

PREVENTING ADDICTION FOR SUSCEPTIBLE SENIORS
 ACT OF 2018

JUNE 19, 2018.—Ordered to be printed

Mr. BRADY of Texas, from the Committee on Ways and Means,
 submitted the following

R E P O R T

[To accompany H.R. 5773]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 5773) to amend title XVIII of the Social Security Act to require Medicare prescription drug plans to establish drug management programs for at-risk beneficiaries, require electronic prior authorization for covered part D drugs, and to provide for other program integrity measures under parts C and D of the Medicare program, having considered the same, report favorably thereon with an amendment and recommend 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 “Preventing Addiction for Susceptible Seniors Act of 2018” or the “PASS Act of 2018”.

SEC. 2. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS UNDER MEDICARE TO ESTABLISH DRUG MANAGEMENT PROGRAMS FOR AT-RISK BENEFICIARIES.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (E) the following new subparagraph:

“(F) With respect to plan years beginning on or after January 1, 2021, a drug management program for at-risk beneficiaries described in paragraph (5).”; and

(2) in paragraph (5)(A), by inserting “(and for plan years beginning on or after January 1, 2021, a PDP sponsor shall)” after “A PDP sponsor may”.

SEC. 3. ELECTRONIC PRIOR AUTHORIZATION FOR COVERED PART D DRUGS.

(a) **INCLUSION IN ELECTRONIC PRESCRIPTION PROGRAM.**—Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the end the following new subparagraph:

“(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 individual 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.”.

(b) **SENSE OF CONGRESS REGARDING ELECTRONIC PRIOR AUTHORIZATION.**—It is the sense of the Congress that—

(1) there should be increased use of electronic prior authorizations for coverage of covered part D drugs for part D eligible individuals enrolled in prescription drug plans under part D of title XVIII of the Social Security Act and MA–PD plans under part C of such title to reduce access delays by resolving coverage issues before prescriptions for such drugs are transmitted; and

(2) greater priority should be placed on increasing the adoption of use of such electronic prior authorizations among prescribers of such drugs, pharmacies, PDP sponsors, and Medicare Advantage organizations.

SEC. 4. PROGRAM INTEGRITY TRANSPARENCY MEASURES UNDER MEDICARE PARTS C AND D.

(a) **IN GENERAL.**—Section 1859 of the Social Security Act (42 U.S.C. 1395w–28) is amended by adding at the end the following new subsection:

“(i) **PROGRAM INTEGRITY TRANSPARENCY MEASURES.**—

“(1) **PROGRAM INTEGRITY PORTAL.**—

“(A) **IN GENERAL.**—Not later than two years after the date of the enactment of this subsection, the Secretary shall, after consultation with stakeholders, establish a secure Internet website portal (or other successor technology) that would allow a secure path for communication between the Secretary, MA plans under this part, prescription drug plans under part D, and an eligible entity with a contract under section 1893 (such as a Medicare drug integrity contractor or an entity responsible for carrying out program integrity activities under this part and part D) for the purpose of enabling through such portal (or other successor technology)—

“(i) the referral by such plans of substantiated fraud, waste, and abuse for initiating or assisting investigations conducted by the eligible entity; and

“(ii) data sharing among such MA plans, prescription drug plans, and the Secretary.

“(B) **REQUIRED USES OF PORTAL.**—The Secretary shall disseminate the following information to MA plans under this part and prescription drug plans under part D through the secure Internet website portal (or other successor technology) established under subparagraph (A):

“(i) Providers of services and suppliers that have been referred pursuant to subparagraph (A)(i) during the previous 12-month period.

“(ii) Providers of services and suppliers who are the subject of an active exclusion under section 1128 or who are subject to a suspension of payment under this title pursuant to section 1862(o) or otherwise.

“(iii) Providers of services and suppliers who are the subject of an active revocation of participation under this title, including for not satisfying conditions of participation.

“(iv) In the case of such a plan that makes a referral under subparagraph (A)(i) through the portal (or other successor technology) with respect to activities of substantiated fraud, waste, or abuse of a provider of services or supplier, if such provider or supplier has been the subject of an administrative action under this title or title XI with respect to similar activities, a notification to such plan of such action so taken.

“(C) **RULEMAKING.**—For purposes of this paragraph, the Secretary shall, through rulemaking, specify what constitutes substantiated fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program Integrity Manual 4.7.1. In carrying out this subsection, a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

“(D) **HIPAA COMPLIANT INFORMATION ONLY.**—For purposes of this subsection, communications may only occur if the communications are 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.

“(2) **QUARTERLY REPORTS.**—Beginning two years after the date of enactment of this subsection, the Secretary shall make available to MA plans under this part and prescription drug plans under part D in a timely manner (but no less frequently than quarterly) and using information submitted to an entity described in paragraph (1) through the portal (or other successor technology) described in such paragraph or pursuant to section 1893, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Information included in each such report shall—

“(A) include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders; and

“(B) be anonymized information submitted by plans without identifying the source of such information.

“(3) **CLARIFICATION.**—Nothing in this subsection shall be construed as precluding or otherwise affecting referrals described in subparagraph (A) that may otherwise be made to law enforcement entities or to the Secretary.”.

(b) **CONTRACT REQUIREMENT TO COMMUNICATE PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRESCRIBERS.**—Section 1857(e)(4)(C) of the Social Security Act (42 U.S.C. 1395w–27(e)(4)(C)) is amended by adding at the end the following new paragraph:

“(5) COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

“(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations and other actions taken by such plans related to providers of services who prescribe a high volume of opioids.

“(B) PROCESS.—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

“(C) REGULATIONS.—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rule-making—

“(i) specify a definition for the term ‘high volume of opioids’ and a method for determining if a provider of services prescribes such a high volume; and

“(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.”

(c) REFERENCE UNDER PART D TO PROGRAM INTEGRITY TRANSPARENCY MEASURES.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:

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

SEC. 5. EXPANDING ELIGIBILITY FOR MEDICATION THERAPY MANAGEMENT PROGRAMS UNDER PART D.

Section 1860D–4(c)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–104(c)(2)(A)(ii)) is amended—

(1) by redesignating subclauses (I) through (III) as items (aa) through (cc), respectively, and adjusting the margins accordingly;

(2) by striking “are part D eligible individuals who—” and inserting “are the following:

“(I) Part D eligible individuals who—”; and

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

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

SEC. 6. MEDICARE NOTIFICATIONS TO OUTLIER PRESCRIBERS OF OPIOIDS.

Section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–104(c)(4)) is amended by adding at the end the following new paragraph:

“(D) OUTLIER PRESCRIBER NOTIFICATION.—

“(i) NOTIFICATION.—Beginning not later than two years after the date of the enactment of this subparagraph, 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 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 threshold established under subclause (II), conduct an analysis to identify prescribers that are outlier opioid prescribers for a period specified by the Secretary.

“(II) ESTABLISHMENT OF THRESHOLD.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish a threshold, 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 Secretary may exclude the following individuals and prescribers from the analysis under this clause:

“(aa) Individuals receiving hospice services.

“(bb) Individuals with a cancer diagnosis.

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

“(iii) CONTENTS OF NOTIFICATION.—The Secretary shall, based on input from stakeholders, specify the resources and other information to be included in notifications provided under clause (i).

“(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.

“(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) OPIOIDS DEFINED.—For purposes of this subparagraph, the term ‘opioids’ has such meaning as specified by the Secretary through program instruction or otherwise.”.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 5773, the “Preventing Addiction for Susceptible Seniors (PASS) Act of 2018,” was ordered reported by the Committee on Ways and Means on May 16, 2018.

The bill requires Medicare prescription drug plans to establish lock-in programs for seniors at-risk of opioid overuse. These programs prevent doctor and pharmacy shopping by requiring individuals to use a single pharmacy for all prescriptions, providing a central location for all transactions that can be monitored for abuse or misuse.

Further, the Secretary of Health and Human Services (HHS) (referred to as the Secretary) is required to establish a standard, secure electronic prior authorization (ePA) system. Currently, ePA systems are not standardized. By ensuring prescriptions are transmitted electronically, plans and providers can better integrate this information in medical records and monitor for abuse or misuse of certain medications.

