requirements described in clause (i).

"(II) RULE OF CONSTRUCTION.—This clause shall authorize the Secretary to establish a process through notice and comment rulemaking to determine whether a child site, as determined by the Administrator of the Centers for Medicare &

Confidential to Victoria Knight

Medicaid Services, complies with the Medicare provider-based rules.

"(iii) CHILD SITE REGISTRATION: COMMUNITY NEED STANDARD.—

"(I) DEFINITIONS.—For purposes of this subsection:

"(aa) The term 'child site' has the definition set forth in Section 340B(b)(4).

"(bb) The term 'Community Vulnerability Score' means the percentile ranking assigned to a ZIP Code Tabulation Area under the Social Vulnerability Index maintained by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR SVI), or such successor or supplementary validated index as the Secretary may designate by regulation, on a scale of 0 to 1 in which a score of 1 represents maximum social vulnerability. The Secretary shall, through notice and comment rulemaking, establish a method for mapping or aggregating the underlying index to the ZIP Code Tabulation Area level. Where the Secretary designates a supplementary or successor index, the Secretary shall ensure that such index is based on publicly available Zip Code Tabulation Area-level or equivalent data, updated at least biennially, and validated for use in identifying medically underserved or socially vulnerable communities.

"(cc) The term 'parent entity' means the covered entity whose eligibility status under subsection (a)(4) forms the basis for a child site's registration.

Confidential to Virginia Knight

"(dd) The term 'qualifying ZIP code' means a ZIP Code Tabulation Area with a Community Vulnerability Score at or above the 50th percentile threshold when ranked nationally — meaning the ZIP Code Tabulation Area falls within the more vulnerable half of all ZIP Code Tabulation Areas in the United States — or at or above the 40th percentile threshold when ranked against all ZIP Code Tabulation Areas within the same State, whichever threshold the covered entity elects to apply. If the ZIP Code Tabulation Area in which a child site's street address is located has not been assigned a Community Vulnerability Score, including because the area is unpopulated, non-residential, or otherwise lacks the underlying data necessary to compute such a score, the qualifying status of such area shall be determined based on the Community Vulnerability Score of the census tract in which the street address is located, or if no such score is available for that census tract, the county in which the street address is located, applying the same national and State-relative percentile thresholds described in this subparagraph. The Secretary shall, through notice and comment rulemaking, define the circumstances under which a Zip Code Tabulation Area is treated as unscored and establish another method for assigning a Community Vulnerability Score.

"(ee) The term 'ZIP Code Tabulation Area' means the geographic unit designated by the United States Census Bureau corresponding to a 5-digit ZIP code, consistent with the geographic units used by the Secretary under this subsection. For purposes of this subsection, a child site's ZIP Code Tabulation Area shall be determined based on the first five digits of the child site's street

Confidential to Victoria Knight

address ZIP code as registered with the Secretary."

"(II) COMMUNITY NEED STANDARD FOR CHILD SITES.—

"(aa) GENERAL REQUIREMENT.—A child site shall meet the community need standard established under this paragraph as a condition of initial registration and continued participation under this section. A child site meets such standard if the covered entity demonstrates that the child site is physically located in a qualifying ZIP Code Tabulation Area, as determined using the street address of the child site in a manner specified by the Secretary through notice and comment rulemaking.

"(bb) APPLICATION TO NEW CHILD SITES.—For a child site seeking registration on or after the date of enactment of this subsection, compliance with item (aa) shall be determined by the Secretary at the time of initial registration based on the Zip Code Tabulation Area in which the child site's street address is situated, as submitted by the covered entity.

"(cc) APPLICATION TO EXISTING CHILD SITES.—For a child site registered as of the date of enactment of this subsection, compliance with item (aa) shall be evaluated at the time of the next applicable recertification of the covered entity. For the purposes of applying the community need standard to a child site registered as of the date of enactment of this subsection, the Secretary shall determine

Confidential to Victoria Knight

eligibility based on the Zip Code Tabulation Area in which the child site's street address is situated at the time of such recertification.

"(dd) ONGOING VALIDATION.—Compliance with the community need standard under item (aa) shall be verified for all child sites on an ongoing basis through the annual recertification process, or such other periodic review as the Secretary may establish.

"(ee) FAILURE TO MEET STANDARD.—A child site that does not satisfy the community need standard under item (aa), as determined by the Secretary, shall be subject to removal from the covered entity's registration in accordance with procedures established by the Secretary, including notice and an opportunity to respond. Removal of a child site from registration under this paragraph shall not affect the continued eligibility of the parent entity or any other child site of the parent entity that satisfies the applicable standard.

"(ff) PAYOR-MIX EXCEPTION.—Notwithstanding item (aa), a child site that does not independently meet the community need standard described in subparagraph (aa) shall nonetheless be deemed to meet such standard if the covered entity demonstrates, to the satisfaction of the Secretary, that not less than 40 percent of patients served by the child site are enrolled in Medicaid, are uninsured, or have incomes at or below 200 percent of the Federal poverty level, as determined using patient data for the most recent 12-month period.

Confidential to Victoria Knight

"(gg) SAFETY-NET EXCEPTION.—The Secretary may grant a temporary exception from the community need standard under item (aa) for a child site that does not otherwise qualify under item (aa) or (ff), if the covered entity demonstrates that—

"(AA) the child site provides primary care, behavioral health, substance use treatment services or other services specifically directed at individuals who are low income, uninsured, or otherwise medically underserved and for which there is no adequate alternative provider within a reasonable geographic proximity — to a patient population that includes a significant proportion of low-income, uninsured, or otherwise medically underserved individuals; and

"(BB) removal of the child site from registration under this section would materially reduce access to such services for such patient population. Any exception granted under this subparagraph shall be for a period not to exceed 2 years, subject to renewal upon re-demonstration. The Secretary shall promulgate regulations specifying the criteria and application process for exceptions under this subparagraph.

"(hh) RULE OF CONSTRUCTION.—A child site shall not fail to satisfy the community need standard solely because the parent entity is located in a different ZIP Code Tabulation Area, provided the child site independently satisfies the requirements of this paragraph.

Confidential to Victoria Knight

"(III) RULEMAKING.—Not later than 6 months after the date of enactment of this subsection, the Secretary shall promulgate regulations to implement this subsection, including the method for determining the Zip Code Tabulation Area in which a child site is located under item (aa) and, where such area is unscored, the method for assigning a Community Vulnerability Score. In promulgating such regulations, the Secretary shall account for geographic disparities in national SVI rankings by providing for a state-relative eligibility determination, consistent with the state-relative threshold established in subparagraph (I)(dd), ensuring that child sites serving communities with relatively high social vulnerability within their State are not disadvantaged solely by lower absolute national percentile rankings.

"(iv) LIMITATION.—Only a child site that meets each of the requirements under this subparagraph may purchase covered outpatient drugs under the 340B program or use covered outpatient drugs purchased under the 340B program by another part of the covered entity that is authorized to participate in such program. Any transfer of 340B drugs to another facility or another part of a covered entity that is not authorized to participate in the 340B program shall be deemed a violation of paragraph (5)(B).".

SEC. 5. IMPROVING PATIENT AFFORDABILITY AND PROTECTIONS.

Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is further amended by adding at the end the following:

"(15) PATIENT ASSISTANCE PROGRAMS.—

Confidential to Victoria Knight

"(A) IN GENERAL.—Covered entities shall maintain and extend their patient financial assistance policy to patients served by their child sites and contract pharmacies. The covered entity shall ensure that its financial assistance policy is transparent to patients at point of care, satisfies the notice requirements in paragraph (C), and publicly reported. The Secretary shall establish a process, through notice and comment rulemaking, to require covered entities to maintain auditable records related to the implementation and enforcement of this paragraph. Nothing in this section shall be construed to require a covered entity to waive or eliminate all patient cost-sharing or other out-of-pocket obligations, or to provide covered outpatient drugs or related services at no cost, except to the extent required under the covered entity's generally applicable financial assistance policy.

"(B) FINANCIAL ASSISTANCE POLICY DEFINED.—In this paragraph, a 'financial assistance policy' means a written financial assistance policy described in section 501(r)(4)(A) of the Internal Revenue Code of 1986, provided to patients—

> "(i) up to at least 400 percent of the Federal poverty level, for covered entities described under subparagraph (L), (M), (N), and (O) of subsection (a)(4);
>
> "(ii) up to at least 200 percent of the Federal poverty level, for all covered entities not described in paragraph 15(b)(i) that are not otherwise subject to sliding fee schedule or grant requirements by law; and
>
> "(iii) a sliding fee scale for covered outpatient drugs dispensed to patients under the drug discount program under this section, as applicable, provided that—
>
> > "(I) for covered entities described under subparagraph (L), (M), (N), and (O) of subsection (a)(4)—

Confidential to Victoria Knight

"(aa) such sliding fee schedule must be made available for all patients up to at least 400 percent of the Federal poverty level; and

"(bb) copayment requirements under such sliding fee schedule must be nominal in amount; or

"(II) such other alternative policy as the Secretary may determine through notice and comment rulemaking with respect to a specific covered entity.

"(C) NOTICE.—

"(i) Covered entities shall provide adequate notice and application of any financial assistance policy described in subparagraph (A).

"(ii) In order to ensure meaningful understanding of eligibility of a patient for a financial assistance policy, any notice described in clause (i) must be made available to patients of the covered entity—

"(I) in a plain-language summary (as defined in 42 U.S. Code 18031(e)(3)(B)) in English; and

"(II) if English is not the primary language in the community served by the covered entity, in the primary language served by such community.

