

REAL-TIME BENEFIT TOOL IMPLEMENTATION ACT

JUNE 11, 2024.—Ordered to be printed

Mr. SMITH of Missouri, from the Committee on Ways and Means,  
 submitted the following

R E P O R T

[To accompany H.R. 7512]

The Committee on Ways and Means, to whom was referred the bill (H.R. 7512) to amend title XVIII of the Social Security Act to ensure implementation of real-time benefit tools under part D of the Medicare program, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:  
Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Real-Time Benefit Tool Implementation Act”.

**SEC. 2. ENSURING IMPLEMENTATION OF REAL-TIME BENEFIT TOOLS UNDER PART D OF THE MEDICARE PROGRAM.**

Section 1860D–4(o) of the Social Security Act (42 U.S.C. 1395w–104(o)) is amended by striking paragraph (1) and inserting the following:

“(1) IN GENERAL.—Not later than January 1, 2027, a PDP sponsor of a prescription drug plan shall implement one or more electronic real-time benefit tools that meet the requirements described in paragraph (2).”.

**I. SUMMARY AND BACKGROUND**

**A. PURPOSE AND SUMMARY**

This bill will provide a firm implementation date of January 1, 2027 for physician-facing real time benefit tools.

**B. BACKGROUND AND NEED FOR LEGISLATION**

As part of the *Consolidated Appropriations Act of 2020*, Congress codified a requirement for Medicare Part D PDPs to support prescriber real-time benefit tools. The Centers for Medicare and Medicaid Services has not implemented the program in the 3 years since the bill passed. This bill will place a firm implementation date of January 1, 2027 to ensure the program is implemented.

**C. LEGISLATIVE HISTORY**

*Background*

H.R. 7512 was introduced on March 1, 2024, and was referred to the Committee on Energy and Commerce and the Committee on Ways and Means.

*Committee Hearings*

The Committee on Ways and Means held the following hearing(s) concerning the policy in H.R. 7512:

On May 16, 2023, the Committee on Ways and Means held a hearing titled, “Hearing on Health Care Price Transparency: A Patient’s Right to Know” to examine how a lack of transparency in America’s health care system increases costs and prevents patients from being effective health care shoppers.

*Committee Action*

The Committee on Ways and Means marked up H.R. 7512, the Real-Time Benefit Tool Implementation Act, on March 6, 2024, and favorably reported the bill, as amended, to the House of Representatives (with quorum being present).

**D. DESIGNATED HEARING**

Pursuant to clause 3(c)(6) of rule XIII, the following hearing was used to develop and consider H.R. 7512:

“Hearing on Health Care Price Transparency: A Patient’s Right to Know” May 16, 2023.

## II. EXPLANATION OF THE BILL

### A. REASONS FOR CHANGE

As part of the *Consolidated Appropriations Act of 2020*, Congress codified a requirement for Medicare Part D PDPs to support prescriber real-time benefit tools. The Centers for Medicare and Medicaid Services has not implemented the program in the 3 years since the bill passed. This bill will place a firm implementation date of January 1, 2027 to ensure the program is implemented.

### B. EXPLANATION OF PROVISIONS

#### *Sec. 1. Short title*

The title of the bill is the *Real Time Benefit Tools Implementation Act*.

#### *Sec. 2. Ensuring implementation of real-time benefit tools under Part D of the Medicare program*

Provides an implementation date of no later than January 1, 2027 for Medicare Part D real time benefit tools.

### C. EFFECTIVE DATE

The bill would become effective January 1, 2027.

## III. VOTES OF THE COMMITTEE

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 7512, “The Real-Time Benefit Tool Implementation Act,” on March 6, 2024.