The bill requires the Secretary to establish a secure Internet website portal (or other successor technology) that would allow for a secure communication between the Centers for Medicare & Medicaid Services (CMS), plans providing Part D coverage, and the Medicare Drug Integrity Contractor (MEDIC) regarding certain program integrity activities. Plans must submit information on the investigations and other actions taken by such plans related to providers who inappropriately prescribe a high volume of opioids.

The bill defines “at-risk” beneficiaries as eligible for the benefits provided under the Medication Therapy Management (MTM) Program. The MTM Program was established in 2003 and is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence.

Lastly, the bill requires the Secretary to notify providers that prescribe opioids in amounts or dosages in excess of their peers. This analysis would be conducted compared to peers in the same specialty and geographic area.

B. BACKGROUND AND NEED FOR LEGISLATION

Many Medicare beneficiaries receive opioid prescriptions through Medicare Part D. Broadly, the Centers for Medicare & Medicaid Services' (CMS) role in Part D oversight is to provide guidance to private plans (plan sponsors) that contract with CMS to offer drug coverage to Medicare beneficiaries. Plan sponsors are encouraged to identify providers that prescribe inappropriate amounts of opioids, and in cases of fraud or abuse, refer those cases for further investigation. Accordingly, CMS has programs and processes in place to monitor overprescribing, crack down on abuse, and identify at-risk beneficiaries.

According to a July 2017 report released by the Department of Health and Human Services Office of Inspector General, one third of Medicare Part D beneficiaries received an opioid prescription in 2016, costing the program \$4.1 billion and representing 79.4 million prescriptions. The analysis also found that 501,008 Part D beneficiaries received high amounts of opioids, and 69,563 received "extreme" amounts—many as a result of "doctor shopping," a practice through which beneficiaries obtain medically unnecessary prescriptions from multiple pharmacies and prescribers.

This legislation enhances CMS and plan actions and authority relating to identification of beneficiaries at risk of opioid abuse or misuse and provides new authority to monitor and reach out to patients that are at risk. The legislation also provides new requirements for CMS to monitor and educate providers that are prescribing opioids in amounts or doses that exceed their peers.

C. LEGISLATIVE HISTORY

Background

H.R. 5773 was introduced on May 11, 2018, and was referred to the Committee on Ways and Means and additionally the Committee on Energy and Commerce.

Committee hearings

On January 17, 2018, the Subcommittee on Oversight held a hearing on the current landscape and CMS actions to prevent opioid misuse.

On February 6, 2018, the Subcommittee on Health held a hearing on removing barriers to prevent and treat opioid abuse and dependence in Medicare.

On April 25, 2018, the Subcommittee on Trade held a hearing on stopping the flow of synthetic opioids in the international mail system.

Committee action

The Committee on Ways and Means marked up H.R. 5773, the "Preventing Addiction for Susceptible Seniors (PASS) Act of 2018," on May 16, 2018, and ordered the bill, as amended, favorably reported (with a quorum being present) by voice vote.

II. EXPLANATION OF THE BILL

A. THE PREVENTING ADDICTION FOR SUSCEPTIBLE SENIORS ACT OF 2018

CURRENT LAW

Under current law, many of the issues addressed by this bill are voluntary on the part of plans or CMS. As a result, there is inconsistency across the nation as to how patients and providers at risk of opioid misuse or abuse are treated.

Plans are not required to have a safe prescribing and dispensing program for beneficiaries that are prescribed opioids. Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 allows Medicare prescription drug plans *to voluntarily* develop a safe prescribing and dispensing program for beneficiaries that are at risk of abusing or diverting medications.

Likewise, electronic prior authorization (ePA) transactions are not required to be standardized across all stakeholders. A recent HHS report entitled “Ways to Improve the Part D Appeals Process” suggested that increased industry use of ePA transactions may help resolve issues at the pharmacy between the ordering provider and the plan, resolving denials before they enter the appeals process unnecessarily. In Part D, the ordering prescriber is not a party to the claim rejection transaction in the pharmacy and cannot provide additional information to resolve the coverage determination criteria. This disconnect can adversely affect beneficiary safety and care.

Additionally, current law Medication Therapy Management (MTM) Programs do not include beneficiaries at risk of opioid abuse or misuse. They are limited to beneficiaries that fit the following criteria:

1. Have multiple chronic diseases (plans may set a minimum threshold at two or three);
2. Are taking multiple Part D drugs (plans may set a minimum threshold at any number equal to or between two and eight); and
3. Are likely to incur annual costs for covered Part D drugs that are greater or equal to a specified amount (the cost threshold for 2018 is \$3,967).

Finally, while the Secretary is required to monitor and profile physicians’ billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality, there is no specific statutory requirement that CMS analyze opioid prescribing patterns to target education to those who are outliers.

REASONS FOR CHANGE

To prevent opioid overuse by increasing program integrity efforts and resources for beneficiaries to help ensure appropriate adherence to prescribed pain medications.

EXPLANATION OF PROVISIONS

Section 1: Short Title: Preventing Addiction for Susceptible Seniors (PASS) Act of 2018

Section 2: Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries.

Requires Medicare prescription drug plans to establish lock-in programs for seniors at-risk of opioid overuse beginning on or after January 1, 2021.

Section 3: Electronic Prior Authorization for Covered Part D Drugs.

Inclusion of Electronic Prescription Program: Requires the Secretary to establish a standard, secure electronic prior authorization (ePA) system for transmittal of prescriptions between providers, pharmacies, and plans no later than January 1, 2021. Such program is required to provide for the secure electronic transmission of a prior authorization request from the prescribing health care professional for coverage of a Part D eligible drug for a Part D eligible individual enrolled in such plan and a response from such plan sponsor to such healthcare professional.

Electronic Transmission Exclusions: For the purpose of electronic prior authorization, a fax, a proprietary payer portal that does not meet standard specified by the Secretary, or an electronic form will not count as an electronic transmission.

Electronic Transmission Standards: The electronic transmission must comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, or other standard setting organizations determined appropriate by the Secretary, and other stakeholders including Prescription Drug Plan sponsors, Medicare Advantage Plan sponsors, healthcare professionals, and health information technology software vendors.

Electronic Transmission Application: The Secretary may require the use of such standards in lieu of any other applicable standards for an electronic transmission.

Sense of Congress: It is the sense of Congress that increased use of electronic prior authorization will reduce access delays by resolving coverage issues before prescriptions for such drugs are transmitted and that a greater priority should be placed on increasing the adoption of electronic prior authorization use.

Section 4: Program Integrity Transparency Measures Under Medicare Parts C and D.

Program Integrity Portal: The Secretary, no later than two years after the date of enactment, is required to establish a secure Internet website portal (or other successor technology) that would allow for a secure communication between the Secretary, Medicare Advantage and Part D plans, and the Medicare Drug Integrity Contractor (MEDIC), or other entity eligible with a contract under section 1893 for carrying out program integrity activities. Nothing in this section is intended to prevent the Secretary from implementing this requirement through new technologies that may deviate from an internet website portal technology, so long as alternative technologies are capable of fulfilling the requirements laid out in statute. The portal is intended to enable referrals by such plans of substantiated fraud, waste, and abuse for initiating or assisting investigations, as well as data sharing among such plans.

Required Uses of Portal: The Secretary is required to use the portal to disseminate the following information to plans: (1) providers

and suppliers that have been referred through the portal during the previous 12-month period for program integrity violations; (2) providers and suppliers who are the subject of an active exclusion under section 1128 or who are subject to suspension of payment under 1862(o); and (3) providers and suppliers who are the subject of an active revocation of Medicare participation for not satisfying conditions of participation. If the plan makes a referral through the portal and such provider or supplier has been the subject of an administrative action under Medicare or Title XI with respect to similar activities, the plans in which the provider or supplier participates are required to be notified. A plan's referrals could result in additional provider education, or in serious cases, disciplinary action.

Rulemaking: The Secretary is required to go through rulemaking to define substantiated fraud, waste, and abuse using existing guidance provided in the Medicare Program Integrity Manual 4.7.1. A fraud hotline tip without further supporting evidence does not constitute sufficient evidence to be considered substantiated fraud, waste, and abuse.

HIPPA Complaint Information: Communications may only occur as permitted under 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.

