

Medical gas	Color
Medical Air	Yellow.
Carbon Dioxide	Gray.
Helium	Brown.
Nitrogen	Black.
Nitrous Oxide	Blue.
Oxygen	Green.
Mixture or Blend	Colors corresponding to each component gas.

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 4. The authority citation for part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 5. Amend § 211.94 by adding new paragraph (e) to read as follows:

§ 211.94 Drug product containers and closures.

* * * * *

(e) *Medical gas containers and closures must meet the following requirements—(1) Gas-specific use outlet connections.* Portable cryogenic medical gas containers that are not manufactured with permanent gas use outlet connections (e.g., those that have been silver-brazed) must have gas-specific use outlet connections that are attached to the valve body so that they cannot be readily removed or replaced (without making the valve inoperable and preventing the containers' use) except by the manufacturer. For the purposes of this paragraph, the term "manufacturer" includes any individual or firm that fills high-pressure medical gas cylinders or cryogenic medical gas containers. For the purposes of this section, a "portable cryogenic medical gas container" is one that is capable of being transported and is intended to be attached to a medical gas supply system within a hospital, health care entity, nursing home, other facility, or home health care setting, or is a base unit used to fill small cryogenic gas containers for use by individual patients. The term does not include cryogenic containers that are not designed to be connected to a medical gas supply system, e.g., tank trucks, trailers, rail cars, or small cryogenic gas containers for use by individual patients (including portable liquid oxygen units as defined at § 868.5655 of this chapter).

(2) *Label and coloring requirements.* The labeling specified at § 201.328(a) of this chapter must be affixed to the container in a manner that does not interfere with other labeling and such that it is not susceptible to becoming worn or inadvertently detached during

normal use. Each such label as well as materials used for coloring medical gas containers must be reasonably resistant to fading, durable when exposed to atmospheric conditions, and not readily soluble in water.

■ 6. Amend § 211.125 by adding a sentence to the end of paragraph (c) to read as follows:

§ 211.125 Labeling issuance.

* * * * *

(c) * * * Labeling reconciliation is also waived for 360° wraparound labels on portable cryogenic medical gas containers.

* * * * *

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27838 Filed 11–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS–1654–CN2]

RIN 0938–AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors in the final rule that was placed on public inspection at the Office of the Federal Register on November 2, 2016 and scheduled for publication in the **Federal Register** on November 15, 2016. That rule is entitled, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes

Prevention Program Model; Medicare Shared Savings Program Requirements."

DATES: This correcting document is effective January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Terri Plumb, (410) 786–4481, Gaysha Brooks, (410) 786–9649, or Annette Brewer (410) 786–6580.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc 2016–26668, that was placed on public inspection at the Office of the Federal Register on November 2, 2016 and scheduled for publication in the **Federal Register** on November 15, 2016, there were technical errors that are identified and corrected in this correcting document.

II. Summary of Errors in the Regulations Text

In the CY 2017 PFS final rule, we inadvertently omitted or included language in § 410.79(b), (c)(1)(ii) and (iv), (c)(2)(i) and § 424.59(a)(1) and (5), (b)(4)(i), and (e)(2)(i).

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** and provide a period for public comment before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest; and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical errors in the CY 2017 PFS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies

that were proposed subject to notice and comment procedures in the CY 2017 PFS final rule. As a result, the correction made through this correcting document is intended to resolve inadvertent errors so that the rule accurately reflects the policies in the final rule.

Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2017 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects the public comment period. Further, such procedures would be unnecessary, because we are not making any substantive revisions to the final rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies in the final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

IV. Correction of Errors in the Regulations Text

In FR Doc. 16–26668 appearing on page 80170 in the **Federal Register** of Tuesday, November 16, 2016, the following corrections are made:

- 1. On pages 80552 and 80553, correct § 410.79 by—
- a. In paragraph (b):
- i. Removing the definition of “Evaluation weight”;
- ii. Revising the definitions of “MDPP supplier”, “Medicare Diabetes Prevention Program (MDPP)”, and “Required minimum weight loss”;
- iii. In the definition of “National Diabetes Prevention Program, removing “(DPP)” and adding in its place the term “(National DPP)”; and
- b. Revising paragraphs (c)(1)(ii), (c)(1)(iv) and (c)(2)(i).

The revisions read as follows:

§ 410.79 Medicare diabetes prevention program expanded model: Conditions of coverage.

* * * * *

(b) * * *

MDPP supplier refers to an entity that has enrolled in Medicare to furnish MDPP services.

Medicare Diabetes Prevention Program (MDPP) refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP eligible beneficiaries.

* * * * *

Required minimum weight loss refers to the percentage by which the beneficiary's updated weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

(c) * * *

(1) * * *

(ii) Have as of the date of attendance at the first core session a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian.

* * * * *

(iv) Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes).

* * * * *

(2) * * *

(i) *Core sessions and core maintenance sessions.* MDPP suppliers must furnish to MDPP eligible beneficiaries the MDPP core benefit. Sixteen core sessions must be furnished at least a week apart over the first 6 months. At least one core maintenance session must be furnished in each of the second 6 months. All core sessions and core maintenance sessions must have a duration of approximately one hour. MDPP suppliers must address at least 16 different curriculum topics in the core sessions and at least 6 different curriculum topics in the core maintenance sessions.

* * * * *

- 2. On page 80558, correct § 424.59 by revising paragraphs (a)(1) and (5), (b)(4)(i), and (e)(2)(i) to read as follows:

§ 424.59 Requirements for Medicare diabetes prevention program suppliers.

(a) * * *

(1) At the time of enrollment has full CDC DPRP recognition.

* * * * *

(5) Submits a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes the coaches' first and last names, SSN, and NPI.

(b) * * *

(4) * * *

(i) Has attended one, four or nine core sessions, or

* * * * *

(e) * * *

(2) * * *

(i) Become eligible to bill for MDPP services again if it meets the requirements of paragraph (a)(1) of this section, and enrolls again in Medicare as an MDPP supplier subject to paragraph (a) of this section.

* * * * *

Dated: November 14, 2016.

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–27733 Filed 11–15–16; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151211999–6343–02]

RIN 0648–XF002

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Georges Bank Cod Trimester Total Allowable Catch Area Closure and Possession and Trip Limit Reductions for the Common Pool Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; area closure and inseason adjustment.

SUMMARY: This action closes the Georges Bank Cod Trimester Total Allowable Catch Area to Northeast multispecies common pool vessels and adjusts the Georges Bank cod possession and trip limit for common pool vessels for the remainder of Trimester 2, through December 31, 2016. The common pool fishery is projected to catch 90 percent of its Trimester 2 quota for Georges Bank cod. The closure and possession and trip limit reductions are intended to prevent an overage of the common pool's quota for this stock.

DATES: This action is effective November 15, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Management Specialist, (978) 282–8493.

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR 648.82(n)(2)(ii) require the Regional Administrator to close a common pool Trimester Total Allowable Catch (TAC) Area for a stock when 90 percent of the Trimester TAC is projected to be caught. The closure applies to all common pool vessels fishing with gear capable of catching that stock for the remainder of the trimester.

As of November 5, 2016, the common pool fishery has caught approximately 87 percent of the Trimester 2 TAC (4.2 mt) for Georges Bank (GB) cod. We