"(D) IMPLEMENTATION FOR CONTRACT PHARMACIES.—The financial assistance policies under this section shall apply to contract pharmacies by the following timeline:

"(i) prospectively to all newly registered contract pharmacy locations after the enactment of this clause; or

Confidential to Victoria Knight

"(ii) Not later than 3 years after the date of enactment of this clause for all other contract pharmacy locations.

"(E) OVERSIGHT.—The Comptroller General of the United States shall conduct a study and report to Congress on the impact of requirements of this paragraph on patient access to covered outpatient drugs purchased under this section.

"(F) RULE OF CONSTRUCTION.—Compliance with this paragraph shall not be considered a prohibited act under section 1128A, 1128B(b), or 1877 of the Social Security Act.

"(16) MEDICAL DEBT.—

"(A) PROHIBITIONS.—

"(i) IN GENERAL.—Covered entities described under subparagraph (L), (M), (N), and (O) of subsection (a)(4) shall not—

"(I) sell a patient's debt to another party;

"(II) report adverse information about an individual to consumer credit reporting agencies or credit bureaus; and

"(III) defer or deny, or require a payment before providing, medically necessary care, because of an individual's non-payment of one or more bills.

"(ii) EXCEPTION.—A covered entity described under subparagraph (L), (M), (N), and (O) of subsection (a)(4) may sell an individual's debt to another party if the party's sole purpose is to pay for the individual's debt in full.

Confidential to Victoria Knight

"(B) DEBT COLLECTION.—

"(i) IN GENERAL.—Except as provided in clause (ii), covered entities described under subparagraph (L), (M), (N), and (O) of subsection (a)(4) shall not take any legal action to collect debt from a patient at such covered entity.

"(ii) EXCEPTION.—A covered entity described under subparagraph (L), (M), (N), and (O) of subsection (a)(4) may collect debt only from patients with a clear ability to pay, as demonstrated by the greater of—

"(I) income at or above 600 percent of the Federal poverty level; or

"(II) assets valued at more than 400 percent of the patient's outstanding balance of debt owed to the covered entity.

"(iii) INTEREST.—A covered entity described under subparagraph (L), (M), (N), and (O) of subsection (a)(4) shall be prohibited from charging interest on any outstanding balance of debt owed by a patient to such covered entity that is more than the allowable percentage specified in the applicable usury laws or regulations of the state in which the covered entity is located.

"(C) MONITORING COMPLIANCE.—

"(i) IN GENERAL.—The Secretary shall conduct an annual review, in a form and manner established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of this subparagraph, to monitor covered entity compliance with the requirements of this paragraph.

"(ii) ENFORCEMENT.—If the Secretary finds that, as a result of a review described in clause (i), a

Confidential to Victoria Knight

covered entity is not in compliance with the requirements of this paragraph, the Secretary shall—

"(I) impose civil monetary penalties, which—

"(aa) 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 this subclause; and

"(bb) shall not exceed $5,000 for each instance of noncompliance that may have occurred;

"(II) where the Secretary determines that a violation of this paragraph was systematic and egregious as well as knowing and intentional, refer matters to appropriate authorities within the Office of Inspector General of the Department of Health and Human Services; and

"(III) where the Secretary determines that a covered entity may not be in compliance with the requirements of section 501(r) of the Internal Revenue Code of 1986, refer matters to appropriate authorities within the Internal Revenue Service.

"(D) GAO REPORT.—Not later than 2 years after the enactment of this subparagraph, and every 2 years thereafter, the Comptroller General of the United States shall submit to the Secretary and to the appropriate committees of Congress a report that—

"(i) analyzes covered entity compliance with the requirements described in this paragraph; and

"(ii) makes recommendations with respect to policies intended to improve compliance with the requirements described in this paragraph.

Confidential to Victoria Knight

"(E) INSPECTOR GENERAL REPORT.—The Inspector General of the Department of Health and Human Services shall conduct an annual risk-based assessment of covered entity compliance with the requirements of this paragraph.".

SEC. 6. DATA REPORTING FOR TRANSPARENCY.

Section 340B(d) of the Public Health Service Act (42 U.S.C. 256b(d)) is amended by adding at the end the following:

"(5) REPORTING OF PROGRAM SAVINGS.—

"(A) IN GENERAL.—Not later than 1 year after the date of enactment of this paragraph, and annually thereafter, each covered entity shall report to the Secretary, as an addendum to the Medicare cost report most recently submitted by such entity, or in the case of a covered entity that does not submit a Medicare cost report, by direct report to the Secretary, the following information with respect to the entity, including all sites and contract pharmacy arrangements of the entity, for the preceding year:

"(i) The total number of individuals who were dispensed or administered covered outpatient drugs purchased under this section during such preceding year that were subject to an agreement under subsection (a)(1).

"(ii) The total number of prescriptions filled with covered outpatient drugs purchased under this section and billed to insurance, organized by type of health insurance coverage (as specified by the Secretary through notice and comment rulemaking, including by 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, health insurance coverage offered in the individual or group market or a group

Confidential to VictoriaKnight

health plan (as such terms are defined in section 2791), and uninsured).

"(iii) (I) The cost incurred at each site for charity care, based on the charity care level of the covered entity, defined as a fraction, the numerator of which is the amount of charity care reported on worksheet S–10 of the Medicare cost report (or any successor), and the denominator of which is the total operating cost of the hospital, as reported for the most recent cost reporting period; or

"(II) in the case of a covered entity that is not required to submit a Medicare cost report that indicates charity care levels, a qualitative description of the charity care provided by such entity, in the aggregate, in such manner that is not overly burdensome to covered entities, as the Secretary may require through notice and comment rulemaking.

"(iv) A description of the covered entity's use of the savings received through participation in the drug discount program under this section, including a description of health care services or health-related benefits used to benefit the patients and communities served by the covered entity, delineated by categories of services and benefits and populations served, including such services and benefits provided to underserved and uninsured patients and communities.

"(v) The financial demographics of patients of the covered entity, including—

"(I) the percentage of patients eligible for financial assistance programs and sliding scale fees;

"(II) the percentage of patients who reside in a health professional shortage area (as defined in section 332) or a medically underserved community (as defined in section 799B), or who are part of a medically underserved population (as defined in

Confidential to VictoriaKnight

section 330(b)(3)), and the percentage of uninsured patients;

"(III) the percentage patients who are Medicaid beneficiaries;

"(IV) the percentage of patients who are Children's Health Insurance Program beneficiaries;

"(V) to the extent data are available, the percentage of patients earning below each of each of the following levels of the Federal Poverty Level: 100 percent, 200 percent, 300 percent, and 400 percent; and

"(VI) the number of patients who receive assistance from another party in paying for a prescription drug and the mean amount of discount or benefit received.

"(vi) Policies of the covered entity to—

"(I) promote access and adherence to prescribed medications; and

"(II) promote access to prescription medicines for patients earning under 200 percent of the Federal Poverty Level.

"(vii) In the case of a nongovernmental hospital, any contracts between such hospital and a State or local governmental entity, and any modifications to any such contract.

"(viii) Any third-party administrators in contract with the covered entity for the administration of the drug discount program.

"(ix) The funding shortfall for the covered entity attributable to services provided to Medicare and

Confidential to Victoria Knight

Medicaid beneficiaries, as reported on the Internal Revenue Service Form 990.

"(x) The number of patients using the outpatient services of the covered entity.

"(xi) Operation costs to the covered entity related to the drug discount program under this section.

"(xii) The names and addresses of all contract pharmacy locations.

"(xii) Utilization rates of outpatient hospital services furnished to patients earning below each of the following level of the Federal Poverty Level: 100 percent, 200 percent, 300 percent, and 400 percent.

"(B) RECORDS RETENTION.—Covered entities shall retain such records for a period of at least 3 years and provide such records and reports pursuant to standards established by the Secretary through notice and comment rulemaking for purposes of carrying out this paragraph.

"(C) AVAILABILITY OF INFORMATION.—

"(i) IN GENERAL.—Not later than 30 days after receiving the information reported by covered entities under subparagraph (A), the Secretary shall publish such information on the public website of the Department of Health and Human Services, which may include the website of the 340B Office of Pharmacy Affairs Information System (or a successor to such system).

"(ii) FORMAT.—Data published under clause (i) shall be published in an electronic and searchable format that shows each category of data reported both in the aggregate and identified by individual covered entity(ies) described in subsection (a)(4). In carrying out this paragraph, with respect to data reported

Confidential to Victoria Knight

pursuant to subparagraph (A), the Secretary shall ensure that any proprietary information be redacted from contracts submitted pursuant to paragraph (5)(A)(vii) before posting such contracts.

"(D) REPORTS TO CONGRESS.—Not later than 1 year after the date of the enactment of this subparagraph, and annually thereafter, the Secretary shall submit a report to Congress on the information collected under subparagraph (A).

"(E) REGULATIONS.—The Secretary shall promulgate regulations to carry out this paragraph.".

SEC. 7. ENHANCING PROGRAM INTEGRITY.

(a) AUDITS.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is further amended by adding at the end the following new subsection:

"(g) AUDITS BY THE SECRETARY.—

"(1) IN GENERAL.—In addition to the audits otherwise authorized under this section, the Secretary may audit covered entities, including the contract pharmacies and child sites of such entities, and manufacturers to assess compliance with requirements under this section, including identifying any statutory violations related to: improperly claiming eligibility for the program under this section, drug diversion, duplicate discounts, use of contract pharmacies, claiming of a discount under this section on a drug that is not a covered outpatient drug purchased under this section, or failing to provide an accurate ceiling price.