H.R. 7512 was ordered favorably reported to the House of Representatives as amended by a roll call vote of 42 yeas to 0 nays (with a quorum being present). The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Smith (MO) .....	X	.....	.....	Mr. Neal .....	X	.....	.....
Mr. Buchanan .....	X	.....	.....	Mr. Doggett .....	X	.....	.....
Mr. Smith (NE) .....	X	.....	.....	Mr. Thompson .....	X	.....	.....
Mr. Kelly .....	X	.....	.....	Mr. Larson .....	X	.....	.....
Mr. Schweikert .....	X	.....	.....	Mr. Blumenauer .....	X	.....	.....
Mr. LaHood .....	X	.....	.....	Mr. Pascrell .....	X	.....	.....
Dr. Wenstrup .....	X	.....	.....	Mr. Davis .....	X	.....	.....
Mr. Arrington .....	X	.....	.....	Ms. Sánchez .....	X	.....	.....
Dr. Ferguson .....	X	.....	.....	Ms. Sewell .....	X	.....	.....
Mr. Estes .....	X	.....	.....	Ms. DelBene .....	X	.....	.....
Mr. Smucker .....	X	.....	.....	Ms. Chu .....	X	.....	.....
Mr. Hern .....	X	.....	.....	Ms. Moore .....	X	.....	.....
Ms. Miller .....	X	.....	.....	Mr. Kildee .....	X	.....	.....
Dr. Murphy .....	X	.....	.....	Mr. Beyer .....	.....	.....	.....
Mr. Kustoff .....	X	.....	.....	Mr. Evans .....	X	.....	.....
Mr. Fitzpatrick .....	X	.....	.....	Mr. Schneider .....	X	.....	.....
Mr. Steube .....	X	.....	.....	Mr. Panetta .....	X	.....	.....
Ms. Tenney .....	X	.....	.....	Mr. Gomez .....	X	.....	.....
Mrs. Fischbach .....	X	.....	.....				
Mr. Moore .....	X	.....	.....				
Mrs. Steel .....	X	.....	.....				
Ms. Van Duyn .....	X	.....	.....				
Mr. Feenstra .....	X	.....	.....				

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Ms. Malliotakis .....	X	.....	.....				
Mr. Carey .....	X	.....	.....				

#### **IV. BUDGET EFFECTS OF THE BILL**

##### **A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS**

With respect to clause 3(d) of rule XIII of the Rules of the House of Representatives, a cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not made available to the Committee in time for the filing of this report.

##### **B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY**

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involved no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

#### **V. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE**

With respect to the requirements of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a) of the *Congressional Budget Act of 1974* and with respect to requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the *Congressional Budget Act of 1974*, the Committee has requested but not received a cost estimate for this bill from the Director of Congressional Budget Office. The Chairman of the Committee shall cause such estimate and statement to be printed in the Congressional Record upon its receipt by the Committee.

#### **VI. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE**

##### **A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS**

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

##### **B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES**

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill does not authority funding, so no statement of general performance goals and objectives is required.

##### **C. INFORMATION RELATING TO UNFUNDED MANDATES**

This information is provided in accordance with section 423 of the *Unfunded Mandates Reform Act of 1995* (Pub. L. No. 104-4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has deter-

mined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

**D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND  
LIMITED TARIFF BENEFITS**

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

**E. DUPLICATION OF FEDERAL PROGRAMS**

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

**VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS  
REPORTED**

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows.

Section 1860D–4(o) of the Social Security Act is amended by striking paragraph (1) and inserting the following:

“(1) *IN GENERAL.*—Not later than January 1, 2027, a PDP sponsor of a prescription drug plan shall implement one or more electronic real-time benefit tools that meet the requirements described in paragraph (2).”

**CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED**

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

**SOCIAL SECURITY ACT**

\* \* \* \* \*

**TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND  
DISABLED**

\* \* \* \* \*

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM  
 Subpart 1—Part D Eligible Individuals and Prescription Drug  
 Benefits

\* \* \* \* \*

BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG  
 COVERAGE

SEC. 1860D—4. (a) DISSEMINATION OF INFORMATION.—

(1) GENERAL INFORMATION.—

(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and, subject to subparagraph (C), including the information described in subparagraph (B).

(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

(I) the risks associated with prolonged opioid use; and

(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

(aa) in the case of an MA–PD plan under part C, under such plan; and

(bb) in the case of a prescription drug plan, under such plan and under parts A and B.

