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for failing to timely exercise its right to a hearing.

PART 181 [RESERVED]

PART 182—PRICE TRANSPARENCY FOR COVID–19 DIAGNOSTIC TESTS

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AUTHORITY: Section 3202(b), Pub. L. 116–136, 134 Stat. 281.

SOURCE: 85 FR 71203, Nov. 6, 2020, unless otherwise noted.

Subpart A—General Provisions

§ 182.10 Basis and scope.

This part implements section 3202(b)(1) of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136, March 27, 2020) (CARES Act), which requires that during the emergency period declared under section 319 of the PHS Act (42 U.S.C. 247d), providers of diagnostic tests for COVID–19 make public the cash price for such tests on a public internet website of such provider. This part also implements section 3202(b)(2) of the CARES Act, which authorizes the Secretary to impose a civil monetary penalty (CMP) on any provider of a diagnostic test for COVID–19 that does not comply with section 3202(b)(1) of the CARES Act and that has not completed a corrective action plan to comply with that section, in an amount that does not exceed $300 per day that the violation is ongoing.

§ 182.20 Definitions.

The following definitions and abbreviated terms apply to this part:

Cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID–19 diagnostic test.

COVID–19 for purposes of this part is the abbreviated term for the virus called SARS-CoV–2 and the disease it causes, called coronavirus disease 2019.

Diagnostic test for COVID–19 (''COVID–19 diagnostic test'') means a COVID–19 *in vitro* diagnostic test described in section 6001 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020), as amended by section 3201 of the CARES Act (Pub. L. 116–136, March 27, 2020).

Provider of a diagnostic test for COVID–19 (''provider'') means any facility that performs one or more COVID–19 diagnostic tests.

§ 182.30 Applicability.

(a) *General applicability*. The requirements of this part apply to each provider of a diagnostic test for COVID–19 as defined at § 182.20.

(b) *Duration of requirements*. The requirements of this part are applicable during the public health emergency (PHE) determined to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the PHS Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

Subpart B—Public Disclosure Requirements

§ 182.40 Requirements for making public cash prices for a diagnostic test for COVID–19.

(a) *General rules*. (1) Except as provided under paragraph (b) of this section, a provider of a COVID–19 diagnostic test must make public the information described in paragraph (c) of this section electronically via the internet.

(2) The information described in paragraph (c) of this section, or a link to such information, must appear in a conspicuous location on a searchable homepage of the provider's website.

(3) The information described in paragraph (c) of this section must be displayed in a manner that is easily accessible, without barriers, and ensures that the information is accessible:

(i) Free of charge;

(ii) Without having to establish a user account or password; and

(iii) Without having to submit personal identifiable information (PII).

(4) The provider must include all of the following terms on its homepage:

(i) The provider's name;

(ii) The term ''price'';

(iii) The term ''cost'';

(iv) The term ''test'';

(v) The term ''COVID''; and

(vi) The term ''coronavirus''.

(b) *Exception*. A provider of a COVID–19 diagnostic test that does not have its own website must make public the information described in paragraph (c) of this section:

(1) In writing, within two business days upon request; and

(2) On a sign posted prominently at the location where the provider offers a COVID–19 diagnostic test, if such location is accessible to the public.

(c) *Required information*. For purposes of paragraphs (a) and (b) of this section, the provider must make public the following information:

(1) A plain-language description of each COVID–19 diagnostic test that is offered by the provider;

(2) The billing code used for each COVID–19 diagnostic test;

(3) The provider's cash price for each such COVID–19 diagnostic test; and

(4) Any additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID–19 diagnostic test.

Subpart C—Monitoring and Penalties for Noncompliance

§ 182.50 Monitoring and enforcement.

(a) *Monitoring*. (1) CMS may evaluate whether a provider has complied with the requirements under § 182.40.

(2) CMS may use methods to monitor and assess provider compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

(i) CMS' evaluation of complaints made to CMS.

(ii) CMS review of an individual's or entity's analysis of noncompliance as stated in the complaint.

(iii) CMS review of providers' websites.