Quarterly Reports: Beginning two years after the date of enactment, the Secretary is required to report to plans, in a timely manner but not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity based on the information submitted through the portal. Information included in such reports must include: (1) administrative actions, pertinent information related to opioid overprescribing and other data determined appropriate by the Secretary in consultation with stakeholders; and (2) anonymized information submitted by plans without identifying the source of such information.

Clarification: Nothing in this section should be construed as precluding or otherwise affecting referrals that may otherwise be made to law enforcement entities or to the Secretary.

Contract Requirement to Communicate Plan Corrective Actions Against Opioid Over-Prescribers: Plans are required to submit to the Secretary, on or after January 1, 2021, information on the investigations and other actions taken by such plans related to providers who inappropriately prescribe a high volume of opioids. The Committee does not intend for this requirement to take effect if the Secretary has not yet established a functional portal for the plans to report corrective actions.

Process: No later than January 1, 2021, the Secretary is required, in consultation with stakeholders, to establish a process under which plans will submit information to the Secretary. The Committee urges CMS to provide plans with sufficient guidance in a timely manner to smooth reporting and compliance with these provisions. The Secretary, in developing this process, is encouraged to address instances in which a plan may identify a prescriber who prescribes a high volume of opioids, investigates the issue, and determines that no action is necessary.

Regulations: Through rulemaking, the Secretary is required to: (1) define “high volume of opioids,” a method for determining if a provider inappropriately prescribes high volumes of such drugs; (2) establish a process for reporting information related to high volume prescribers; and (3) identify the types of information required to be reported.

Section 5: Expanding Eligibility for Medication Therapy Management Programs Under Part D.

Beneficiaries defined as “at-risk” for opioid overuse are required to be included in the Medication Therapy Management (MTM) Programs, beginning January 1, 2021. The Secretary in implementing these provisions shall ensure that requirements under MTM do not duplicate those case management services provided under the “lock-in” program. Additionally, the Committee intends for the Secretary to establish adequate training protocols, and encourage the use of innovative technologies, that will ensure that pharmacists and other healthcare professionals engaging with the at-risk beneficiary population through MTM are adequately trained to address the needs of this population, particularly as it applies to drugs that when used in combination with an opioid may result in an adverse drug interaction as well as potentiator drugs.

Section 6: Medicare Notification to Outlier Prescribers of Opioids.

Outlier Prescriber Notification: Beginning no later than two years after the date of enactment and annually thereafter, the Secretary is required to notify Medicare Part D prescribers who are outlier prescribers of opioids.

Identification of Outlier Prescribers of Opioids: The Secretary’s analysis shall be based on an established threshold and the valid prescriber National Provider Identifiers on claims for covered Part D drugs provided under prescription drug plans or Medicare Advantage Prescription Drug Plans. The Committee intends for all Part D opioid prescribers to be subject to analysis, with exceptions established below.

Establishment of Threshold: The Secretary, after consultation with stakeholders, shall establish a threshold, based on prescriber specialty and geographic area for identifying an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area. The intent of the Committee is for the threshold to reflect a statistically valid method for identifying prescribers whose prescribing patterns vary significantly from other physicians in their specialty and geographic area, modeled after the Comparative Billing Reports CMS has previously developed for opioid prescribers in other parts of Medicare.

Exclusions: The Secretary may exclude the following individuals and prescribers from the analysis: (1) individuals receiving hospice services, (2) individuals with a cancer diagnosis, and (3) prescribers who are subjects of an investigation by the Inspector General.

Contents of Notification: Based on input from stakeholders, the Secretary is required to specify the resources and other information to be included in the notifications to prescribers.

Frequency: Beginning five years after the date of enactment, the Secretary may change the frequency of the notifications based on stakeholder input.

Expansion to Other Prescriptions: The Secretary may also expand notifications to concurrent prescriptions used in combination with

opioids that are considered to have adverse side effects when used in such combination and potentiator drugs.

EFFECTIVE DATE

Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries: Effective beginning on or after January 1, 2021.

Inclusion of Electronic Prescription Program: The Secretary is required to establish a standard, secure electronic prior authorization (ePA) system no later than January 1, 2021.

Program Integrity Portal: No later than two years after the date of enactment, the Secretary is required to establish a secure Internet website portal (or other successor technology).

Quarterly Reports: Beginning two years after the date of enactment, the Secretary is required to report to plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity based on the information submitted through the portal.

Contract Requirement to Communicate Plan Corrective Actions Against Opioid Over-Prescribers: On or after January 1, 2021, plans are required to submit to the Secretary information on the investigations and other actions taken by such plans related to providers who prescribe a high volume of opioids. No later than January 1, 2021, the Secretary is required to establish a process under which plans will submit to the Secretary information.

Expanding Eligibility for Medication Therapy Management Programs Under Part D: Effective January 1, 2021, beneficiaries defined as “at-risk” for opioid overuse are required to be eligible.

Outlier Prescriber Notification: No later than two years after the date of enactment, the Secretary is required to annually notify Medicare Part D prescribers of their outlier status.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 5773, the PASS Act of 2018, on May 16, 2018.

The Chairman’s amendment in the nature of a substitute was adopted by a voice vote (with a quorum being present).

The bill, H.R. 5773, was ordered favorably reported as amended by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 5773, as reported. The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

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 involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET
OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2018.

Hon. KEVIN BRADY,
*Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for the opioid-related legislation ordered to be reported on May 16, 2018.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

MARK P. HADLEY
(For Keith Hall, Director).

Enclosure.

Opioid Legislation

Summary: On May 16, 2018, the House Committee on Ways and Means ordered seven bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Expand Medicare coverage of treatment for opioid use disorder;
- Give Medicare providers and health plans additional tools to curtail inappropriate prescribing and use of opioids;
- Require the completion of studies and reports related to opioid use and misuse in Medicare; and
- Require the United States Postal Service and Customs and Border Protection (CBP) to reduce illegal shipment of opioids across international borders.

Because the bills are related, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting four of the bills would affect direct spending; therefore, pay-as-you-go procedures apply for those bills. None of the bills would affect revenues.

CBO estimates that although enacting one bill of the seven included in this document (H.R. 5776) would increase net direct spending and on-budget deficits over the four consecutive 10-year periods beginning in 2029, those effects would not exceed the threshold established by the Congress for long-term costs. CBO estimates that none of the remaining bills would increase net direct

spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

None of the bills contain intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all seven bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that those differences would be small. The effects of this legislation fall within functions 550 (health), 570 (Medicare), and 750 (administration of justice).

Basis of estimate: For this estimate, CBO assumes that all of the legislation will be enacted late in 2018 and that authorized and estimated amounts will be appropriated each year. Outlays for discretionary programs are estimated based on historical spending patterns for similar programs.

Uncertainty

CBO aims to produce estimates that generally reflect the middle of a range of the most likely budgetary outcomes that would result if the legislation was enacted. Because data on the utilization of mental health and substance abuse treatment under Medicaid and Medicare is scarce, CBO cannot precisely predict how patients or providers would respond to some policy changes or what budgetary effects would result. In addition, several of the bills would give the Department of Health and Human Services (HHS) considerable latitude in designing and implementing policies. Budgetary effects could differ from those provided in CBO's analyses depending on those decisions.

Direct Spending

Table 1 lists the four bills included in this estimate that would affect direct spending.

H.R. 5676, the Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018, would allow prescription drug plans to suspend payments to pharmacies while fraud investigations are pending. CBO expects that enacting the legislation would reduce payments by those plans to pharmacies and result in lower premiums for benefits under Medicare's Part D. CBO estimates that the reduction in premiums would lower federal spending for Part D by \$9 million over the 2019–2028 period.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–2023	2019–2028
INCREASES OR DECREASES (–) IN DIRECT SPENDING													
H.R. 5676, Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018:													
Budget Authority	0	0	–1	–1	–1	–1	–1	–1	–1	–1	–1	–1	–4
Outlays	0	0	–1	–1	–1	–1	–1	–1	–1	–1	–1	–1	–4
H.R. 5773, Preventing Addiction for Susceptible Seniors Act of 2018: ^a													
Budget Authority	0	0	0	–6	–7	–7	–7	–8	–9	–9	–11	–20	–64
Outlays	0	0	0	–6	–7	–7	–7	–8	–9	–9	–11	–20	–64
H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018: ^a													
Budget Authority	0	8	0	20	20	25	30	30	35	35	40	73	243
Outlays	0	2	4	22	20	25	30	30	35	35	40	73	243
H.R. 5788, Securing the International Mail Against Opioids Act of 2018: ^a													
Budget Authority	0	0	*	*	*	*	*	*	*	*	*	*	*
Outlays	0	0	*	*	*	*	*	*	*	*	*	*	*

¹ Annual amounts may not sum to totals because of rounding. * = between –\$500,000 and \$500,000.