(C) TARGETED PROVISION OF INFORMATION.—A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees

under the plan, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

(3) PROVISION OF SPECIFIC INFORMATION.—

(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) CLAIMS INFORMATION.—A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) for a year preceding 2025, the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

(b) ACCESS TO COVERED PART D DRUGS.—

(1) ASSURING PHARMACY ACCESS.—

(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) USE OF STANDARDIZED TECHNOLOGY.—

(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

(B) STANDARDS.—

(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be suffi-

cient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

(i) IN GENERAL.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to

take into account new therapeutic uses and newly approved covered part D drugs.

(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(i) FORMULARY REQUIREMENTS.—

(I) IN GENERAL.—Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) EXCEPTIONS.—The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(I) IN GENERAL.—Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

(II) CRITERIA.—The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) IMPLEMENTATION.—The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) REQUIREMENT FOR CERTAIN CATEGORIES AND CLASSES UNTIL CRITERIA ESTABLISHED.—Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.

- (II) Antidepressants.
- (III) Antineoplastics.
- (IV) Antipsychotics.
- (V) Antiretrovirals.
- (VI) Immunosuppressants for the treatment of transplant rejection.

(H) USE OF SINGLE, UNIFORM EXCEPTIONS AND APPEALS PROCESS.—Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(I) REQUIRED INCLUSION OF SELECTED DRUGS.—

(i) IN GENERAL.—For 2026 and each subsequent year, the PDP sponsor offering a prescription drug plan shall include each covered part D drug that is a selected drug under section 1192 for which a maximum fair price (as defined in section 1191(c)(3)) is in effect with respect to the year.

(ii) CLARIFICATION.—Nothing in clause (i) shall be construed as prohibiting a PDP sponsor from removing such a selected drug from a formulary if such removal would be permitted under section 423.120(b)(5)(iv) of title 42, Code of Federal Regulations (or any successor regulation).

(4) ENSURING ACCESS DURING COVID–19 PUBLIC HEALTH EMERGENCY PERIOD.—

(A) IN GENERAL.—During the emergency period described in section 1135(g)(1)(B), subject to subparagraph (B), a prescription drug plan or MA–PD plan shall, notwithstanding any cost and utilization management, medication therapy management, or other such programs under this part, permit a part D eligible individual enrolled in such plan to obtain in a single fill or refill, at the option of such individual, the total day supply (not to exceed a 90-day supply) prescribed for such individual for a covered part D drug.

(B) SAFETY EDIT EXCEPTION.—A prescription drug plan or MA–PD plan may not permit a part D eligible individual to obtain a single fill or refill inconsistent with an applicable safety edit.

(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically

appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).

(F) With respect to plan years beginning on or after January 1, 2022, a drug management program for at-risk beneficiaries described in paragraph (5).

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

(A) DESCRIPTION.—

(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are the following:

(I) Part D eligible individuals who—

(aa) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(bb) are taking multiple covered part D drugs; and

(cc) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).

(B) ELEMENTS.—Such program—

(i) may include elements that promote—

(I) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(II) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other com-

pliance programs and other appropriate means; and

(III) detection of adverse drug events and patterns of overuse and underuse of prescription drugs; and

(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—

(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under section 1852(n)(2), including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and

(II) cost-effective means by which an enrollee may so safely dispose of such drugs.

(C) REQUIRED INTERVENTIONS.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Patient Protection and Affordable Care Act, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) ASSESSMENT.—The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E) AUTOMATIC ENROLLMENT WITH ABILITY TO OPT-OUT.—The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

(G) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

(3) REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES.—The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

(4) REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

(A) IN GENERAL.—For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) PROCEDURES.—

(i) VALIDITY OF PRESCRIBER NATIONAL PROVIDER IDENTIFIERS.—The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) INFORMING BENEFICIARIES OF REASON FOR DENIAL.—The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) REPORT.—Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

(D) NOTIFICATION AND ADDITIONAL REQUIREMENTS WITH RESPECT TO OUTLIER PRESCRIBERS OF OPIOIDS.—

(i) NOTIFICATION.—Not later than January 1, 2021, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information as specified in accordance with clause (iii).