"(2) STANDARDS.—The Secretary shall conduct audits described in this section in accordance with generally accepted standards, as may be prescribed by the Comptroller General of

Confidential to Victoria Knight

the United States, and shall make the protocol for such audits publicly available.

"(3) REQUIREMENTS.—The Secretary may not close an audit described in paragraph (1) before a corrective action plan required by the Secretary has been fully implemented, as applicable.

"(4) 340B VENDOR INFORMATION.—To meet the requirements for submission of information for audits under this clause, covered entities shall contract only with vendors agreeing to—

> "(A) submit data to the Secretary and independent auditors contracting with covered entities necessary to determine the covered entity's compliance with statutory and regulatory requirements under this program, prohibitions on drug diversion and duplicate discounts, use of contract pharmacies, and claims for discounts on covered outpatient drugs purchased pursuant to agreements under subsection (a)(1); and
>
> "(B) respond to requests from auditors in a timely manner.

"(5) CONSEQUENCES OF AUDIT.—The Secretary shall ensure that, in the case of an audit finding that an entity did not meet one or more of the eligibility criteria for being a covered entity, as defined in subsection (a)(4), the full period under review in an audit, the audit results in consequences that are consistent and appropriate with the violation, which may include disenrollment, and that do not treat the failure to meet eligibility criteria as an issue that can be corrected retroactively. Nothing in this subsection shall be construed to limit the authority of the Secretary to impose any remedy or consequence otherwise available under this Section.

"(6) REGULATIONS.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall promulgate

Confidential to Victoria Knight

regulations to establish the audit and reporting procedures required by this subsection.

"(h) INDEPENDENT AUDITS OF COVERED ENTITIES AND CONTRACT PHARMACY LOCATIONS.—

"(1) On a biennial basis, each covered entity shall engage an independent auditor to conduct an audit of the covered entity's and each of its child site's and contract pharmacy location's compliance with this section. The independent auditor shall not—

"(A) have any direct or indirect financial interest in the covered entity or its contract pharmacy;

"(B) have any decision-making authority with respect to the covered entity; or

"(C) intervene with the governance of the covered entity.

"(2) Upon conclusion of each audit, each covered entity shall—

"(A) review the methodology used by the auditor to identify the full scope of any noncompliance;

"(B) identify and fully correct all violations that have been identified in such independent audit of the covered entity;

"(C) take steps to prevent such violations effectively in the future;

"(D) specifically disclose to the Secretary—

"(i) the methodology used by the independent auditor described in subparagraph (A);

"(ii) the nature and extent of any identified non-compliance; and

Confidential to Victoria Knight

"(iii) steps taken to prevent such violations effectively in the future;

"(E) assign responsibility to certify the audit results make corrections under subparagraph (B) to a corporate officer of the covered entity; and

"(F) within a reasonable time period, disclose to the manufacturer of the affected covered outpatient drug any purchase made under the drug discount program under this section that, at the time of the purchase of such drug, did not fully satisfy the requirements of the program. If the aggregate amount owed to a manufacturer as a result of an audit under this subsection exceeds the de minimis threshold established by the Secretary through notice and comment rulemaking, the covered entity shall repay the manufacturer an amount equal to the reduction in the price of the affected drugs, plus interest on such amount calculated using the applicable short-term interest rate determined by the Secretary of the Treasury under section 1274(d) of the Internal Revenue Code of 1986 for the period for which the covered entity is liable. In establishing the de minimis threshold, the Secretary shall consider the administrative costs associated with calculating, processing, and receiving repayments. Amounts may not be divided, allocated, or otherwise structured for the purpose of avoiding the repayment requirement under this subparagraph."

"(3) Not later than 1 year after the date of enactment of this paragraph, the Secretary shall—

"(A) promulgate regulations governing how auditors engaged by covered entities under this subsection shall determine whether and to what extent a covered entity is meeting its requirements under this section, including requirements regarding nonprofit status and any contract required under subsection (a)(4)(L)(i), as applicable; and

"(B) promulgate regulations to establish the audit and reporting procedures required by this subsection.".

Confidential to Virginia Knight

(2) ADDITIONAL SANCTIONS AUTHORITY.—Section 340B(d)(2)(B) of the Public Health Service Act (42 U.S.C. 256b(d)(2)(B)) is amended—

(A) in clause (v)(II), by inserting "or where the covered entity fails to implement a corrective action plan relating to a violation involving improperly claiming eligibility for the drug discount program under this section, drug diversion, duplicate discounts, compliance with contract pharmacy requirements, or claiming a discount or rebate on a drug that is not a covered outpatient drug, within 6 months of the Secretary notifying the entity of the requirement for such plan" after "knowing and intentional,"; and

(B) by adding at the end the following:

"(vi) Increasing the frequency of audits conducted for entities previously found to be in violation of requirements of the drug discount program under this section that relate to eligibility, drug diversion, duplicate discounts, compliance with contract pharmacy requirements, or claiming a discount or rebate on a drug that is not a covered outpatient drug, and assigning responsibility for making corrections relating to such a violation to a corporate officer of the entity.

"(vii) Establishing—

"(I) a process by which the Secretary provides for proper and timely notification of a potential violation by a covered entity, including the specific basis for the potential violation and the information relied upon by the Secretary in identifying such potential violation;

"(II) a process for a covered entity to develop, submit, and implement a corrective action plan, subject to approval and monitoring by the Secretary, which shall—

Confidential to Victoria Knight

"(aa) provide two months to submit a corrective action plan following notification of a potential violation under subclause (I); and;

"(bb) require the Secretary, not later than 2 months after the date of submission of such plan, to approve the plan or request changes to the plan; and

"(cc) require such plan to identify the specific basis for the finding of noncompliance and the actions the covered entity will take to correct such noncompliance, prevent recurrence, and demonstrate ongoing compliance;

"(III) standards for timelines for correction and demonstration of compliance that are reasonable and proportionate to the nature, scope, and severity of the violation, including the extent of any affected claims, the risk of diversion or duplicate discounts, and whether the violation reflects isolated error, repeated conduct, or willful disregard of applicable requirements;

"(IV) circumstances under which, during the period in which a corrective action plan is in effect, the Secretary may temporarily suspend the covered entity's eligibility to participate in the drug discount program under this section, if the Secretary determines that such suspension is necessary to protect program integrity, including cases involving willful disregard, repeated or egregious noncompliance, failure to respond to a Secretary-approved audit, or failure to implement a prior corrective action plan; and

"(V) a process for the Secretary to publicly report, in a de-identified manner, on the types and

Confidential to Victoria Knight

scope of violations found in audits conducted under this section.

"(viii) Disenrolling from the program covered entities that fail to implement a corrective action plan and correct violations in accordance with the time frame set forth in the Corrective Action Plan pursuant to the process described in subparagraph (B)(vii), related to any statutory violation of this section.

"(ix) The imposition of civil monetary penalties, which shall be assessed according to standards established in regulations to be promulgated by the Secretary, for covered entities that knowingly or intentionally continue to contract with third-party administrators or contract pharmacies that are not in compliance with the requirements of subsection (a)(13).

"(x) Notwithstanding the foregoing, if the Secretary determines that a covered entity has engaged in a pattern of noncompliance, as evidenced by: (1) 3 or more separate final audit reports finding violations of the requirements of this section within a 2-year period, or (2) 5 or more such reports within a 5-year period. The Secretary may take any one or more of the following actions with respect to such repeat noncompliant entity: (A) require the entity to implement an accelerated corrective action plan within a timeframe determined appropriate by the Secretary; (B) impose civil monetary penalties without providing an additional period for corrective action; or (C) remove the entity from the drug discount program under this section and disqualify the entity from re-entry into such program for a period of time determined by the Secretary.".

(b) PRIVATE NON-PROFIT HOSPITAL ELIGIBILITY BASED ON CONTRACTS WITH STATE OR LOCAL GOVERNMENTS MEETING SPECIFIED CRITERIA.—Section 340B(a)(5) of the Public Health Service Act (42

Confidential to Victoria's Knight

U.S.C. 256b(a)(5)), as amended by the preceding sections, is further amended by adding at the end the following:

"(E) PRIVATE NON-PROFIT HOSPITAL ELIGIBILITY BASED ON CONTRACTS WITH STATE OR LOCAL GOVERNMENTS MEETING SPECIFIED CRITERIA.—In the case of a hospital, whether registered or seeking to register for the drug discount program under this section as a covered entity described under subparagraph (L), (M), (N), or (O) of paragraph (4), that claims to be eligible for the program by virtue of being a private non-profit hospital that has a contract with a State or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare, the Secretary shall take all of the following steps, each of which shall be documented:

"(i) Prior to registering or approving annual recertification of such a hospital (or while carrying out any program audit of such a hospital), the Secretary shall obtain and review the hospital's contract with a State or local government and shall verify and document that—

"(I) the document provided by the hospital is a contract, in that it is a mutually binding agreement for the hospital to provide health care services or supplies in exchange for something of value;

"(II) the contract clearly lists the name of the hospital and the unit of State or local government that are parties to the contract and is signed and appropriately dated by appropriate officials of the hospital and the unit of State or local government;

"(III) the contract specifies an effective date;

"(IV) the contract clearly is in effect and not expired at the time of registration (or at the time of recertification, in the case of annual recertification,

Confidential to Victoria Knight

or for the full period examined in an audit, in the case of an audit); and

"(V) the contract explicitly requires that the hospital provide health care services, and that such services must be provided to individuals who are both low-income and not eligible for either the Medicaid program or the Medicare program.