(b) *Actions to address provider noncompliance*. If CMS concludes that the provider is noncompliant with one or more of the requirements of § 182.40, CMS may take any of the following actions:

(1) Provide a written warning notice to the provider of the specific violation(s).

(2) Request that the provider submit and comply with a corrective action plan under § 182.60.

(3) Impose a civil monetary penalty on the provider if the provider fails to respond to CMS' request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS.

§ 182.60 Corrective action plans.

(a) *Violations requiring a corrective action plan*. If CMS determines a provider's noncompliance with the requirements of this part continues after a warning notice, a corrective action plan may be required. A violation may include, but is not limited to, the following:

(1) A provider's failure to make public its cash price information required by § 182.40.

(2) A provider's failure to make public its cash price information in the form and manner required under § 182.40.

(b) *Notice of violation*. CMS may request that a provider submit and comply with a corrective action plan, specified in a notice of violation issued by CMS to a provider.

(c) *Compliance with corrective action plan requests and corrective actions*. (1) A provider required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the provider, and must comply with the requirements of the corrective action plan approved by CMS.

(2) A provider's corrective action plan must specify elements including, but not limited to:

(i) The corrective actions or processes the provider will take to address the deficiency or deficiencies identified by CMS.

(ii) The timeframe by which the provider will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS' review and approval of a provider's corrective action plan, CMS may monitor and evaluate the provider's compliance with the corrective actions specified in the corrective action plan.

(d) *Noncompliance with corrective action plan requests and requirements.* (1) A provider's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the provider.

(2) A provider's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 182.70 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a provider identified by CMS as noncompliant according to § 182.50, and that fails to respond to CMS' request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS as described in § 182.60(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS will provide a written notice of imposition of a civil monetary penalty to the provider via certified mail or another form of traceable carrier.

(2) This notice to the provider may include, but is not limited to, the following:

(i) The basis for the provider's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the provider has violated.

(B) The provider's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 182.60(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the provider is required to meet the requirements of this part.

(B) A date determined by CMS, such as one resulting from monitoring activities specified in § 182.50, or development of a corrective action plan as specified in § 182.60.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) A statement of the provider's right to a hearing according to subpart D of this part.

(vii) A statement that the provider's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 182.90.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a provider for a violation of each requirement of this part.

(2) The maximum daily dollar amount for a civil monetary penalty to which a provider may be subject is $300. Even if the provider is in violation of multiple discrete requirements of this part, the maximum total sum that a single provider may be assessed per day is $300.

(3) The maximum daily amount of the civil monetary penalty will be adjusted annually using the multiplier determined by the Office of Management and Budget for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A provider must pay the

civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a provider requests a hearing, pursuant to subpart D of this part, the provider must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(4) In the event a civil money penalty is not paid in full within 60 days, CMS will follow the collections activities set forth in 45 CFR part 30.

(e) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

Subpart D—Appeals of Civil Monetary Penalties

§ 182.80 Appeal of penalty.

(a) A provider upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) ''Respondent'' means a provider, as defined in § 182.20 that received a notice of imposition of a civil monetary penalty according to § 182.70(b).

(2) In deciding whether the amount of a civil money penalty is reasonable, the administrative law judge (ALJ) may only consider evidence of record relating to the following:

(i) The provider's posting(s) of its cash price information, if available.

(ii) Material the provider timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the provider's compliance according to § 182.70(a)(2).

(3) The ALJ's consideration of evidence of acts other than those at issue in the instant case under § 150.445(g) of this title does not apply.

§ 182.90 Failure to request a hearing.

(a) If a provider does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in § 182.70(b), CMS may impose the civil monetary penalty indicated in such notice without right of appeal in accordance with this part.

(1) If the 30th calendar day described paragraph (a) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this title, unless the provider can show good cause, as determined at § 150.405(b) of this title, for failing to timely exercise its right to a hearing.

PARTS 183 [RESERVED]

PART 184—PHARMACY BENEFIT MANAGER STANDARDS UNDER THE AFFORDABLE CARE ACT

Sec.

184.10 Basis and scope.
184.20 Definitions.
184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

AUTHORITY: 42 U.S.C. 1302, 1320b–23.

SOURCE: 86 FR 24295, May 5, 2021, unless otherwise noted.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that