^a This bill also would affect spending subject to appropriation.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5773 would lower federal spending by \$64 million over the 2019–2028 period by reducing the number of prescriptions filled and Medicare’s payments for controlled substances.

Two provisions of H.R. 5773 would have no significant budgetary effect; they are described later in this document.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would appropriate \$8 million in 2019, which would be available until expended, for Federally Qualified Health Centers and Rural Health Clinics to support training in the treatment of opioid use disorder. CBO expects that \$8 million would be spent between 2019 and 2021.

H.R. 5776 also would expand the availability of medication-assisted treatment (MAT) for Medicare beneficiaries with opioid use disorder. The bill would allow treatment programs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) to become Medicare-participating providers.¹ H.R. 5776 also would direct the Secretary of HHS to create a new schedule of bundled payments for MAT through certified programs and grant the Secretary considerable discretion for defining bundles and establishing payment rates.

CBO projects that, beginning in 2021, about 3,000 Medicare beneficiaries who would not be treated for opioid abuse under current law would newly enroll each year in treatment offered by SAMHSA-certified programs and that the annual cost per participant would range from about \$6,000 to about \$10,000, depending largely on the medications dispensed and the period for which beneficiaries adhered to the protocol. CBO’s projection of the number of beneficiaries who would receive treatment takes into consideration the number of beneficiaries estimated to have opioid-use disorder, the number already receiving some form of treatment, and the availability of providers to treat those who newly enroll in MAT. To develop a per capita treatment cost, CBO analyzed rates for MAT paid by other payers, as well as Medicare spending for health care services typically used by people receiving MAT. CBO estimates that the new MAT benefit would increase direct spending by \$235 million over the 2019–2028 period.

CBO estimates that enacting H.R. 5776 would increase net Medicare spending by \$243 million over the 2019–2028 period. (If enacted, H.R. 5776 would also affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5788, the Securing the International Mail Against Opioids Act of 2018, would establish a new fee for certain items mailed to the United States from overseas, beginning January 1, 2020. Ini-

¹MAT combines behavioral therapy and pharmaceutical treatment for substance use disorders. Under current law, methadone (an opioid used to treat and manage dependence on other drugs, such as heroin) can be dispensed only by SAMHSA-certified treatment programs, which do not participate in Medicare. Other drugs used in MAT, including buprenorphine and naltrexone, can be dispensed more widely.

tially, the fee for most such items would be one dollar, but the amount could be adjusted annually thereafter. Using information provided by CBP, CBO estimates that about \$100 million in new fees would be collected over the 2020–2028 period. The collections would be divided equally between CBP and the Postal Service and spent by those agencies on activities related to the processing of inbound mail. CBO estimates that the net effect on federal spending in each year would be insignificant. (If enacted, H.R. 5788 would also affect spending subject to appropriation; those effects are described below.)

Spending Subject to Appropriation

For this document, CBO has grouped bills with spending that would be subject to appropriation into three general categories:

- Bills with provisions that would have no budgetary effect;
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 2); and
- Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that three of the bills have provisions that would not significantly affect direct spending, revenues, or spending subject to appropriation.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting that Section 3 of H.R. 5773 would not significantly affect direct spending for Part D.

Section 5 of that bill would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this provision, CBO estimates that its enactment would not significantly affect direct spending for Part D.

Section 6 of that bill would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements, CBO estimates that enacting that provision would not impose additional administrative costs on the agency.

H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. The bill also would require Medicare Advantage plans and prescription drug plans to provide information regarding safe disposal of controlled substances in home health risk assessments and medication therapy management programs, respectively. In CBO's estimation, neither proposal would have a budgetary effect because those activities would not impose significant administrative costs on plans or federal agencies.

In addition, H.R. 5775 would restrict the use of certain pain-related questions on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which is administered by the Centers for Medicare & Medicaid Services (CMS). The survey is one measure used in CMS’s Hospital Value-Based Purchasing (VBP) Program, which adjusts payments to acute care hospitals on the basis of the quality of care they provide to Medicare beneficiaries. Because the VBP program is funded by reducing base payments to all hospitals, CBO estimates that changing the HCAHPS survey would not affect the total amount paid by Medicare.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, in section 3, would require CMS, beginning on January 1, 2020, to review and possibly modify payments made through Medicare’s Hospital Outpatient Prospective Payment System for certain opioid and nonopioid pain management treatments and technologies. CMS could revise payments if the Secretary of HHS determined that there was a financial incentive to use opioids in place of nonopioid medications. The budget neutrality requirement under current law would apply to such revisions, and the rest of the payment rates within the system would be subject to offsetting adjustments. Because the changes would be made in a budget-neutral manner, CBO estimates that this provision would have no budgetary effect.

Section 6 of H.R. 5776 would explicitly authorize the Center for Medicare and Medicaid Innovation (CMMI) to test approaches for expanding beneficiaries’ awareness of psychological services and to help those beneficiaries curtail use of hospital-based mental health or behavioral health services. Because CMMI already has that authority, CBO estimates that enacting the legislation would not affect federal spending.

Estimated Authorizations. Table 2 shows CBO’s estimates of the authorization of appropriations for provisions in four bills. For those estimates, CBO assumes that appropriated funds would be available to implement those provisions.

H.R. 5723, the Expanding Oversight of Opioid Prescribing and Payment Act of 2018, would require the Medicare Payment Advisory Commission to report to the Congress on payments for pain treatment, incentives for prescribing opioids in inpatient and outpatient settings, and documented tracking of opioid use from Medicare claims data. CBO estimates that producing such a report would cost less than \$500,000 over the 2019–2023 period.

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 5723, Expanding Oversight of Opioid Prescribing and Payment Act of 2018:							
Estimated Authorization Level	0	*	0	0	0	0	*
Estimated Outlays	0	*	0	0	0	0	*
H.R. 5773, Preventing Addiction for Susceptible Seniors Act of 2018: ^a							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
H.R. 5776, Medicare and Opioid Safe Treatment Act of 2018: ^a							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5788, Securing the International Mail Against Opioids Act of 2018: ^a							
Estimated Authorization Level	0	100	0	0	0	0	100
Estimated Outlays	0	40	40	20	0	0	100

Annual amounts may not sum to totals because of rounding. * = between zero and \$500,000.

^aThis bill also would affect mandatory spending.

H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5773 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5773 would cost approximately \$9 million over the 2019–2023 period.

H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would direct the Secretary of HHS to report to the Congress on the availability of supplemental benefits to pay for treatment or prevention of substance abuse among enrollees in Medicare Advantage plans. The Secretary also would report on coverage of and payment for pain treatment and substance use disorders under Medicare. CBO estimates that producing those reports would cost \$1 million over five years.

H.R. 5788, the Securing the International Mail Against Opioids Act of 2018, would direct the Postal Service, CBP, and other federal agencies to collaborate to develop technology to detect opioids and other drugs that enter the United States in the mail. Using information provided by CBP, CBO estimates that it would cost roughly \$100 million over the 2019–2021 period to deploy drug detection systems at international mail facilities.

Other Authorizations. CBO has determined that provisions in two bills—H.R. 5774, Combating Opioid Abuse for Care in Hospitals Act of 2018; and H.R. 5776, the Medicare and Safe Opioid Treatment Act of 2018—would increase authorization levels, but has not completed estimates of amounts. Any spending that would result from those authorizations would be subject to future appropriation action.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Four of the bills discussed in this document contain direct spending and are subject to pay-as-you-go procedures. Details about the amount of direct spending in those bills can be found in Table 1.