(ii) IDENTIFICATION OF OUTLIER PRESCRIBERS OF OPIOIDS.—

(I) IN GENERAL.—The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA-PD plans under part C and based on the thresholds established under subclause (II), identify prescribers that are outlier opioids prescribers for a period of time specified by the Secretary.

(II) ESTABLISHMENT OF THRESHOLDS.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish thresholds, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.

(III) EXCLUSIONS.—The following shall not be included in the analysis for identifying outlier prescribers of opioids under this clause:

(aa) Claims for covered part D drugs for part D eligible individuals who are receiving hospice care under this title.

(bb) Claims for covered part D drugs for part D eligible individuals who are receiving oncology services under this title.

(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Inspector General of the Department of Health and Human Services.

(iii) CONTENTS OF NOTIFICATION.—The Secretary shall include the following information in the notifications provided under clause (i):

(I) Information on how such prescriber compares to other prescribers within the same specialty and geographic area.

(II) Information on opioid prescribing guidelines, based on input from stakeholders, that may include the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain and guidelines developed by physician organizations.

(III) Other information determined appropriate by the Secretary.

(iv) MODIFICATIONS AND EXPANSIONS.—

(I) FREQUENCY.—Beginning 5 years after the date of the enactment of this subparagraph, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input and changes in opioid prescribing utilization and trends.

(II) EXPANSION TO OTHER PRESCRIPTIONS.—The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.

(v) ADDITIONAL REQUIREMENTS FOR PERSISTENT OUTLIER PRESCRIBERS.—In the case of a prescriber who the Secretary determines is persistently identified under clause (ii) as an outlier prescriber of opioids, the following shall apply:

(I) Such prescriber may be required to enroll in the program under this title under section 1866(j) if such prescriber is not otherwise required to enroll, but only after other appropriate remedies have been provided, such as the provision of education funded through section 6052 of the SUPPORT for Patients and Communities Act, for a period determined by the Secretary as sufficient to correct the prescribing patterns that lead to identification of such prescriber as a persistent outlier prescriber of opioids. The Secretary shall determine the length of the period for which such prescriber is required to maintain such enrollment,

which shall be the minimum period necessary to correct such prescribing patterns.

(II) Not less frequently than annually (and in a form and manner determined appropriate by the Secretary), the Secretary, consistent with clause(iv)(I), shall communicate information on such prescribers to sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA-PD plan.

(vi) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make aggregate information under this subparagraph available on the internet website of the Centers for Medicare & Medicaid Services. Such information shall be in a form and manner determined appropriate by the Secretary and shall not identify any specific prescriber. In carrying out this clause, the Secretary shall consult with interested stakeholders.

(vii) OPIOIDS DEFINED.—For purposes of this subparagraph, the term “opioids” has such meaning as specified by the Secretary.

(viii) OTHER ACTIVITIES.—Nothing in this subparagraph shall preclude the Secretary from conducting activities that provide prescribers with information as to how they compare to other prescribers that are in addition to the activities under this subparagraph, including activities that were being conducted as of the date of the enactment of this subparagraph.

(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may (and for plan years beginning on or after January 1, 2022, a PDP sponsor shall) establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary’s access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) REQUIREMENT FOR NOTICES.—

(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for

at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) TIMING OF NOTICES.—

(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

(i) IN GENERAL.—Except as provided in clause (v), for purposes of this paragraph, the term “at-risk beneficiary for prescription drug abuse” means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors,

entities delegated by plan sponsors, and biopharmaceutical manufacturers; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

(I) receives hospice care under this title;

(II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(iii) PROGRAM SIZE.—The Secretary shall establish policies, including the guidelines developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

(iv) CLINICAL CONTACT.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

(v) TREATMENT OF ENROLLEES WITH A HISTORY OF OPIOID-RELATED OVERDOSE.—

(I) IN GENERAL.—For plan years beginning not later than January 1, 2021, a part D eligible individual who is not an exempted individual described in clause (ii) and who is identified under this clause as a part D eligible individual with a history of opioid-related overdose (as defined by the Secretary) shall be included as a potentially at-risk beneficiary for prescription drug abuse under the drug management program under this paragraph.