"(ii) The Secretary shall verify the existence of contracts meeting the requirements of clause (i) for all covered entities described in this subparagraph and registered as of the date of enactment of this clause by no later than 1 year after the date of enactment of this clause.

"(iii) The Secretary shall not register or recertify any covered entity described in this subparagraph if the entity's contract with a State or local government does not satisfy subclauses (I) through (V) of clause (i).".

(c) VERIFICATION OF CERTAIN COVERED ENTITIES.—Section 340B(a)(4)(L)(i) of the Public Health Service Act (42 U.S.C. 256b(a)(4)(L)(i)) is amended by inserting "(provided that such a private non-profit hospital annually submits to the Secretary verification of such an active contract with a State or local government and verification of its non-profit status)" before the semicolon.

(d) AMENDMENT.—Section 340B(a)(7) of the Public Health Service Act (42 U.S.C. 256b(a)(7)) is amended by inserting at the end the following:

"(F) NON-PROFIT STATUS.—The Secretary shall verify the non-profit status of any hospital, whether registered or seeking to register for the drug discount program as a covered entity described under subparagraph (L), (M), (N), or (O) of subsection (a)(4), that claims, in connection with drug discount program registration, annual recertification, or an audit, to meet drug discount program

Confidential to VictoriaKnight

eligibility criteria in part by being a private non-profit hospital. The Secretary shall verify the non-profit status of all such hospitals using reliable publicly available information, such as by matching data reported by hospitals against data from the Internal Revenue Service or from the Centers for Medicare and Medicaid Services on the hospital's federal tax status. The Secretary shall verify all registered covered entities described under this section are in compliance with these requirements within one year of the enactment of this subparagraph.".

SEC. 8. FACILITATING DATA EXCHANGE TO IMPROVE PROGRAM INTEGRITY.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding the following new section:

"SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEARINGHOUSE.

"(a) GENERAL.—For a period of four (4) years from the enactment of this section, a manufacturer shall offer covered outpatient drugs at the ceiling price required under section 340B(a)(1) of the Public Health Service Act as a reduction in the purchase price and not through retrospective rebates or other post-sale payments. This obligation shall not apply to rebates for the AIDS Drug Assistance Programs who have implemented a rebate model prior to the effective date of this section.

"(b) CLEARINGHOUSE PERFORMANCE.—Notwithstanding any other provision of this section, the obligation under subsection (a) shall automatically conclude at the end of the period described in such subsection if the Secretary has not certified, in a public report validated by the Office of Inspector General, that the conditions described in paragraphs (1) through (4) have been satisfied. If such certification is not made as of the end of the period described in subsection (a), no provision of this subsection shall be construed to impose any additional or continuing limitation on the form, timing, or mechanism by which a manufacturer makes available the ceiling

Confidential to Victoria Knight

price required under section 340B(a)(1) of the Public Health Service Act—

"(1) all claims for 340B drugs described in subsection (g) are submitted to, and processed through, the clearinghouse entity with a contract in effect under subsection (f);

"(2) not less than 90 percent of the value of such claims submitted during the most recent 12-month period are identified by such clearinghouse entity as unique transactions that do not result in duplicate discounts or other applicable overlapping price concessions;

"(3) not less than 90 percent of the value of claims for 340B drugs as described in subsection (g) are adjudicated, including identification of any duplicate discounts, rebates, or other overlapping price concessions, within timeframes established by the Secretary through notice and comment rulemaking; and

"(4) not less than 95 percent of the value of claims for 340B drugs as described in subsection (g) contain the data elements required by the Secretary and are determined to be complete and accurate at the time of initial submission.

"(c) ONGOING VALIDATION OF CLEARINGHOUSE PERFORMANCE.—

"(1) PERIODIC OIG REPORTS.—If the obligation under subsection (a) remains in effect after the end of the 4-year period described in subsection (a), the Inspector General of the Department of Health and Human Services shall issue public reports evaluating whether the clearinghouse entity with a contract in effect under subsection (f) continues to satisfy the performance benchmarks described in subsection (b). Such reports shall be issued—

"(A) not later than 2 years after the end of the 4-year period described in subsection (a);

"(B) not later than 5 years after the end of the 4-year period described in subsection (a); and

Confidential to Victoria Knight

"(C) every 5 years thereafter.

"(2) CONTENTS.—Each report under paragraph (1) shall assess, with respect to the most recent 12-month period for which data are available, whether the performance benchmarks described in subsection (b) continue to be satisfied.

"(3) CORRECTIVE PERIOD.—If a report issued under paragraph (1) determines that one or more of the performance benchmarks described in subsection (b) are not being maintained, the clearinghouse entity shall have 6 months from the date of issuance of such report to cure the deficiency.

"(4) FOLLOW-UP REPORT.—Not later than 60 days after the end of the 6-month corrective period described in paragraph (3), the Inspector General shall issue a follow-up public report evaluating whether the deficiency has been cured and whether the applicable performance benchmarks are being maintained.

"(5) FAILURE TO MAINTAIN PERFORMANCE BENCHMARKS.—The obligation under subsection (a) shall cease to apply if the follow-up report issued under paragraph (4) determines that the deficiency has not been cured or that one or more of the applicable performance benchmarks are not being maintained.

"(d) INTERIM PERFORMANCE REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue a preliminary public report, validated by the Office of Inspector General, detailing the progress made towards accomplishing the goals and standards in subsection (b). The report shall include the data, methodology, and assumptions used by the Secretary and identify any material operational, data-quality, or compliance barriers affecting achievement of such benchmarks.

"(e) SPECIAL RULE FOR SELECTED DRUGS.—Notwithstanding subsection (b) and any other provision of this section requiring a covered entity to submit data to the third-party entity with a contract in effect under subsection (f), with respect to a drug that is a selected drug (as defined in section 1192(c))—

Confidential to Victoria Knight

"(1) each covered entity shall transmit directly to the manufacturer, in a timely manner and in accordance with standards established by the Secretary through notice and comment rulemaking, claims-level data sufficient to enable the manufacturer to prevent duplicate discounts, rebates, or other overlapping price concessions and to validate compliance with the requirements of this section and section 1191, et seq.; and

"(2) a covered entity that fails to comply with paragraph (1) shall, following written notice from the Secretary identifying the specific failure and a 30-day period to cure such failure, be subject to civil monetary penalties in an amount of $5,000 per day during the period of such non-compliance following the expiration of such cure period.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(f) CLEARINGHOUSE CONTRACTING ENTITY.—Not later than 1 year after the date of enactment of this section, the Secretary shall enter into a contract with an independent, third-party clearinghouse entity (who shall be free of conflicts of interest with covered entities, manufacturers, health plans, pharmacy benefit managers, and of other conflicts of interest as specified by the Secretary) for purposes of carrying out the clearinghouse duties under subsection (g) with respect to the drug discount program under section 340B of the Public Health Service Act to facilitate robust and verifiable data exchange between relevant parties in order to improve program integrity under section 340B of the Public Health Service Act. Such contract shall provide that the third-party entity shall perform the duties described in subsection (g) and shall be for a 4-year term that may be renewed after a subsequent bidding process or using competitive procedures, as defined in section 132 of title 41, United States Code.

"(g) DUTIES.— With respect to any 340B drug dispensed or administered to an individual, without regard to the individual's insurance status or the type or source of payment for the drug, a

Confidential to Victoria Knight

third-party entity with a contract in effect under subsection (f) shall—

"(1) establish a procedure for collecting data elements specified in subparagraph (A), including any additional data elements required by the secretary pursuant to subparagraph (A)(iv) to improve program integrity of the drug discount program under section 340B of the Public Health Service Act, such that—

"(A) Pharmacy benefit and medical benefit claims-level data elements reported under this section shall include the data elements specified in clauses (i) through (iv) of this subparagraph;

"(i) with respect to a pharmacy benefit claim—

"(I) the date of service;

"(II) the date on which the drug was prescribed;

"(III) the prescription number;

"(IV) the fill number;

"(V) the 11-digit National Drug Code for the drug dispensed;

"(VI) the quantity dispensed;

"(VII) the prescriber identifier;

"(VIII) the identifier of the dispensing pharmacy or other service provider, including the National Provider Identifier, as applicable;

"(IX) the 340B identification number of the covered entity;

"(X) the prescription benefit bank identification number; and

Confidential fo Victoria Knight

"(XI) the prescription benefit processor control number;

"(ii) with respect to a medical benefit claim—

"(I) the date of service;

"(II) the claim number;

"(III) the claim line number;

"(IV) the quantity of the drug furnished;

"(V) the unit of measure;

"(VI) the physician or other furnishing provider identifier;

"(VII) the applicable Healthcare Common Procedure Coding System code and any applicable modifiers;

"(VIII) the 11-digit National Drug Code for the drug furnished;

"(IX) the National Provider Identifier of the billing provider;

"(X) the 340B identification number of the covered entity;

"(XI) the health plan identifier; and

"(XII) the name of the health plan;

"(iii) with respect to a pharmacy benefit claim or medical benefit claim described in clause (i) or (ii)—

"(I) the name of the wholesaler;

"(II) the wholesaler account number;

"(III) the invoice date;

"(IV) the invoice number;

Confidential to Victoria Knight

"(V) the National Provider Identifier of the pharmacy or other location to which the drug was shipped;

"(VI) the 11-digit National Drug Code for the drug purchased;

"(VII) the number of package units purchased; and

"(VIII) the 340B identification number of the covered entity; and

"(iv) such additional data elements as the Secretary determines necessary to carry out this section to improve the integrity of the drug discount program under section 340B of the Public Health Service Act."