Increase in long-term direct spending and deficits: CBO estimates that although enacting H.R. 5776, the Medicare and Opioid Safe Treatment Act of 2018, would increase net direct spending and on-budget deficits over the four consecutive 10-year periods beginning in 2029, those effects would not exceed the threshold established by the Congress for long-term costs (\$2.5 billion for net direct spending and \$5 billion for on-budget deficits). CBO estimates that none of the remaining bills would increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

Mandates: None of the bills contains intergovernmental or private-sector mandates as defined in UMRA.

Previous CBO estimate: On June 6, 2018, CBO issued an estimate for 59 opioid-related bills ordered reported by the House Committee on Energy and Commerce on May 9 and May 17, 2018. Several of those bills contain provisions that are identical or similar to those in the legislation ordered reported by the Committee on Ways and Means, and for those provisions, CBO's estimates are the same.

In particular, several sections in H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018, contain provisions that are identical or similar to those in five bills listed in the other estimate:

- Section 2, which would require prescription drug plans to implement drug management programs, is identical to a provision in H.R. 5675.
- Section 3, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to a provision in H.R. 4841.
- Section 4, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to a provision in H.R. 5715.
- Section 5, which would expand medication therapy management, is the same as a provision in H.R. 5684.
- Section 6, regarding prescriber notification, is identical to H.R. 5716.

In addition, in this estimate, a provision related to Medicare beneficiary education in section 2 of H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, is the same as a provision in H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, in CBO's estimate for the Committee on Energy and Commerce.

Estimate prepared by: Federal costs, Medicare: Philippa Haven, Lori Housman, Jamease Kowalczyk, Lara Robillard, Sarah Sajewski, Colin Yee, and Rebecca Yip; U.S. Postal Service and Customs and Border Protection: Mark Grabowicz; Mandates: Andrew Laughlin; Fact Checking: Zachary Byrum and Kate Kelly.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Kim P. Cawley, Chief, Natural Resources Cost Estimates Unit; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, Assistant Director for Budget Analysis.

V. 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 contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding 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 determined 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 Sec. 3(g)(2) of H. Res. 5 (114th Congress), 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).

F. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (114th Congress), the following statement is made concerning directed rule makings: The Committee estimates that the bill requires no directed rule makings within the meaning of such section.

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

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

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 (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, 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 C—MEDICARE+CHOICE PROGRAM

* * * * *

CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) **IN GENERAL.**—The Secretary shall not permit the election under section 1851 of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1853 to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) **MINIMUM ENROLLMENT REQUIREMENTS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) APPLICATION TO MSA PLANS.—In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) ALLOWING TRANSITION.—The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) CONTRACT PERIOD AND EFFECTIVENESS.—

(1) PERIOD.—Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) TERMINATION AUTHORITY.—In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part;

or

(C) no longer substantially meets the applicable conditions of this part.

(3) EFFECTIVE DATE OF CONTRACTS.—The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) PREVIOUS TERMINATIONS.—

(A) IN GENERAL.—The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) EARLIER RE-ENTRY PERMITTED WHERE CHANGE IN PAYMENT POLICY.—Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1853 for that Medicare+Choice payment area.

(5) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) ENROLLEE NOTICE AT TIME OF TERMINATION.—Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled with the organization under this part.

(4) DISCLOSURE.—

(A) IN GENERAL.—Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual prac-

tice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) PARTY IN INTEREST DEFINED.—For the purposes of this paragraph, the term “party in interest” means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) ACCESS TO INFORMATION.—Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) LOAN INFORMATION.—The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) REVIEW TO ENSURE COMPLIANCE WITH CARE MANAGEMENT REQUIREMENTS FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5).

(e) ADDITIONAL CONTRACT TERMS.—

(1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) COST-SHARING IN ENROLLMENT-RELATED COSTS.—

(A) IN GENERAL.—A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) AUTHORIZATION.—The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization' or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 (relating to enrollment and dissemination of information), section 1860D-1(c), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program).

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to \$100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to \$200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D-12(b)(3)(D) for the fiscal year.

(D) LIMITATION.—In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 and section 1860D-1(c) and section 4360 of the Omnibus Budget Reconciliation Act of 1990; or

(ii)(I) \$200,000,000 in fiscal year 1998;

(II) \$150,000,000 in fiscal year 1999;

(III) \$100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of \$100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of \$200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) MEDICARE+CHOICE PORTION DEFINED.—In this paragraph, the term “Medicare+Choice portion” means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term “applicable portion” means, for a fiscal year—

(i) with respect to MA organizations, the Secretary’s estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary’s estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.

(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) *COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.*—

(A) *IN GENERAL.*—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations and other actions taken by such plans related to providers of services who prescribe a high volume of opioids.

(B) *PROCESS.*—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

(C) *REGULATIONS.*—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rulemaking—

(i) specify a definition for the term “high volume of opioids” and a method for determining if a provider of services prescribes such a high volume; and

(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.

(f) *PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.*—

(1) *REQUIREMENT.*—A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) *SECRETARY’S OPTION TO BYPASS NONCOMPLYING ORGANIZATION.*—In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary’s payments (and the Secretary’s costs in making the payments).

(3) *INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.*—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) *PROMPT PAYMENT.*—Section 1860D–12(b)(4).

(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D–12(b)(5).

(C) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D–12(b)(6).

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1854;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii);

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than \$25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than \$100,000 for each such determination, except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), \$15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) OTHER INTERMEDIATE SANCTIONS.—In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than \$25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than \$10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization

of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than \$100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) CIVIL MONEY PENALTIES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(h) PROCEDURES FOR TERMINATION.—

(1) IN GENERAL.—The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) CONTRACTS WITH MA ORGANIZATIONS.—To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may

waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

* * * * *

DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 1859. (a) DEFINITIONS RELATING TO MEDICARE+CHOICE ORGANIZATIONS.—In this part—

(1) MEDICARE+CHOICE ORGANIZATION.—The term “Medicare+Choice organization” means a public or private entity that is certified under section 1856 as meeting the requirements and standards of this part for such an organization.

(2) PROVIDER-SPONSORED ORGANIZATION.—The term “provider-sponsored organization” is defined in section 1855(d)(1).

(b) DEFINITIONS RELATING TO MEDICARE+CHOICE PLANS.—

(1) MEDICARE+CHOICE PLAN.—The term “Medicare+Choice plan” means health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization pursuant to and in accordance with a contract under section 1857.

(2) MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLAN.—The term “Medicare+Choice private fee-for-service plan” means a Medicare+Choice plan that—

(A) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary such rates for such a provider based on utilization relating to such provider; and

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

Nothing in subparagraph (B) shall be construed to preclude a plan from varying rates for such a provider based on the specialty of the provider, the location of the provider, or other factors related to such provider that are not related to utilization, or to preclude a plan from increasing rates for such a provider based on increased utilization of specified preventive or screening services.

(3) MSA PLAN.—

(A) IN GENERAL.—The term “MSA plan” means a Medicare+Choice plan that—

(i) provides reimbursement for at least the items and services described in section 1852(a)(1) in a year

but only after the enrollee incurs countable expenses (as specified under the plan) equal to the amount of an annual deductible (described in subparagraph (B));

(ii) counts as such expenses (for purposes of such deductible) at least all amounts that would have been payable under parts A and B, and that would have been payable by the enrollee as deductibles, coinsurance, or copayments, if the enrollee had elected to receive benefits through the provisions of such parts; and

(iii) provides, after such deductible is met for a year and for all subsequent expenses for items and services referred to in clause (i) in the year, for a level of reimbursement that is not less than—

(I) 100 percent of such expenses, or

(II) 100 percent of the amounts that would have been paid (without regard to any deductibles or coinsurance) under parts A and B with respect to such expenses,

whichever is less.

(B) DEDUCTIBLE.—The amount of annual deductible under an MSA plan—

(i) for contract year 1999 shall be not more than \$6,000; and

(ii) for a subsequent contract year shall be not more than the maximum amount of such deductible for the previous contract year under this subparagraph increased by the national per capita Medicare+Choice growth percentage under section 1853(c)(6) for the year.

If the amount of the deductible under clause (ii) is not a multiple of \$50, the amount shall be rounded to the nearest multiple of \$50.

(4) MA REGIONAL PLAN.—The term “MA regional plan” means an MA plan described in section 1851(a)(2)(A)(i)—

(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(C) the service area of which is one or more entire MA regions.

