

## REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (b)(1)(C), (2), (4), is classified generally to Title 26, Internal Revenue Code.

**§ 1396w-3a. Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled substances**

**(a) In general**

Subject to subsection (d), beginning October 1, 2021, a State—

(1) shall require each covered provider to check, in accordance with such timing, manner, and form as specified by the State, the prescription drug history of a covered individual being treated by the covered provider through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance; and

(2) in the case that such a provider is not able to conduct such a check despite a good faith effort by such provider—

(A) shall require the provider to document such good faith effort, including the reasons why the provider was not able to conduct the check; and

(B) may require the provider to submit, upon request, such documentation to the State.

**(b) Qualified prescription drug monitoring program described**

A qualified prescription drug monitoring program described in this subsection is, with respect to a State, a prescription drug monitoring program administered by the State that, at a minimum, satisfies each of the following criteria:

(1) The program facilitates access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible:

(A) Information regarding the prescription drug history of a covered individual with respect to controlled substances.

(B) The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period.

(C) The name, location, and contact information (or other identifying number selected by the State, such as a national provider identifier issued by the National Plan and Provider Enumeration System of the Centers for Medicare & Medicaid Services) of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period.

(2) The program facilitates the integration of information described in paragraph (1) into the workflow of a covered provider, which may include the electronic system the covered provider uses to prescribe controlled substances.

A qualified prescription drug monitoring program described in this subsection, with respect to a State, may have in place, in accordance with applicable State and Federal law, a data-sharing agreement with the State Medicaid pro-

gram that allows the medical director and pharmacy director of such program (and any designee of such a director who reports directly to such director) to access the information described in paragraph (1) in an electronic format. The State Medicaid program under this subchapter may facilitate reasonable and limited access, as determined by the State and ensuring documented beneficiary protections regarding the use of such data, to such qualified prescription drug monitoring program for the medical director or pharmacy director of any managed care entity (as defined under section 1396u-2(a)(1)(B) of this title) that has a contract with the State under section 1396b(m) of this title or under section 1396d(t)(3) of this title, or the medical director or pharmacy director of any entity that has a contract to manage the pharmaceutical benefit with respect to individuals enrolled in the State plan (or under a waiver of the State plan). All applicable State and Federal security and privacy laws shall apply to the directors or designees of such directors of any State Medicaid program or entity accessing a qualified prescription drug monitoring program under this section.

**(c) Application of privacy rules clarification**

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 subsection (b) in the same manner as the Secretary is required under subparagraph (J) of section 1395w-104(c)(5) of this title to clarify privacy requirements related to the sharing of data described in such subparagraph.

**(d) Ensuring access**

In order to ensure reasonable access to health care, the Secretary shall waive the application of the requirement under subsection (a), with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1395w-104(c)(5)(D)(ii)(II) of this title).

**(e) Reports**

**(1) State reports**

Each State shall include in the annual report submitted to the Secretary under section 1396r-8(g)(3)(D) of this title, beginning with such reports submitted for 2023, information including, at a minimum, the following information for the most recent 12-month period:

(A) The percentage of covered providers (as determined pursuant to a process established by the State) who checked the prescription drug history of a covered individual through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance.

(B) Aggregate trends with respect to prescribing controlled substances such as—

(i) the quantity of daily morphine milligram equivalents prescribed for controlled substances;

(ii) the number and quantity of daily morphine milligram equivalents pre-

scribed for controlled substances per covered individual; and

(iii) the types of controlled substances prescribed, including the dates of such prescriptions, the supplies authorized (including the duration of such supplies), and the period of validity of such prescriptions, in different populations (such as individuals who are elderly, individuals with disabilities, and individuals who are enrolled under both this subchapter and subchapter XVIII).

(C) Whether or not the State requires (and a detailed explanation as to why the State does or does not require) pharmacists to check the prescription drug history of a covered individual through a qualified prescription drug monitoring program described in subsection (b) before dispensing a controlled substance to such individual.