"(B) claims-level data under this section shall be submitted and must be adjudicated within timeframes established by the Secretary through notice and comment rulemaking, with such timeframes taking into account operational capabilities of covered entities; and

"(C) reclassification of historical claims by covered entities from non-340B to 340B beyond 6 months after the drug is furnished is prohibited, except that the Secretary may permit such reclassification upon a showing of good cause by the covered entity;

"(2) request and receive, in the most efficient and least burdensome manner practicable, with an established timeframe for such reporting—

"(A) claims-level rebate file data under section 1927, from State Medicaid agencies;

"(B) claims-level data from covered entities and, to the extent necessary, contract pharmacies, health plans, entities

Confidential for Victoria Knight

providing pharmacy benefit management services to health plans;

"(C) claims-level rebate file data from commercially paid claims that are eligible under Section 340B; and

"(D) any other data specified by the Secretary as necessary to carry out this section;

"(3) request, receive, and maintain data described in paragraph (1) in a confidential manner;

"(4) ensure that claims-level data submissions by covered entities are complete and accurate, and if not, obtain complete and accurate data from the covered entity;

"(5) notify the covered entity, the Secretary, the State Medicaid agency, and the manufacturer of any violation described in section 340B(a)(5)(A) of the Public Health Service Act to allow for remediation;

"(6) provide the manufacturer of a 340B drug with claims-level data submitted by a covered entity, so that the manufacturer may identify units of a 340B drug that may generate a rebate or discount under a voluntary rebate or discount arrangement, such as those related to commercial plans;

"(7) where feasible, share with a covered entity, the Secretary, a State Medicaid agency, and a manufacturer, data the third-party entity identifies in a timely manner with the purpose of preventing any of the violations described in section 2729A(b)(2) of the Public Health Service Act or duplicate discounts for a selected drug under section 1847A(i), section 1860D–14B, section 1192;

"(8) allow covered entities except those described under subparagraph (L), (M), (N), or (O) of section 340B(a)(4) of the Public Health Service Act the option of submitting claims-level data in a batched, retrospective basis that does not require the

Confidential to VictoriaKnight

application of modifiers on individual claims or point-of-sale identification;

"(9) determine total sales of 340B drugs to such individuals for purposes of being used as the basis for determining user fees under section 340B(a)(17) of such Act;

"(10) identify claims and provide manufacturer access to claims data for covered outpatient drugs purchased under the drug discount program under Section 340B of the Public Health Service Act that—

"(A) are selected drugs (as defined in section 1192(c)) to enable manufacturers to meet the nonduplication requirements of section 1193(d);

"(B) are subject to inflation rebates under section 1847A(i) or section 1860D–14B;

"(C) for a rebate or discount submitted by two or more covered entities or child sites with respect to the same unit of a covered outpatient drug purchased under the drug discount program; or

"(D) received reimbursement under a State plan (or waiver of such plan) and ensuring such claims are or were not included in any State rebate request under section 1927 in violation of sections 1903(m)(2)(A)(xiii) or 1927(j)(1) or section 340B(a)(5)(A) of the Public Health Service Act;

"(11) connect claims data and purchasing order data received under this section in a streamlined, timely, and efficient way;

"(12) provide access to state Medicaid agencies to data that is reasonably necessary to prevent duplicate discounts prohibited by section 340B(a)(5) of the Public Health Service Act;

"(13) establish procedures for covered entity reporting that may provide the same function for state Medicaid agencies as covered entity reporting to state Medicaid agencies;

Confidential to Victoria Knight

"(14) respond to requests from covered entities or manufacturers within a number of days established by the Secretary through notice and comment rulemaking;

"(15) facilitate manufacturer reasonable good faith inquiries, reasonable manufacturer audits, duplicate-discount reviews, diversion reviews, and other program integrity activities under section 340B of the Public Health Service Act by receiving, validating, matching, analyzing, and producing claims-level data, validation results, or other outputs necessary to resolve such inquiries, audits, reviews, or activities within timeframes established by the Secretary through notice and comment rulemaking, as well as all standards specified by the Secretary to be promulgated pursuant to section 1150D(g)(16);

"(16) establish, subject to standards established by the Secretary through notice and comment rulemaking, which standards shall be consistent with applicable law, including applicable Federal and State data privacy and security laws and regulations (including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations), uniform confidentiality, access, use, retention, and data-security terms applicable to information submitted to, maintained by, or transmitted through the clearinghouse, including terms governing manufacturer access to and receipt of claims-level data, validation results, or other outputs under this section;

"(17) ensure that the terms described in paragraph (16) apply uniformly to covered entities, manufacturers, health plans, pharmacy benefit managers, and other participating entities and are not subject to individualized negotiation as a condition of submitting information to, receiving information from, or otherwise participating in the clearinghouse process;

"(18) establish procedures to document any failure by a covered entity to timely submit complete and accurate information required under this section and to notify the Secretary and any affected manufacturer of such failure; and

Confidential to Virginia Knight

"(19) maintain, with appropriate safeguards, submitted data elements for a period of 10 years.

"(h) RESTRICTIONS ON CLEARINGHOUSE CONTRACTING ENTITY.—The entity receiving a contract under subsection (f) shall—

"(1) ensure that it has no conflicts of interest, including no direct contractual involvement with any covered entity, or manufacturer participating in the drug discount program under section 340B of the Public Health Service Act or any payer that makes payments for drugs purchased through such program;

"(2) not disclose confidential information obtained through carrying out the clearinghouse duties under this section other than as necessary to carry out the purposes of this section, including for program integrity functions;

"(3) not sell or otherwise generate revenue by licensing or making available the data described in subsection (g)(1); and

"(4) not collect pricing information regarding drugs that are not 340B drugs from covered entities.

"(i) DUTIES OF COVERED ENTITY.—

"(1) IN GENERAL.—Covered entities shall facilitate and participate in data transmission with the third-party clearinghouse entity with a contract in effect under subsection (f), including submission of data elements established by the Secretary through notice and comment rulemaking. Such data transmission requirements shall also apply with respect to data relating to 340B drugs dispensed through any external contract pharmacy arrangement, and shall include data maintained by or on behalf of the covered entity by a contract pharmacy or third-party administrator.

"(2) TIMELY AND COMPLETE SUBMISSION.—A covered entity shall timely submit complete and accurate information required under this section to the clearinghouse contracting entity in the form, manner, and time specified by the Secretary through notice and comment rulemaking.

Confidential to Victoria Knight

"(3) FAILURE TO TIMELY SUBMIT INFORMATION.—If a covered entity fails to timely submit complete and accurate information required under this section to the clearinghouse contracting entity, such failure shall be treated as a failure to participate in the clearinghouse process and the affected manufacturer shall provide written notice to the covered entity and the Secretary identifying the specific deficiency. If the covered entity does not cure such failure within 30 days of receipt of such notice, the affected manufacturer may suspend the availability of discounts under section 340B(a)(1) of the Public Health Service Act with respect to such covered entity, in whole or in part, until the covered entity cures such failure.

"(4) LIMITATION ON SEPARATE CONFIDENTIALITY TERMS.—A covered entity may not condition, delay, or deny submission of information to the clearinghouse contracting entity, or otherwise condition, delay, or deny participation in the clearinghouse process, on the execution or individualized negotiation of a confidentiality agreement, data use agreement, or similar agreement that is duplicative of, inconsistent with, or more restrictive than the uniform confidentiality, access, use, retention, and data-security terms established by the Secretary through notice and comment rulemaking under this section.

"(j) RESTRICTIONS ON MANUFACTURER AND PBM USE OF DATA.—

"(1) IN GENERAL.—A manufacturer who receives data under subsection (g) may use such data only for the purpose of preventing duplicate discounts and diversion under section 340B(a)(5) of the Public Health Service Act, preventing duplicate discounts in connection with inflation rebates under section 1847(A)(i) and 1860D–14B as well as for selected drugs (as defined in section 1192(c)) to enable a manufacturer to meet the nonduplication requirements of section 1193(d), and validating compliance with other requirements under the drug discount program under section 340B of the Public Health Service Act.

"(2) RESTRICTIONS ON PLANS, ISSUERS, AND PBMS.—A health plan, third party administrator of a health

Confidential to Medicine Insight

plan, or entity providing pharmacy benefit management services may use data received from the clearinghouse only for the purpose of preventing duplicate discounts and diversion under this section.

"(3) ENFORCEMENT.—Any manufacturer or other person found by the Secretary to have used data received under subsection (g) for uses other than those described in paragraphs (1) and (2), such as for pricing or marketing, shall be subject to civil monetary penalties, established by the Secretary through notice and comment rulemaking.

"(k) PRIVACY, CONFIDENTIALITY, AND DATA SECURITY REQUIREMENTS.—

"(1) IN GENERAL.—The information exchange required under this section shall occur pursuant to standards established by the Secretary through notice and comment rulemaking, including uniform confidentiality, access, use, retention, and data-security terms applicable to information submitted to, maintained by, or transmitted through the clearinghouse contracting entity, including terms governing manufacturer access to claims-level data, validation results, or other outputs under this section, and in a manner consistent with applicable Federal and State data privacy, security, and breach notification laws.

"(2) PURPOSE OF CLEARINGHOUSE.—The use of the clearinghouse contracting entity under this section is intended to facilitate secure exchange of information for 340B program integrity activities, and the clearinghouse contracting entity shall be required to qualify as a covered entity under the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, provided, however, that no manufacturer shall be required to qualify as a covered entity or business associate under HIPAA in order to obtain and use data from the clearinghouse for only the purposes identified in this Act.