(5) MA LOCAL PLAN.—The term “MA local plan” means an MA plan that is not an MA regional plan.

(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

(A) IN GENERAL.—The term “specialized MA plan for special needs individuals” means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)) and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be.

(B) SPECIAL NEEDS INDIVIDUAL.—The term “special needs individual” means an MA eligible individual who—

(i) is institutionalized (as defined by the Secretary);
 (ii) is entitled to medical assistance under a State plan under title XIX; or
 (iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who—

(I) before January 1, 2022, have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care; and

(II) on or after January 1, 2022, have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under subsection (f)(9)(A).

The Secretary may apply rules similar to the rules of section 1894(c)(4) for continued eligibility of special needs individuals.

(c) OTHER REFERENCES TO OTHER TERMS.—

(1) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—The term “Medicare+Choice eligible individual” is defined in section 1851(a)(3).

(2) MEDICARE+CHOICE PAYMENT AREA.—The term “Medicare+Choice payment area” is defined in section 1853(d).

(3) NATIONAL PER CAPITA MEDICARE+CHOICE GROWTH PERCENTAGE.—The “national per capita Medicare+Choice growth percentage” is defined in section 1853(c)(6).

(4) MEDICARE+CHOICE MONTHLY BASIC BENEFICIARY PREMIUM; MEDICARE+CHOICE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The terms “Medicare+Choice monthly basic beneficiary premium” and “Medicare+Choice monthly supplemental beneficiary premium” are defined in section 1854(a)(2).

(5) MA LOCAL AREA.—The term “MA local area” is defined in section 1853(d)(2).

(d) COORDINATED ACUTE AND LONG-TERM CARE BENEFITS UNDER A MEDICARE+CHOICE PLAN.—Nothing in this part shall be construed as preventing a State from coordinating benefits under a medicaid plan under title XIX with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this title and under such plan.

(e) RESTRICTION ON ENROLLMENT FOR CERTAIN MEDICARE+CHOICE PLANS.—

(1) IN GENERAL.—In the case of a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the society

offering the plan may restrict the enrollment of individuals under this part to individuals who are members of the church, convention, or group described in paragraph (3)(B) with which the society is affiliated.

(2) **MEDICARE+CHOICE RELIGIOUS FRATERNAL BENEFIT SOCIETY PLAN DESCRIBED.**—For purposes of this subsection, a Medicare+Choice religious fraternal benefit society plan described in this paragraph is a Medicare+Choice plan described in section 1851(a)(2) that—

(A) is offered by a religious fraternal benefit society described in paragraph (3) only to members of the church, convention, or group described in paragraph (3)(B); and

(B) permits all such members to enroll under the plan without regard to health status-related factors.

Nothing in this subsection shall be construed as waiving any plan requirements relating to financial solvency.

(3) **RELIGIOUS FRATERNAL BENEFIT SOCIETY DEFINED.**—For purposes of paragraph (2)(A), a “religious fraternal benefit society” described in this section is an organization that—

(A) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Act;

(B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches;

(C) offers, in addition to a Medicare+Choice religious fraternal benefit society plan, health coverage to individuals not entitled to benefits under this title who are members of such church, convention, or group; and

(D) does not impose any limitation on membership in the society based on any health status-related factor.

(4) **PAYMENT ADJUSTMENT.**—Under regulations of the Secretary, in the case of individuals enrolled under this part under a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1854 as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

(f) **REQUIREMENTS REGARDING ENROLLMENT IN SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.**—

(1) **REQUIREMENTS FOR ENROLLMENT.**—In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

(2) **ADDITIONAL REQUIREMENTS FOR INSTITUTIONAL SNPS.**—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(i). In the case of an individual who

is living in the community but requires an institutional level of care, such individual shall not be considered a special needs individual described in subsection (b)(6)(B)(i) unless the determination that the individual requires an institutional level of care was made—

- (i) using a State assessment tool of the State in which the individual resides; and
- (ii) by an entity other than the organization offering the plan.

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(3) ADDITIONAL REQUIREMENTS FOR DUAL SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(ii).

(B) The plan meets the requirements described in paragraph (5).

(C) The plan provides each prospective enrollee, prior to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes—

- (i) the benefits and cost-sharing protections that the individual is entitled to under the State Medicaid program under title XIX; and
- (ii) which of such benefits and cost-sharing protections are covered under the plan.

Such statement shall be included with any description of benefits offered by the plan.

(D) The plan has a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under title XIX. Such benefits may include long-term care services consistent with State policy.

(E) If applicable, the plan meets the requirement described in paragraph (7).

(F) The plan meets the requirements applicable under paragraph (8).

(4) ADDITIONAL REQUIREMENTS FOR SEVERE OR DISABLING CHRONIC CONDITION SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(iii).

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(5) CARE MANAGEMENT REQUIREMENTS FOR ALL SNPS.—

(A) IN GENERAL.—Subject to subparagraph (B), the requirements described in this paragraph are that the organization offering a specialized MA plan for special needs individuals—

(i) have in place an evidenced-based model of care with appropriate networks of providers and specialists; and

(ii) with respect to each individual enrolled in the plan—

(I) conduct an initial assessment and an annual reassessment of the individual’s physical, psychosocial, and functional needs;

(II) develop a plan, in consultation with the individual as feasible, that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided; and

(III) use an interdisciplinary team in the management of care.

(B) IMPROVEMENTS TO CARE MANAGEMENT REQUIREMENTS FOR SEVERE OR DISABLING CHRONIC CONDITION SNPS.—For 2020 and subsequent years, in the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the requirements described in this paragraph include the following:

(i) The interdisciplinary team under subparagraph (A)(ii)(III) includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan.

(ii) Requirements developed by the Secretary to provide face-to-face encounters with individuals enrolled in the plan not less frequently than on an annual basis.

(iii) As part of the model of care under clause (i) of subparagraph (A), the results of the initial assessment and annual reassessment under clause (ii)(I) of such subparagraph of each individual enrolled in the plan are addressed in the individual’s individualized care plan under clause (ii)(II) of such subparagraph.

(iv) As part of the annual evaluation and approval of such model of care, the Secretary shall take into account whether the plan fulfilled the previous year’s goals (as required under the model of care).

(v) The Secretary shall establish a minimum benchmark for each element of the model of care of a plan. The Secretary shall only approve a plan’s model of care under this paragraph if each element of the model of care meets the minimum benchmark applicable under the preceding sentence.

(6) TRANSITION AND EXCEPTION REGARDING RESTRICTION ON ENROLLMENT.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish procedures for the transition of applicable individuals to—

(i) a Medicare Advantage plan that is not a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); or

(ii) the original medicare fee-for-service program under parts A and B.

(B) APPLICABLE INDIVIDUALS.—For purposes of clause (i), the term “applicable individual” means an individual who—

(i) is enrolled under a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); and

(ii) is not within the 1 or more of the classes of special needs individuals to which enrollment under the plan is restricted to.

(C) EXCEPTION.—The Secretary shall provide for an exception to the transition described in subparagraph (A) for a limited period of time for individuals enrolled under a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) who are no longer eligible for medical assistance under title XIX.

(D) TIMELINE FOR INITIAL TRANSITION.—The Secretary shall ensure that applicable individuals enrolled in a specialized MA plan for special needs individuals (as defined in subsection (b)(6)) prior to January 1, 2010, are transitioned to a plan or the program described in subparagraph (A) by not later than January 1, 2013.

(7) AUTHORITY TO REQUIRE SPECIAL NEEDS PLANS BE NCQA APPROVED.—For 2012 and subsequent years, the Secretary shall require that a Medicare Advantage organization offering a specialized MA plan for special needs individuals be approved by the National Committee for Quality Assurance (based on standards established by the Secretary).

(8) INCREASED INTEGRATION OF DUAL SNPS.—

(A) DESIGNATED CONTACT.—The Secretary, acting through the Federal Coordinated Health Care Office established under section 2602 of Public Law 111–148, shall serve as a dedicated point of contact for States to address misalignments that arise with the integration of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this paragraph and, consistent with such role, shall establish—

(i) a uniform process for disseminating to State Medicaid agencies information under this title impacting contracts between such agencies and such plans under this subsection; and

(ii) basic resources for States interested in exploring such plans as a platform for integration, such as a model contract or other tools to achieve those goals.