(II) IDENTIFICATION AND NOTICE.—For purposes of this clause, the Secretary shall—

(aa) identify part D eligible individuals with a history of opioid-related overdose (as so defined); and

(bb) notify the PDP sponsor of the prescription drug plan in which such an individual is enrolled of such identification.

(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—

(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) select—

(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a “prescriber”) who may write prescriptions for such drugs for such beneficiary; and

(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

(iii) BENEFICIARY PREFERENCES.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(I) review such preferences;

(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(III) inform the beneficiary of such selection or change of selection.

(iv) EXCEPTION REGARDING BENEFICIARY PREFERENCES.—In the case that the PDP sponsor deter-

mines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

(I) at least 30 days written notice of the change of selection; and

(II) a rationale for the change.

(v) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary’s designated prescriber and pharmacy.

(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.

(F) TERMINATION OF IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term “frequently abused drug” means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) DATA DISCLOSURE.—

(i) DATA ON DECISION TO IMPOSE LIMITATION.—In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

(ii) DATA TO REDUCE FRAUD, ABUSE, AND WASTE.—The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

(I) SHARING OF INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

(J) PRIVACY ISSUES.—Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

(K) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

- (i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and
- (ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b-3 note)) and materials directed toward such enrollees.

(L) APPLICATION UNDER MA-PD PLANS.—Pursuant to section 1860D-21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA-PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(M) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.

(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

(A) IN GENERAL.—A tool described in this paragraph is any of the following:

- (i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.
- (ii) Retrospective utilization review to identify—
  - (I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and
  - (II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.
- (iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA-PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

- (i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and
- (ii) the name and prescription records of individuals described in paragraph (5)(C).

(C) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that plan sponsor compliance reviews and program audits biennially include a certification that utilization

management tools under this paragraph are in compliance with the requirements for such tools.

(6) PROVIDING PRESCRIPTION DRUG PLANS WITH PARTS A AND B CLAIMS DATA TO PROMOTE THE APPROPRIATE USE OF MEDICATIONS AND IMPROVE HEALTH OUTCOMES.—

(A) PROCESS.—Subject to subparagraph (B), the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor, on a periodic basis and in an electronic format, beginning in plan year 2020, data described in subparagraph (D) with respect to enrollees in such plan. Such data shall be provided without regard to whether such enrollees are described in clause (ii) of paragraph (2)(A).

(B) PURPOSES.—A PDP sponsor may use the data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in clause (i) of paragraph (2)(A).

(ii) To improving care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For any other purpose determined appropriate by the Secretary.

(C) LIMITATIONS ON DATA USE.—A PDP sponsor shall not use data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To inform coverage determinations under this part.

(ii) To conduct retroactive reviews of medically accepted indications determinations.

(iii) To facilitate enrollment changes to a different prescription drug plan or an MA-PD plan offered by the same parent organization.

(iv) To inform marketing of benefits.

(v) For any other purpose that the Secretary determines is necessary to include in order to protect the identity of individuals entitled to, or enrolled for, benefits under this title and to protect the security of personal health information.

(D) DATA DESCRIBED.—The data described in this clause are standardized extracts (as determined by the Secretary) of claims data under parts A and B for items and services furnished under such parts for time periods specified by the Secretary. Such data shall include data as current as practicable.

(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D-1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) ELECTRONIC PRESCRIPTION PROGRAM.—

(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(E) ELECTRONIC PRIOR AUTHORIZATION.—

(i) IN GENERAL.—Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—

(I) a prior authorization request from the prescribing health care professional for coverage of a covered part D drug for a part D eligible indi-

vidual enrolled in a part D plan (as defined in section 1860D–23(a)(5)) to the PDP sponsor or Medicare Advantage organization offering such plan; and

(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.

(ii) ELECTRONIC TRANSMISSION.—

(I) EXCLUSIONS.—For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).

(II) STANDARDS.—In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

(III) APPLICATION.—Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.

(3) STANDARDS.—

(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

- (i) patient safety;
- (ii) the quality of care provided to patients; and
- (iii) efficiencies, including cost savings, in the delivery of care.