Confidential to Victoria Knight

"(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(A) limit, narrow, or create any new precondition to the disclosure of claims-level, utilization, or other information that may otherwise be disclosed under applicable law for purposes of 340B program integrity activities; or

"(B) require the execution or individualized negotiation of a confidentiality agreement, data use agreement, or similar agreement not otherwise required by law as a condition of disclosing, submitting, receiving, maintaining, or using information in accordance with this section.

"(l) REPAYMENT TO MANUFACTURERS.—The Secretary shall, establish through notice and comment rulemaking, establish a process to require covered entities to work with affected manufacturers regarding identified duplicate discounts and diversion of 340B drugs, regardless of the method used to dispense the 340B drug, which shall include repayment plus accrued interest—

"(1) by the covered entity as a result of the covered entity's noncompliance with section 340B of the Public Health Service Act; or

"(2) by a State Medicaid program of rebates improperly requested by the State Medicaid program.

"(m) PROHIBITED ACTIONS OF GROUP HEALTH PLANS AND PBMS.—

"(1) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual coverage (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), or an entity providing pharmacy benefit management services may not interfere with the ability of covered entities, contract pharmacies (as such terms are defined in section 340B of the Public Health Service Act (42 U.S.C. 256b), or manufacturers of drugs to prevent duplicate

Confidential to Victoria Knight

discounts or to recoup the full amount of any identified duplicate discounts pursuant to the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 254b).

"(2) ENFORCEMENT.—The Secretary of Health and Human Services shall impose civil monetary penalties on any group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates paragraph (1).

"(n) STATE MEDICAID AGENCIES.—In accordance with requirements established by the Secretary through notice and comment rulemaking, each State's agency responsible for the administration of a state plan under section 1902(a)(5) of the Social Security Act (42 U.S.C. 1396a(a)(5)) shall establish and publish written procedures that—

"(1) specify the extent to which a 340B drug may be dispensed to a Medicaid beneficiary, including beneficiaries of managed care programs;

"(2) effectively identify when a 340B drug is dispensed to a Medicaid beneficiary; and

"(3) exclude 340B drugs dispensed to Medicaid beneficiaries from requests for rebates under section 1927.

"(o) DEFINITIONS.—In this section:

"(1) COVERED ENTITY.—The term 'covered entity' means an entity described in section 340B(a)(4) of the Public Health Service Act.

"(2) FEDERAL HEALTH CARE PROGRAM.—The term 'Federal health care program' has the meaning given that term in section 1128B(f).

"(3) HEALTH PLANS.—The term 'health plan' has the meaning given that term in section 1128C(c).

Confidential to Victoria Knight

"(4) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 1927(k)(5).

"(5) 340B DRUG.—The term '340B drug' means a drug that is—

"(A) a covered outpatient drug (as defined for purposes of section 340B of the Public Health Service Act); and

"(B) purchased under an agreement in effect under such section.

"(p) OVERSIGHT.—Not later than 1 year after implementation of the clearinghouse, the Secretary shall:

"(1) engage an independent auditor to conduct an annual audit of the clearinghouse contracting entity to ensure compliance with this section, including but not limited to timely and accurate adjudication of claims; timely and complete transmission of data to relevant parties; and timely and substantive engagement with covered entities and manufacturers, when requested. If the Secretary finds through these audits that the clearinghouse contracting entity is not in compliance with this section, the Secretary shall take appropriate action to ensure compliance, which may include the imposition of civil monetary penalties against the clearinghouse contracting entity, or early termination of its contract, provided another compliant solution is available.

"(2) issue a report to Congress detailing coordinated efforts, including through the use of existing resources to address requests from covered entities (as defined in section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4))) for payment under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for medical assistance for a drug that is subject to an agreement under section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) if the drug is subject to the payment of a rebate to the State under section 1927 of the Social Security Act (42 U.S.C. 1396r–8), as prohibited under section 340B(a)(5)(A) of the Public Health Service Act (42 U.S.C.

Confidential to Victoria Knight

256b(a)(5)(A)), and to prevent the duplicate discounts for covered outpatient drugs that are— selected drugs (as defined in section 1192(c) of the Social Security Act) to enable manufacturers to meet the nonduplication requirements of section 1193(d) of such Act; or subject to inflation rebates under as defined by section 1847A(i) or section 1860D–14B of the Social Security Act.

"(q) REGULATIONS.—The Secretary of Health and Human Services, in consultation with the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration, shall, through notice and comment rulemaking, promulgate such regulations as are necessary to implement the provisions of this section, advance the purpose of the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b), and prevent duplicate discounts and diversion through the clearinghouse established by the amendment made by this section.".

SEC. 9. PROHIBITION ON DISCRIMINATORY PRACTICES AND CONTRACTING.

(a) IN GENERAL.—Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended by inserting after section 2729 (42 U.S.C. 300gg-19b) the following:

"SEC. 2730. ANTI-DISCRIMINATION AND PERMISSIBLE 340B ARRANGEMENTS.

"(a) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity (as defined in section 340B(a)(4)) or a contract pharmacy (as defined in section 340B(b)(5)), or a participant, beneficiary, or enrollee of such plan or coverage by imposing requirements, exclusions, reimbursement terms, or other conditions on such entity or pharmacy that differ from those applied to entities or pharmacies that are not covered entities or contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or

Confidential to Victoria Knight

that the entity or pharmacy dispenses covered outpatient drugs (as defined in section 1927(k) of the Social Security Act), including by taking any action prohibited under subsection (b).

"(b) SPECIFIED PROHIBITED ACTIONS.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity, a contract pharmacy, or a participant or beneficiary in a group health plan or health insurance offered by a health insurance issuer offering group or individual health insurance by doing any of the following:

"(1) Reimbursing a covered entity or contract pharmacy for a quantity of a covered outpatient drug purchased under section 340B in an amount less than such plan, issuer, or pharmacy benefit manager, as applicable, would pay to any other similarly situated (as specified by the Secretary through notice and comment rulemaking) entity or pharmacy that is not a covered entity or a contract pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or pharmacy dispenses covered outpatient drugs purchased under section 340B.

"(2) Imposing any terms or conditions on covered entities or contract pharmacies with respect to any of the following that differ from such terms or conditions applied to other similarly situated entities or pharmacies that are not covered entities or contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or pharmacy dispenses covered outpatient drugs purchased under this section—

"(A) fees, chargebacks, clawbacks, adjustments, or other assessments;

"(B) professional dispensing fees;

"(C) restrictions or requirements regarding participation in standard or preferred pharmacy networks;

Confidential to VictoriaKnight

"(D) requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles; or

"(E) any other restrictions, conditions, practices, or policies that, as specified by the Administrator of the Health Resources and Services Administration through notice and comment rulemaking, interfere with the ability of a covered entity to maximize the value of discounts provided under section 340B.

"(3) Interfering with an individual's choice to receive a drug purchased under Section 340B from a covered entity or contract pharmacy, whether in person or via direct delivery, mail, or other form of shipment.

"(4) Requiring a covered entity or specified pharmacy to identify, either directly or through a third party, covered outpatient drug purchased under the 340B program. Other than through the 340B Data Clearinghouse established at section 1150D.

"(5) Refusing to contract with a covered entity or contract pharmacy for reasons other than those that apply equally to entities or pharmacies that are not covered entities or contract pharmacies, or on the basis that the covered entity is described in section 340B(a)(4).

"(6) Denying coverage of a covered outpatient drug purchased under the 340B program on the basis of its status as a 340B eligible drug if the group health plan or health insurance issuer otherwise covers the identical drug not purchased under 340B.

"(c) PROHIBITION.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not enter into a contract or other agreement, or any other arrangement regardless of whether such arrangement is memorialized in writing, with a covered entity (as defined in section 340B(a)(4)) in which the covered entity provides a share of any discount or savings for a covered outpatient drug under

Confidential to Victoria Knight

section 340B to the group health plan, health insurance issuer, or pharmacy benefit manager, and may not condition network participation, preferred formulary placement, claim routing, or any other benefit on the covered entity's agreement to share any such discount or savings.

"(d) ENFORCEMENT MECHANISM.—The Secretary shall impose a civil monetary penalty on any pharmacy benefit manager that violates the requirements of this section. Such penalty shall not exceed $5,000 per violation per day. The Secretary shall issue proposed regulations to implement this subsection not later than 60 days after the date of the enactment of this subsection and shall finalize such regulations not later than 180 days after such date of enactment.".

(b) SSA.—Section 1860D(12) of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new subsection:

"(i) NONDISCRIMINATION.—PDP sponsors may not include any provision in a prescription drug plan that requires covered entities under Section 340B of the Public Health Service Act to make use of contract pharmacy sites that do not meet the requirements set forth in Section 340B for the use of contract pharmacies or are otherwise inconsistent with patient need and access.".

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

"(i) PERMITTED THIRD PARTY ADMINISTRATOR ARRANGEMENTS.—

"(1) A covered entity under this section may only contract with a third-party administrator for the purposes of administering the dispensing of covered drugs under this section if compensation for the third-party administrator is in the form of bona fide services fees.

"(2) Bona fide service fees as described in paragraph (1) may not be determined as a percentage of revenue to the covered

Confidential to Victoria Knight

entity for covered drugs under this section or by any other metric tied to revenue for covered drugs to the covered entity or volume of covered drugs dispensed by the covered entity.

"(3) HRSA may, pursuant to standards established through notice and comment rulemaking, levy Civil Monetary Penalties upon covered entities for knowing and intentional non-compliance with requirements under paragraphs (1) and (2).".