(B) UNIFIED GRIEVANCES AND APPEALS PROCESS.—

(i) IN GENERAL.—Not later than April 1, 2020, the Secretary shall establish procedures, to the extent feasible as determined by the Secretary, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) for items and services provided by specialized MA plans

for special needs individuals described in subsection (b)(6)(B)(ii) under this title and title XIX. With respect to items and services described in the preceding sentence, procedures established under this clause shall apply in place of otherwise applicable grievances and appeals procedures. The Secretary shall solicit comment in developing such procedures from States, plans, beneficiaries and their representatives, and other relevant stakeholders.

(ii) PROCEDURES.—The procedures established under clause (i) shall be included in the plan contract under paragraph (3)(D) and shall—

(I) adopt the provisions for the enrollee that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review under an integrated process;

(II) take into account differences in State plans under title XIX to the extent necessary;

(III) be easily navigable by an enrollee; and

(IV) include the elements described in clause (iii), as applicable.

(iii) ELEMENTS DESCRIBED.—Both unified appeals and unified grievance procedures shall include, as applicable, the following elements described in this clause:

(I) Single written notification of all applicable grievances and appeal rights under this title and title XIX. For purposes of this subparagraph, the Secretary may waive the requirements under section 1852(g)(1)(B) when the specialized MA plan covers items or services under this part or under title XIX.

(II) Single pathways for resolution of any grievance or appeal related to a particular item or service provided by specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this title and title XIX.

(III) Notices written in plain language and available in a language and format that is accessible to the enrollee, including in non-English languages that are prevalent in the service area of the specialized MA plan.

(IV) Unified timeframes for grievances and appeals processes, such as an individual's filing of a grievance or appeal, a plan's acknowledgment and resolution of a grievance or appeal, and notification of decisions with respect to a grievance or appeal.

(V) Requirements for how the plan must process, track, and resolve grievances and appeals, to ensure beneficiaries are notified on a timely basis of decisions that are made throughout the griev-

ance or appeals process and are able to easily determine the status of a grievance or appeal.

(iv) CONTINUATION OF BENEFITS PENDING APPEAL.—The unified procedures under clause (i) shall, with respect to all benefits under parts A and B and title XIX subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under this title and title XIX.

(C) REQUIREMENT FOR UNIFIED GRIEVANCES AND APPEALS.—For 2021 and subsequent years, the contract of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) with a State Medicaid agency under paragraph (3)(D) shall require the use of unified grievances and appeals procedures as described in subparagraph (B).

(D) REQUIREMENTS FOR INTEGRATION.—

(i) IN GENERAL.—For 2021 and subsequent years, a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) shall meet one or more of the following requirements, to the extent permitted under State law, for integration of benefits under this title and title XIX:

(I) The specialized MA plan must meet the requirements of contracting with the State Medicaid agency described in paragraph (3)(D) in addition to coordinating long-term services and supports or behavioral health services, or both, by meeting an additional minimum set of requirements determined by the Secretary through the Federal Coordinated Health Care Office established under section 2602 of the Patient Protection and Affordable Care Act based on input from stakeholders, such as notifying the State in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees, assigning one primary care provider for each enrollee, or sharing data that would benefit the coordination of items and services under this title and the State plan under title XIX. Such minimum set of requirements must be included in the contract of the specialized MA plan with the State Medicaid agency under such paragraph.

(II) The specialized MA plan must meet the requirements of a fully integrated plan described in section 1853(a)(1)(B)(iv)(II) (other than the requirement that the plan have similar average levels of frailty, as determined by the Secretary, as the PACE program), or enter into a capitated contract with the State Medicaid agency to provide long-term services and supports or behavioral health services, or both.

(III) In the case of a specialized MA plan that is offered by a parent organization that is also the parent organization of a Medicaid managed care

organization providing long term services and supports or behavioral services under a contract under section 1903(m), the parent organization must assume clinical and financial responsibility for benefits provided under this title and title XIX with respect to any individual who is enrolled in both the specialized MA plan and the Medicaid managed care organization.

(ii) SUSPENSION OF ENROLLMENT FOR FAILURE TO MEET REQUIREMENTS DURING INITIAL PERIOD.—During the period of plan years 2021 through 2025, if the Secretary determines that a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) has failed to comply with clause (i), the Secretary may provide for the application against the Medicare Advantage organization offering the plan of the remedy described in section 1857(g)(2)(B) in the same manner as the Secretary may apply such remedy, and in accordance with the same procedures as would apply, in the case of an MA organization determined by the Secretary to have engaged in conduct described in section 1857(g)(1). If the Secretary applies such remedy to a Medicare Advantage organization under the preceding sentence, the organization shall submit to the Secretary (at a time, and in a form and manner, specified by the Secretary) information describing how the plan will come into compliance with clause (i).

(E) STUDY AND REPORT TO CONGRESS.—

(i) IN GENERAL.—Not later than March 15, 2022, and, subject to clause (iii), biennially thereafter through 2032, the Medicare Payment Advisory Commission established under section 1805, in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1900, shall conduct (and submit to the Secretary and the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on) a study to determine how specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) perform among each other based on data from Healthcare Effectiveness Data and Information Set (HEDIS) quality measures, reported on the plan level, as required under section 1852(e)(3) (or such other measures or data sources that are available and appropriate, such as encounter data and Consumer Assessment of Healthcare Providers and Systems data, as specified by such Commissions as enabling an accurate evaluation under this subparagraph). Such study shall include, as feasible, the following comparison groups of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii):

(I) A comparison group of such plans that are described in subparagraph (D)(i)(I).

(II) A comparison group of such plans that are described in subparagraph (D)(i)(II).

(III) A comparison group of such plans operating within the Financial Alignment Initiative demonstration for the period for which such plan is so operating and the demonstration is in effect, and, in the case that an integration option that is not with respect to specialized MA plans for special needs individuals is established after the conclusion of the demonstration involved.

(IV) A comparison group of such plans that are described in subparagraph (D)(i)(III).

(V) A comparison group of MA plans, as feasible, not described in a previous subclause of this clause, with respect to the performance of such plans for enrollees who are special needs individuals described in subsection (b)(6)(B)(ii).

(ii) ADDITIONAL REPORTS.—Beginning with 2033 and every five years thereafter, the Medicare Payment Advisory Commission, in consultation with the Medicaid and CHIP Payment and Access Commission, shall conduct a study described in clause (i).

(9) LIST OF CONDITIONS FOR CLARIFICATION OF THE DEFINITION OF A SEVERE OR DISABLING CHRONIC CONDITIONS SPECIALIZED NEEDS INDIVIDUAL.—

(A) IN GENERAL.—Not later than December 31, 2020, and every 5 years thereafter, subject to subparagraphs (B) and (C), the Secretary shall convene a panel of clinical advisors to establish and update a list of conditions that meet each of the following criteria:

(i) Conditions that meet the definition of a severe or disabling chronic condition under subsection (b)(6)(B)(iii) on or after January 1, 2022.

(ii) Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals described in such subsection on or after such date and—

(I) as a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such condition would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

(II) have a low prevalence in the general population of beneficiaries under this title or a disproportionately high per-beneficiary cost under this title.

(B) INCLUSION OF CERTAIN CONDITIONS.—The conditions listed under subparagraph (A) shall include HIV/AIDS,

end stage renal disease, and chronic and disabling mental illness.

(C) REQUIREMENT.—In establishing and updating the list under subparagraph (A), the panel shall take into account the availability of varied benefits, cost-sharing, and supplemental benefits under the model described in paragraph (2) of section 1859(h), including the expansion under paragraph (1) of such section.

(g) SPECIAL RULES FOR SENIOR HOUSING FACILITY PLANS.—

(1) IN GENERAL.—In the case of a Medicare Advantage senior housing facility plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the service area of such plan may be limited to a senior housing facility in a geographic area.

(2) MEDICARE ADVANTAGE SENIOR HOUSING FACILITY PLAN DESCRIBED.—For purposes of this subsection, a Medicare Advantage senior housing facility plan is a Medicare Advantage plan that—

(A) restricts enrollment of individuals under this part to individuals who reside in a continuing care retirement community (as defined in section 1852(1)(4)(B));

(B) provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that the Secretary determines is adequate;

(C) provides transportation services for beneficiaries to specialty providers outside of the facility; and

(D) has participated (as of December 31, 2009) in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year.