(C) DESIGN CRITERIA.—Such standards shall—

- (i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;
- (ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and
- (iii) be designed so that they permit electronic exchange of drug labeling and drug listing information

maintained by the Food and Drug Administration and the National Library of Medicine.

(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1171(8))

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with affected standard setting organizations and industry users.

(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) EVALUATION AND REPORT.—

(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and phar-

macies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

(i) a prescription issued when the practitioner and dispensing pharmacy are the same entity;

(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(iii) a prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

(v) a prescription issued by a practitioner prescribing a drug under a research protocol;

(vi) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

(vii) a prescription issued by a practitioner—

(I) for an individual who receives hospice care under this title; and

(II) that is not covered under the hospice benefit under this title; and

(viii) a prescription issued by a practitioner for an individual who is—

(I) a resident of a nursing facility (as defined in section 1919(a)); and

(II) dually eligible for benefits under this title and title XIX.

(C) DISPENSING.—(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations.

(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

(D) ENFORCEMENT.—The Secretary shall, through rule-making, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).

(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the

Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) APPEALS.—

(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D-2(b)(4)(C)(i).

(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) TIMING OF NOTICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) REQUIREMENTS WITH RESPECT TO SALES AND MARKETING ACTIVITIES.—The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1851(h)(4)(C) on conducting activities described in section 1851(j)(1).

(2) The requirement under section 1851(h)(4)(D) to conduct activities described in section 1851(j)(2) in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1851(h)(6).

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1851(h)(7).

(m) PROHIBITION ON LIMITING CERTAIN INFORMATION ON DRUG PRICES.—A PDP sponsor and a Medicare Advantage organization shall ensure that each prescription drug plan or MA-PD plan offered by the sponsor or organization does not restrict a pharmacy that dispenses a prescription drug or biological from informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug or biological to the enrollee under the plan and a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage.

(n) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1859(i).

(o) REAL-TIME BENEFIT INFORMATION.—

[(1) IN GENERAL.—After the Secretary has adopted a standard under paragraph (3) for electronic real-time benefit tools, and at a time determined appropriate by the Secretary, a PDP sponsor of a prescription drug plan shall implement one or more of such tools that meet the requirements described in paragraph (2).]

(1) IN GENERAL.—*Not later than January 1, 2027, a PDP sponsor of a prescription drug plan shall implement one or more electronic real-time benefit tools that meet the requirements described in paragraph (2).*

(2) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to an electronic real-time benefit tool, are that the tool is capable of—

(A) integrating with electronic prescribing and electronic health record systems of prescribing health care profes-

sionals for the transmission of formulary and benefit information in real time to such professionals; and

(B) with respect to a covered part D drug, transmitting such information specific to an individual enrolled in a prescription drug plan, including the following:

(i) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

(ii) Cost-sharing information and the negotiated price for such drug and such alternatives at multiple pharmacy options, including the individual’s preferred pharmacy and, as applicable, other retail pharmacies and a mail order pharmacy.

(iii) The formulary status of such drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alternatives included in the formulary of such plan.

(3) STANDARDS.—In order to be treated (for purposes of this subsection) as an electronic real-time benefit tool described in paragraph (1), such tool shall comply with technical standards adopted by the Secretary in consultation with the National Coordinator for Health Information Technology through notice and comment rulemaking. Such technical standards adopted by the Secretary shall be developed by a standards development organization, such as the National Council for Prescription Drug Programs, that consults with stakeholders such as PDP sponsors, Medicare Advantage organizations, beneficiary advocates, health care professionals, and health information technology software vendors.

(4) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to prohibit the application of paragraph (b)(7) of section 423.160 of title 42, Code of Federal Regulations, as is to be added to such section pursuant to the final rule published in the Federal Register on May 23, 2019, and titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses” (84 Fed. Reg. 23832 through 23884); or

(B) to allow a PDP sponsor to use a real-time benefit tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy type over their preferred pharmacy or pharmacy type nor prohibit the designation of an individual’s preferred pharmacy under such tool.

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