(d) CONFORMING AMENDMENTS.—

(1) EMPLOYEE RETIREMENT INCOME SECURITY ACT (ERISA).—Section 715(a)(1) of ERISA (29 U.S.C. 1185d(a)(1)) is amended by inserting "and subsequent legislation" after "as amended by the Patient Protection and Affordable Care Act".

(2) INTERNAL REVENUE CODE.—Section 9815(a)(1) of the Internal Revenue Code of 1986 (26 U.S.C. 9815(a)(1)) is amended by inserting "and subsequent legislation" after "as amended by the Patient Protection and Affordable Care Act".

SEC. 10. ENSURING HRSA HAS ADEQUATE RESOURCES TO OVERSEE THE PROGRAM.

(a) IN GENERAL.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), as amended by the preceding sections, is further amended by adding at the end the following:

"(17) USER FEE PROGRAM.—

"(A) IN GENERAL.—Beginning in fiscal year 2027, the Secretary shall assess and collect fees from covered entities participating in the program under this section, in accordance with this paragraph.

"(B) FEE AMOUNTS.—The fees described in subparagraph (A) shall be assessed and collected from each covered entity on an annual basis, in an amount determined

Confidential to Victoria Knight

by the Secretary through procedures established through notice and comment rulemaking.

"(i) In general, the fee shall be 0.1 percent of the dollar amount paid by the covered entity for covered outpatient drugs under this section in the previous year.

"(C) USE OF FEES.—Any fees collected under this paragraph from covered entities shall be used by the Secretary for purposes of administering this section and enhancing program integrity and oversight activities under this section, including—

"(i) the development of a multi-functional web-based system to collect fees under this paragraph;

"(ii) the establishment, use, and maintenance of the data clearinghouse under section 1150D of the Social Security Act;

"(iii) the improvement of the integrity, transparency, security, searchability, and reliability of the 340B Office of Pharmacy Affairs Information System (or a successor to such system), including to ensure that such system continues to meet the needs of external stakeholders;

"(iv) improvements to the compliance tool used to integrate all information related to manufacturers that have entered into agreements with the Secretary under paragraph (1) and covered entities;

"(v) audits under this section of covered entities and such manufacturers; and

"(vi) any other uses for the purposes of program integrity, as the Secretary determines appropriate.

"(D) SUPPLEMENT NOT SUPPLANT.—Any fees collected under this paragraph shall be used to supplement

Confidential to Victoria Knight

and not supplant amounts otherwise provided in appropriations Acts to carry out this section.

"(E) REGULATIONS.—The Secretary shall promulgate regulations as necessary to implement the user fee program under this paragraph, which shall include establishment of a process to provide for exceptions to the fee amount under subparagraph (B), including the circumstances under which such exceptions may apply to certain covered entities.

"(F) OVERSIGHT OF USER FEE PROGRAM.—The Inspector General of the Department of Health and Human Services shall—

"(i) conduct an annual review of the user fee program under this paragraph for the first 5 years of such program; and

"(ii) not later than September 30 of each year for which a review is required under clause (i), submit to Congress a report on the review conducted under clause (i), together with such recommendations as the Inspector General determines appropriate.".

(b) CONFORMING AMENDMENT.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended, in the matter preceding subparagraph (A), by inserting ", has submitted user fees to the Secretary in the amount assessed under paragraph (17) for the current year," after "paragraph (5)". Section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)(1)) is further amended by inserting ", and has submitted user fees to the Secretary in the amount assessed under paragraph (17) for the current year," after the first reference to "agreement" in such paragraph.

(c) FUNDING.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following new subsection:

"(j) AUTHORIZATIONS OF APPROPRIATIONS.—

Confidential to Victoria Knight

"(1) AUTHORIZATION OF APPROPRIATIONS FOR AUDITS, INVESTIGATIONS, AND OTHER OVERSIGHT AND ENFORCEMENT ACTIVITIES.—In addition to amounts made available under subsection (d)(4), there are authorized to be appropriated $3,000,000 for each of fiscal years 2027 through 2031, for purposes of conducting audits, investigations, and other oversight and enforcement activities with respect to the drug discount program under this section, including audits of covered entities and manufacturers.

"(2) AUTHORIZATION OF APPROPRIATION FOR GENERAL PURPOSES.—In addition to amounts made available under paragraph (1) and subsection (d)(4), there are authorized to be appropriated $9,000,000 for each of fiscal years 2028 through 2031, for purposes of implementing the activities under this section, including audits of covered entities and manufacturers.".

(d) DIRECT HIRE AUTHORITY.—Section 340B(d) of the Public Health Service Act (42 U.S.C. 256b(d)) is amended by adding at the end the following new paragraph:

"(6) DIRECT-HIRE AUTHORITY.—Notwithstanding section 3304(a)(3) of title 5, United States Code, and sections 3309 through 3318 of such title, and section 337 of title 5 of the Code of Federal Regulations (or any successor regulations), the Secretary may, beginning on the date of the enactment of this paragraph, exercise direct-hire authority to appoint a minimum of twenty qualified candidates to permanent positions within the competitive service in order to carry out management and oversight activities under this section, with respect to covered entities and manufacturers participating in the drug discount program under this section.".

SEC. 11. STUDIES AND REPORTS.

(a) COST OF DISPENSING STUDIES AND REPORT.—

Confidential to Victoria Knight

(1) STUDY.—Not later than 1 year after the date of the enactment of this section, the Secretary shall conduct a study on dispensing fees and reimbursements that health plans and pharmacy benefit managers pay to pharmacies, separated by each category of payer (at a minimum, Medicare, Medicaid, and commercial payors) and whether the drug is purchased under section 340B. The Secretary shall repeat this study not less than every 24 months thereafter.

(2) REPORT.—Not later than 90 days after the completion of each study conducted under paragraph (1), the Secretary shall submit to Congress a report containing the results of such study, including—

(A) the amount of dispensing fees for covered outpatient drugs purchased under section 340B and covered outpatient drugs not purchased under section 340B;

(B) whether such fees are reasonable; and

(C) any recommendations for further Congressional action with respect to dispensing fees and the establishment of acceptable standards for dispensing fees.

(b) COMPTROLLER GENERAL STUDY AND REPORT ON 340B DISCOUNT.—

(1) STUDY.—Not later than 1 year after the date of the enactment of this section, the Comptroller General of the United States shall conduct a study of the 340B discount (the unit rebate amount referenced in section 340B(a)(1) of the Public Health Service Act) that is retained by—

(A) contract pharmacies;

(B) health plans;

(C) pharmacy benefit managers;

(D) third-party vendors;

Confidential to Victoria Knight

(E) patients; and

(F) covered entities.

(2) REPORT.—Not later than 2 years after enactment, the Comptroller General of the United States shall submit to Congress a report detailing the results of this study.

(A) Information shall be aggregated for each type of covered entity, and by arrangements the covered entity has with each different entity specified in subparagraphs (A) through (D) of paragraph (1), describing the amount of the 340B discount retained by the covered entity and the entities specified in subparagraphs (A) through (D) of paragraph (1).

(B) The report shall include recommendations to Congress on a standardized set of definitions to collect this information and a calculation methodology.

(c) GAO REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the debt collection practices of hospitals, including hospitals that participate in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) as covered entities described in subparagraphs (L) through (O) of subsection (a)(4)of such section.

(d) REPORTS TO CONGRESS.—

(1) INITIAL REPORT.—Not later than 1 year after the date of the enactment of this subsection, the Comptroller General of the United States shall submit a report to Congress on the following:

(A) analyzing such contracts between state and local governments and covered entities described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that claim to be eligible for the drug discount program under this section by virtue of being a private non-profit hospital that has a contract with a state or local government to provide health

Confidential to Victoria Knight

care services to low-income individuals who are not eligible for Medicaid or Medicare;

(B) assessing the amount of care the contracts described in subparagraph (A) obligate the covered entity to provide to individuals at or below 400 percent of the Federal Poverty Level, who are ineligible for Medicare under title XVIII of the Social Security Act and Medicaid under title XIX of such Act;

(C) assessing the amount of charity care and uncompensated care covered entities reporting under this section provide to individuals earning at or below 400 percent of the Federal Poverty Level;

(D) analyzing the difference between the aggregate gross reimbursement and aggregate acquisition costs received by each covered entity for covered outpatient drugs purchased under the 340B program;

(E) analyzing the degree to which Federally Qualified Health Centers, as such term is defined in subsection (a)(4)(A), are subject to the violations under section 2730(b) of the Public Health Service Act, and the effect of these violations on Federally Qualified Health Centers' ability to provide affordable care to underserved populations; and

(F) analyzing how the contracts described in subparagraph (A) define low-income individuals and whether the Secretary reviews such determinations.

(2) SUBSEQUENT REPORT.—Not later than 2 years after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a final report on the information collected under paragraph (1) regarding the difference between the aggregate payment received by each such covered entity (including child sites of such entity and adding information on all sources of payment received by the covered entity and its child sites) for drugs

Confidential to Victoria Knight

purchased under this section and the aggregate costs paid by the covered entity (including its child sites) to acquire such drugs.

(3) CLARIFICATION.—When submitting these reports, the Comptroller General of the United States shall not provide copies of unredacted contracts or any work materials to Congress or any other parties.

SEC. 12. MEANINGS.

Section 340B(b) of the Public Health Service Act (42 U.S.C. 256b(b)), as amended by the preceding sections, is further amended by adding at the end the following:

"(4) CHILD SITE.—In this section, the term 'child site' means any outpatient department, clinic, or facility that is separately registered under this section as an outpatient facility of a covered entity described in subparagraph (L), (M), (N), or (O) of paragraph (a)(4) and that is not itself the covered entity's principal operating location or the location through which the covered entity satisfies the requirements for eligibility under subsection (a)(4).