(D) An accounting of any data or privacy breach of a qualified prescription drug monitoring program described in subsection (b), the number of covered individuals impacted by each such breach, and a description of the steps the State has taken to address each such breach, including, to the extent required by State or Federal law or otherwise determined appropriate by the State, alerting any such impacted individual and law enforcement of the breach.

**(2) Report by CMS**

Not later than October 1, 2023, the Administrator of the Centers for Medicare & Medicaid Services shall publish on the publicly available website of the Centers for Medicare & Medicaid Services a report including the following information:

(A) Guidance for States on how States can increase the percentage of covered providers who use qualified prescription drug monitoring programs described in subsection (b).

(B) Best practices for how States and covered providers should use such qualified prescription drug monitoring programs to reduce the occurrence of abuse of controlled substances.

**(f) Increase to FMAP and Federal matching rates for certain expenditures relating to qualified prescription drug monitoring programs**

**(1) In general**

With respect to a State that meets the condition described in paragraph (2) and any quarter occurring during fiscal year 2019 or fiscal year 2020, the Federal medical assistance percentage or Federal matching rate that would otherwise apply to such State under section 1396b(a) of this title for such quarter, with respect to expenditures by the State for activities under the State plan (or a waiver of such plan) to design, develop, or implement a prescription drug monitoring program (and to make connections to such program) that satisfies the criteria described in paragraphs (1) and (2) of subsection (b), shall be equal to 100 percent.

**(2) Condition**

The condition described in this paragraph, with respect to a State, is that the State (in

this paragraph referred to as the “administering State”) has in place agreements with all States that are contiguous to such administering State that, when combined, enable covered providers in all such contiguous States to access, through the prescription drug monitoring program, the information that is described in subsection (b)(1) of covered individuals of such administering State and that covered providers in such administering State are able to access through such program.

**(g) Rule of construction**

Nothing in this section prevents a State from requiring pharmacists to check the prescription drug history of covered individuals through a qualified prescription drug monitoring program before dispensing controlled substances to such individuals.

**(h) Definitions**

In this section:

**(1) Controlled substance**

The term “controlled substance” means a drug that is included in schedule II of section 812(c) of title 21 and, at the option of the State involved, a drug included in schedule III or IV of such section.

**(2) Covered individual**

The term “covered individual” means, with respect to a State, an individual who is enrolled in the State plan (or under a waiver of such plan). Such term does not include an individual who—

(A) is receiving—

(i) hospice or palliative care; or

(ii) treatment for cancer;

(B) is a resident of a long-term care facility, of a facility described in section 1396d(d) of this title, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(C) the State elects to treat as exempted from such term.

**(3) Covered provider**

**(A) In general**

The term “covered provider” means, subject to subparagraph (B), with respect to a State, a health care provider who is participating under the State plan (or waiver of the State plan) and licensed, registered, or otherwise permitted by the State to prescribe a controlled substance (or the designee of such provider).

**(B) Exceptions**

**(i) In general**

Beginning October 1, 2021, for purposes of this section, such term does not include a health care provider included in any type of health care provider determined by the Secretary to be exempt from application of this section under clause (ii).

**(ii) Exceptions process**

Not later than October 1, 2020, the Secretary, after consultation with the National Association of Medicaid Directors,

national health care provider associations, Medicaid beneficiary advocates, and advocates for individuals with rare diseases, shall determine, based on such consultations, the types of health care providers (if any) that should be exempted from the definition of the term “covered provider” for purposes of this section.

(Aug. 14, 1935, ch. 531, title XIX, §1944, as added Pub. L. 115-271, title V, §5042(a), Oct. 24, 2018, 132 Stat. 3967.)

#### REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c), is section 264(c) of Pub. L. 104-191, title II, Aug. 21, 1996, 110 Stat. 2033, which is set out as a note under section 1320d-2 of this title.