(h) NATIONAL TESTING OF MEDICARE ADVANTAGE VALUE-BASED INSURANCE DESIGN MODEL.—

(1) IN GENERAL.—In implementing the Medicare Advantage Value-Based Insurance Design model that is being tested under section 1115A(b), the Secretary shall revise the testing of the model under such section to cover, effective not later than January 1, 2020, all States.

(2) TERMINATION AND MODIFICATION PROVISION NOT APPLICABLE UNTIL JANUARY 1, 2022.—The provisions of section 1115A(b)(3)(B) shall apply to the Medicare Advantage Value-Based Insurance Design model, including such model as revised under paragraph (1), beginning January 1, 2022, but shall not apply to such model, as so revised, prior to such date.

(3) FUNDING.—The Secretary shall allocate funds made available under section 1115A(f)(1) to design, implement, and evaluate the Medicare Advantage Value-Based Insurance Design model, as revised under paragraph (1).

(i) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—

(1) PROGRAM INTEGRITY PORTAL.—

(A) IN GENERAL.—*Not later than two years after the date of the enactment of this subsection, the Secretary shall, after consultation with stakeholders, establish a secure Internet website portal (or other successor technology) that would allow a secure path for communication between the Secretary, MA plans under this part, prescription drug*

plans under part D, and an eligible entity with a contract under section 1893 (such as a Medicare drug integrity contractor or an entity responsible for carrying out program integrity activities under this part and part D) for the purpose of enabling through such portal (or other successor technology)—

(i) the referral by such plans of substantiated fraud, waste, and abuse for initiating or assisting investigations conducted by the eligible entity; and

(ii) data sharing among such MA plans, prescription drug plans, and the Secretary.

(B) **REQUIRED USES OF PORTAL.**—The Secretary shall disseminate the following information to MA plans under this part and prescription drug plans under part D through the secure Internet website portal (or other successor technology) established under subparagraph (A):

(i) Providers of services and suppliers that have been referred pursuant to subparagraph (A)(i) during the previous 12-month period.

(ii) Providers of services and suppliers who are the subject of an active exclusion under section 1128 or who are subject to a suspension of payment under this title pursuant to section 1862(o) or otherwise.

(iii) Providers of services and suppliers who are the subject of an active revocation of participation under this title, including for not satisfying conditions of participation.

(iv) In the case of such a plan that makes a referral under subparagraph (A)(i) through the portal (or other successor technology) with respect to activities of substantiated fraud, waste, or abuse of a provider of services or supplier, if such provider or supplier has been the subject of an administrative action under this title or title XI with respect to similar activities, a notification to such plan of such action so taken.

(C) **RULEMAKING.**—For purposes of this paragraph, the Secretary shall, through rulemaking, specify what constitutes substantiated fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program Integrity Manual 4.7.1. In carrying out this subsection, a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse

(D) **HIPAA COMPLIANT INFORMATION ONLY.**—For purposes of this subsection, communications may only occur if the communications are 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.

(2) **QUARTERLY REPORTS.**—Beginning two years after the date of enactment of this subsection, the Secretary shall make available to MA plans under this part and prescription drug plans under part D in a timely manner (but no less frequently than quarterly) and using information submitted to an entity de-

scribed in paragraph (1) through the portal (or other successor technology) described in such paragraph or pursuant to section 1893, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Information included in each such report shall—

(A) include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders; and

(B) be anonymized information submitted by plans without identifying the source of such information.

(3) CLARIFICATION.—Nothing in this subsection shall be construed as precluding or otherwise affecting referrals described in subparagraph (A) that may otherwise be made to law enforcement entities or to the Secretary.

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 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).

(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) 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 dis-

pense (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 sufficient 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.

(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, 2021, 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 part D eligible individuals who—]** *are the following:*

(I) *Part D eligible individuals who—*

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

[(II)] *(bb)* are taking multiple covered part D drugs; and

[(III)] *(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 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 compliance programs and other appropriate means; and

(iii) detection of adverse drug events and patterns of overuse and underuse of prescription 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 pro-

vided 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) **OUTLIER PRESCRIBER NOTIFICATION.**—

(i) **NOTIFICATION.**—*Beginning not later than two years after the date of the enactment of this subparagraph, 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 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 threshold established under subclause (II), conduct an analysis to identify prescribers that are outlier opioid prescribers for a period specified by the Secretary.*

(II) **ESTABLISHMENT OF THRESHOLD.**—*For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish a threshold, 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 Secretary may exclude the following individuals and prescribers from the analysis under this clause:

(aa) *Individuals receiving hospice services.*

(bb) *Individuals with a cancer diagnosis.*

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

(iii) *CONTENTS OF NOTIFICATION.*—The Secretary shall, based on input from stakeholders, specify the resources and other information to be included in notifications provided under clause (i).

(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.

(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) *OPIOIDS DEFINED.*—For purposes of this subparagraph, the term “opioids” has such meaning as specified by the Secretary through program instruction or otherwise.

(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, 2021, 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) and the option of an automatic escalation to external review;

(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) and the option of an automatic escalation to external review;

(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.—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 indi-

vidual 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.

(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 determines 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 the option of an automatic escalation to external review to the extent provided by the Secretary.

(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 individual 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 subpara-

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

(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.

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

* * * * *

LETTERS OF EXCHANGE

Congress of the United States

U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS

1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625

Washington, DC 20515-6548

<http://waysandmeans.house.gov>KEVIN BRADY, TEXAS,
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MINORITY CHIEF OF STAFF

June 8, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden,

I write to you regarding several opioid bills the Committee on Ways and Means ordered favorably reported to address the opioid epidemic. The following bills were also referred to the Committee on Energy and Commerce.

I ask that the Committee on Energy and Commerce waive formal consideration of the following bills so that they may proceed expeditiously to the House Floor:

- H.R. 5774, Combating Opioid Abuse for Care in Hospitals (COACH) Act;
- H.R. 5775, Providing Reliable Options for Patients and Educations Resources (PROPER) Act;
- H.R. 5776, Medicare and Opioid Safe Treatment (MOST) Act;
- H.R. 5773, Preventing Addition for Susceptible Seniors (PASS) Act;
- H.R. 5676, Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act; and
- H.R. 5723, Expanding Oversight of Opioid Prescribing and Payment Act.

I acknowledge that by waiving formal consideration of the bills, the Committee on Energy and Commerce is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bills that fall within your Rule X jurisdiction. I would support your effort to seek appointment of an appropriate number of conferees on any House-Senate conference involving this legislation.

I will include a copy of our letters in the *Congressional Record* during consideration of this legislation on the House floor.

Sincerely,


Kevin Brady
Chairman

cc: The Honorable Paul Ryan, Speaker
The Honorable Richard E. Neal
The Honorable Frank Pallone
Thomas J. Wickham, Jr., Parliamentarian

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (201) 225-2927
Minority (202) 225-3641

June 8, 2018

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Brady:

Thank you for your letter regarding the following bills, which were also referred to the Committee on Energy and Commerce:

- H.R. 5774, Combatting Opioid Abuse for Care in Hospitals (COACH) Act;
- H.R. 5775, Providing Reliable Options for Patients and Educations Resources (PROPER) Act;
- H.R. 5776, Medicare and Opioid Safe Treatment (MOST) Act;
- H.R. 5773, Preventing Addition for Susceptible Seniors (PASS) Act;
- H.R. 5676, Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act; and
- H.R. 5723, Expanding Oversight of Opioid Prescribing and Payment Act.

I wanted to notify you that the Committee will forgo action on these bills so that they may proceed expeditiously to the House floor.

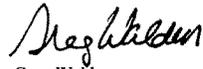
I appreciate your acknowledgment that by forgoing formal consideration of these bills, the Committee on Energy and Commerce is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bills that fall within its Rule X jurisdiction. I also

Letter to the Honorable Kevin Brady
Page 2

appreciate your offer to support the Committee's request for the appointment of conferees in the event of a House-Senate conference involving this legislation.

Thank you for your assistance on this matter.

Sincerely,



Greg Walden
Chairman