"(5) CONTRACT PHARMACY.—In this section, the term 'contract pharmacy' means a pharmacy that, pursuant to a contract or other arrangement with a covered entity, dispenses or otherwise furnishes covered outpatient drugs to patients on behalf of the covered entity, whether in person, by mail, or through any other delivery method.".

SEC. 13. REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES AND SUBGRANTEES.

Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is further amended by adding at the end the following:

Confidential to Victoria Knight

"(F) ADDITIONAL REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES; REQUIREMENTS FOR SUBGRANTEES.—

"(i) ADDITIONAL REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES.—A covered entity described in one of subparagraphs (A) through (K) of paragraph (4) shall, as a condition of participation in the program under this section—

"(I) be a nonprofit or public entity (as determined by the Secretary);

"(II) be eligible to purchase a covered outpatient drug subject to an agreement under this section only with respect to a patient receiving a health care service at a registered covered entity site, and such service and such drug are within the scope and time period of the Federal grant, project, or Federal grant-authorizing statute, as applicable, that qualifies such covered entity for participation in the program under this section;

"(III) oversee the participation in the program under this section of any subgrantee with which such covered entity enters into an enforceable written agreement in accordance with subclause (IV) and be directly liable for noncompliance by any such subgrantee with any requirement under this section;

"(IV) have an enforceable written agreement with any subgrantee, which shall apply to all registered sites of such subgrantee, and require such subgrantee to comply with all requirements under this section otherwise applicable to the covered entity and to maintain written records, which shall be made available to the Secretary upon request, sufficient to demonstrate such subgrantee's receipt of eligible Federal funds or an in-kind contribution

Confidential to Victoria Knight

purchased with such funds, as described in clause (iii), and the grant under which such subgrantee receives such funds or contribution; and

"(V) maintain written records sufficient to demonstrate such entity authorized such subgrantee to, prior to purchasing covered outpatient drugs subject to an agreement under this section, register each subgrantee site in the covered entity identification system established under subsection (d)(2)(B)(iv) to participate in the program under this section as a subgrantee of such entity and provide the Secretary with such registration information as requested to demonstrate such subgrantee's receipt of eligible Federal funds or an in-kind contribution purchased with such funds, as described in clause (iii), and the grant under which the subgrantee receives such funds or contribution.

"(ii) REQUIREMENTS FOR SUBGRANTEES.—Notwithstanding any other provision in this section, a subrecipient of a Federal grant shall be eligible to participate in the program under this section only if such subrecipient is a subgrantee (as defined in clause (iii)) and such subgrantee—

"(I) is a nonprofit or public entity (as determined by the Secretary);

"(II) prior to purchasing covered outpatient drugs subject to an agreement under this section—

"(aa) enters into an enforceable written agreement with the covered entity providing eligible Federal funds or an in-kind contribution, pursuant to clause (i)(IV);

"(bb) maintains written records, which shall be made available to the Secretary upon request, sufficient to demonstrate such

Confidential to Victoria Knight

subgrantee's receipt of eligible Federal funds or an in-kind contribution purchased with such funds, as described in clause (iii), and the grant under which such subgrantee receives such funds or contribution; and

"(cc) registers each subgrantee site to participate in the program under this section in the covered entity identification system established under subsection (d)(2)(B)(iv);

"(III) purchases covered outpatient drugs subject to an agreement under this section only with respect to a patient receiving a health care service at a registered subgrantee site, and such service and such drug are within the scope and time period of the Federal grant, project, or grant-authorizing statute, as applicable, that qualifies such subgrantee for participation in the program under this section;

"(IV) in the case of a subgrantee that receives an in-kind contribution from a covered entity described in paragraph (4)(K), demonstrates to such covered entity and to the Secretary, upon initial registration to participate in the program under this section and on an annual basis thereafter, that the number of individuals aged 19 to 64 years receiving a health care service at the registered subgrantee site during the most recent calendar year who are enrolled under a State plan under title XIX of the Social Security Act (or a waiver of such plan), as a share of all individuals aged 19 to 64 years receiving a health care service at the registered subgrantee site during such calendar year, exceeds the number of individuals aged 19 to 64 years who reside in the State where such subgrantee site is located and are enrolled under a State plan under title XIX of such Act (or a waiver of such plan), as a share of all individuals aged 19 to 64 who reside in such State, each as measured by data available

Confidential to Victoria Knight

from the American Community Survey of the Bureau of the Census for the calendar year preceding the most recent calendar year;

"(V) in the case of a subgrantee that receives an in-kind contribution from a covered entity described in paragraph (4)(K), submits to such covered entity and to the Secretary, upon receipt of each in-kind contribution described in clause (iii)—

"(aa) a written plan in a form specified by the Secretary describing how such contribution will be used to further the goals of the relevant Federal grant, how such subgrantee will ensure that purchases of covered outpatient drugs under the program under this section are consistent with the goals of such grant, and how such subgrantee will ensure compliance with the requirements under subparagraph (A) and (B); and

"(bb) a written plan in a form specified by the Secretary and using criteria established by the Secretary through notice and comment rulemaking to determine the date upon which its eligibility to participate in the program under this section, as a result of such contribution, shall terminate (absent such subgrantee's receipt of additional funds or contributions described in clause (iii));

"(VI) subject to subclause (VII), immediately notifies the Secretary, disenrolls from the program under this section, and discontinues making purchases under such program and representing to third parties that it may purchase under such program as of the date described in subclause (V)(bb) or if, at any time during its participation in the program under this section, it no longer meets

Confidential to Victoria Knight

one or more applicable requirements under this section; and

"(VII) not later than 30 days following the date on which the covered entity with which such subgrantee has an agreement pursuant to clause (i) ceases participation in the program under this section, such subgrantee either—

"(aa) disenrolls from the program under this section and discontinues making purchases under such program and representing to third parties that such subgrantee may purchase under such program; or

"(bb) enters into an enforceable written agreement with a different covered entity described in one of subparagraphs (A) through (K) of paragraph (4) that is participating in the program under this section, and satisfies all applicable requirements under this section with respect to such different covered entity.

"(iii) SUBGRANTEE DEFINED.—

"(I) IN GENERAL.—In this subparagraph, the term 'subgrantee' means a subrecipient of a Federal grant that—

"(aa) receives eligible Federal funds from a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) in the form of nonnominal and ongoing payments by such covered entity directly to such subrecipient to directly support the provision of health care services by such subrecipient to individuals within the scope and time period of the Federal grant, project, or Federal grant-authorizing statute, as applicable, that qualifies such covered entity for

Confidential to Victoria Knight

participation in the program under this section; or

"(bb) receives in-kind contributions from a covered entity described in paragraph (4)(K) and such contributions—

"(AA) are ongoing and are in the form of real property, equipment, supplies, or services;

"(BB) subject to subclause (II), have a value exceeding $25,000 per year, which shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics and determined by the subrecipient and approved by the covered entity providing such contribution in a manner specified by the Secretary;

"(CC) are specifically identifiable and provided by such covered entity directly to such subrecipient; and

"(DD) directly support the provision of health care items and services by such subrecipient solely to individuals within the scope and time period of the Federal grant that qualifies such covered entity for participation in the program under this section.

"(II) EXCLUSION.—The requirement specified in subclause (I)(bb)(BB) shall not apply with respect to a subrecipient of a Federal grant that receives in-kind contributions from a covered entity described in paragraph (4)(K) if—

Confidential to Victoria Knight

"(aa) as of January 1, 2025, such subrecipient is participating in the program under this section as such a subrecipient and is in compliance with all requirements under this section otherwise applicable to such subrecipient; and

"(bb) with respect to any in-kind contribution such subrecipient receives after January 1, 2025, such subrecipient has continuously participated in the program under this section as such a subrecipient in compliance with all requirements under this section for the period beginning on January 1, 2025, and continuing through the date on which program participation ends as determined in the plan submitted to the Secretary pursuant to clause (ii)(V)(bb) or any such earlier date on which program participation ends.

"(iv) RULE OF CONSTRUCTION.—For purposes of this section, any subgrantee that is not itself a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) shall be subject to the obligations under this section applicable to the covered entity with which such subgrantee has an enforceable written agreement pursuant to clause (i). Further, for purposes of this section, each registered site of such subgrantee shall be subject to the requirements set forth in subparagraph (F) as if such site were the covered entity with which such subgrantee has an enforceable written agreement pursuant to clause (i).".

SEC. 14. EFFECTIVE DATE.

(a) IN GENERAL.—Except as otherwise expressly provided in this Act, the amendments made by this Act shall take effect on the date of enactment of this Act.

Confidential to Victoria Knight

(b) Regulations; TRANSITION PERIOD.—

(1) REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall, through notice and comment rulemaking, promulgate such final regulations as are necessary to implement this Act and the amendments made by this Act, including any such regulations required elsewhere in this Act or in amendments made by this Act.

(2) TRANSITION PERIOD.—In promulgating the regulations required under paragraph (1), the Secretary shall establish appropriate transition periods for covered entities, manufacturers, contract pharmacies, and other affected parties to come into compliance with the requirements imposed by this Act and the amendments made by this Act. Such transition periods shall not be less than 180 days from the date of enactment for any substantive new compliance obligation imposed on a covered entity or manufacturer by this Act, unless a longer or shorter transition period is specifically provided elsewhere in this Act.

(c) CONSTRUCTION.—Any reference in this Act to the "date of enactment of this section" shall be construed as referring to the date of enactment of this Act unless the context clearly requires otherwise.

Confidential to Victoria Knight