#### GUIDANCE

Pub. L. 115-271, title V, §5042(b), Oct. 24, 2018, 132 Stat. 3970, provided that: “Not later than October 1, 2019, the Administrator of the Centers for Medicare & Medicaid Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall issue guidance on best practices on the uses of prescription drug monitoring programs required of prescribers and on protecting the privacy of Medicaid beneficiary information maintained in and accessed through prescription drug monitoring programs.”

#### DEVELOPMENT OF MODEL STATE PRACTICES

Pub. L. 115-271, title V, §5042(c), Oct. 24, 2018, 132 Stat. 3970, provided that:

“(1) IN GENERAL.—Not later than October 1, 2020, the Secretary of Health and Human Services shall develop and publish model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize data-sharing agreements described in the matter following paragraph (2) of section 1944(b) of the Social Security Act [42 U.S.C. 1396w-3a(b)], as added by subsection (a), for the following purposes:

“(A) Monitoring and preventing fraud, waste, and abuse.

“(B) Improving health care for individuals enrolled in a State plan under title XIX of such Act [42 U.S.C. 1396 et seq.] (or under a waiver of such plan) who—

“(i) transition in and out of coverage under such title;

“(ii) may have sources of health care coverage in addition to coverage under such title; or

“(iii) pay for prescription drugs with cash.

“(C) Any other purposes specified by the Secretary.

“(2) ELEMENTS OF MODEL PRACTICES.—The model practices described in paragraph (1)—

“(A) shall include strategies for assisting States in allowing the medical director or pharmacy director (or designees of such a director) of managed care organizations or pharmaceutical benefit managers to access information with respect to all covered individuals served by such managed care organizations or pharmaceutical benefit managers to access as a single data set, in an electronic format; and

“(B) shall include any appropriate beneficiary protections and privacy guidelines.

“(3) CONSULTATION.—In developing model practices under this subsection, the Secretary shall consult with the National Association of Medicaid Directors, managed care entities (as defined in section 1932(a)(1)(B) of the Social Security Act [42 U.S.C. 1396u-2(a)(1)(B)]) with contracts with States pursuant to section 1903(m) of such Act [42 U.S.C. 1396b(m)], pharmaceutical benefit managers, physicians and other health care providers, beneficiary advocates, and individuals with expertise in health care technology related to prescription drug monitoring programs and electronic health records.”

### § 1396w-4. State option to provide coordinated care through a health home for individuals with chronic conditions

#### (a) In general

Notwithstanding section 1396a(a)(1) of this title (relating to statewideness), section 1396a(a)(10)(B) of this title (relating to comparability), and any other provision of this subchapter for which the Secretary determines it is necessary to waive in order to implement this section, beginning January 1, 2011, a State, at its option as a State plan amendment, may provide for medical assistance under this subchapter to eligible individuals with chronic conditions who select a designated provider (as described under subsection (h)(5)), a team of health care professionals (as described under subsection (h)(6)) operating with such a provider, or a health team (as described under subsection (h)(7)) as the individual's health home for purposes of providing the individual with health home services.

#### (b) Health home qualification standards

The Secretary shall establish standards for qualification as a designated provider for the purpose of being eligible to be a health home for purposes of this section.

#### (c) Payments

##### (1) In general

A State shall provide a designated provider, a team of health care professionals operating with such a provider, or a health team with payments for the provision of health home services to each eligible individual with chronic conditions that selects such provider, team of health care professionals, or health team as the individual's health home. Payments made to a designated provider, a team of health care professionals operating with such a provider, or a health team for such services shall be treated as medical assistance for purposes of section 1396b(a) of this title, except that, subject to paragraph (4), during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 90 percent.

##### (2) Methodology

###### (A) In general

The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of health home services. Such methodology for determining payment—

(i) may be tiered to reflect, with respect to each eligible individual with chronic conditions provided such services by a designated provider, a team of health care professionals operating with such a provider, or a health team, as well as the severity or number of each such individual's chronic conditions or the specific capabilities of the provider, team of health care professionals, or health team; and

(ii) shall be established consistent with section 1396a(a)(30)(A) of this title.

###### (B) Alternate models of payment

The methodology for determining payment for provision of health home services under