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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 561 and 562

Iranian Financial Sanctions Regulations and Iranian Human Rights Abuses Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending the Iranian Financial Sanctions Regulations, changing the heading of the Iranian Human Rights Abuses Sanctions Regulations to the Iranian Sector and Human Rights Abuses Sanctions Regulations, and amending the renamed Iranian Sector and Human Rights Abuses Sanctions Regulations to implement Executive Order 13871 of May 8, 2019 (''Imposing Sanctions With Respect to the Iron, Steel, Aluminum and Copper Sectors of Iran'').

DATES: *Effective Date:* August 7, 2019.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website (*www.treasury.gov/ofac*).

Background

On August 16, 2010, OFAC issued the Iranian Financial Sanctions Regulations, 31 CFR part 561 (75 FR 49836, August 16, 2010) (IFSR) to implement provisions of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195) (22 U.S.C. 8501–8551). Since then, OFAC has amended the IFSR several times.

On February 11, 2011, OFAC issued the Iranian Human Rights Abuses Sanctions Regulations, 31 CFR part 562 (76 FR 7695, February 11, 2011) (Iranian Human Rights Regulations) to implement Executive Order 13553 of September 28, 2010 (75 FR 60567, October 1, 2010) (E.O. 13553). The Iranian Human Rights Regulations were published in abbreviated form for the purpose of providing immediate guidance to the public. OFAC amended the Iranian Human Rights Regulations on June 30, 2011 (76 FR 38534, June 30, 2011).

On May 8, 2019, the President, invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (IEEPA), issued Executive Order 13871 (84 FR 20761, May 10, 2019) (E.O. 13871). In E.O. 13871, the President found that it remains the policy of the United States to deny Iran all paths to both a nuclear weapon and intercontinental ballistic missiles, and to counter the totality of Iran's malign influence in the Middle East. He also found it is the policy of the United States to deny the Iranian government revenue, including revenue derived from the export of products from Iran's iron, steel, aluminum, and copper sectors, that may be used to provide funding and support for the proliferation of weapons of mass destruction, terrorist groups and networks, campaigns of regional aggression, and military expansion. In light of these findings, the President issued E.O. 13871 in order to take further steps with respect to the national emergency declared with respect to the actions and polices of the Government of Iran in Executive Order 12957 of March 15, 1995 (60 FR 14615, March 17, 1995), and to supplement the authorities provided in the Iran Freedom and Counter-Proliferation Act of 2012 (subtitle D of title XII of Pub. L. 112–239).

Section 1(a) of E.O. 13871 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any U.S. person of any person determined by the Secretary of the Treasury, in consultation with the Secretary of State: (i) To be operating in the iron, steel, aluminum, or copper sector of Iran, or to be a person that owns, controls, or operates an entity that is part of the iron, steel, aluminum, or copper sector of Iran; (ii) to have knowingly engaged, on or after May 8, 2019, in a significant transaction for the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran; (iii) to have knowingly engaged, on or after May 8, 2019, in a significant transaction for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran; (iv) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, any person whose property and interests in property are blocked pursuant to section 1 of E.O. 13871; or (v) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to section 1 of E.O. 13871. The property and interests in property of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

Section 2(a) of E.O. 13871 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to impose certain sanctions on a foreign financial institution (FFI) upon determining the FFI has, on or after May 8, 2019, knowingly conducted or facilitated any significant financial transaction: (i) For the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran; (ii) for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran; or (iii) for or on behalf of any person whose property and interests in property are blocked pursuant to E.O. 13871. Section 2(b) of E.O. 13871 provides that, with respect to any FFI determined to meet any of the criteria section 2(a)(i) through (iii) of E.O. 13871, the Secretary of the Treasury may prohibit the opening, and prohibit or impose strict conditions on

the maintaining, in the United States of a correspondent account or payable-through account by such FFI.

In Section 3 of E.O. 13871, the President determined that the making of donations of certain articles, such as food, clothing, and medicine, intended to be used to relieve human suffering, as specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)), by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13871 would seriously impair his ability to deal with the national emergency declared in E.O. 12957. The President therefore prohibited the donation of such items unless authorized by OFAC.

Section 4 of E.O. 13871 provides that the prohibition on any transaction or dealing in blocked property or interests in property includes the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 13871 and the receipt of any contribution or provision of funds, goods, or services from any such person.

Section 6 of E.O. 13871 prohibits any transaction that evades or avoids, has the purpose of evading or avoiding, or attempts to violate any of the prohibitions set forth in E.O. 13871, as well as any conspiracy formed to violate such prohibitions.

Section 7 of E.O. 13871 exempts transactions for the conduct of the official business of the Federal Government or the United Nations (including its specialized agencies, programmes, funds, and related organizations) by employees, grantees, or contractors thereof.

Section 10 of E.O. 13871 authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA, as may be necessary to carry out the purposes of E.O. 13871. Section 10 of E.O. 13871 also provides that the Secretary of the Treasury may, consistent with applicable law, redelegate any of these functions within the Department of the Treasury.

Section 12 of E.O. 13871 states that the measures taken pursuant to E.O. 13871 are in response to actions of the Government of Iran occurring after the conclusion of the 1981 Algiers Accords, and are intended solely as a response to those later actions.

As set forth in more detail below, OFAC is implementing the correspondent or payable-through account sanctions set forth in section 2 of E.O. 13871 in the IFSR, 31 CFR part 561, and the blocking sanctions set forth in section 1 of E.O. 13871 in the Iranian Human Rights Regulations, 31 CFR part 562. Additionally, OFAC is renaming the Iranian Human Rights Regulations, 31 CFR part 562, as the Iranian Sector and Human Rights Abuses Sanctions Regulations (ISHR).

Amendments to the IFSR

OFAC is redesignating the existing § 561.205 as § 561.220 and adding a new § 561.205 to subpart B of the IFSR to implement the correspondent account or payable-through account sanctions in section 2 of E.O. 13871. Additionally, in subpart C, which defines key terms used throughout the IFSR, OFAC is adding new §§ 561.331 through 561.339 to provide definitions of aluminum, aluminum products, aluminum sector of Iran, copper, copper products, copper sector of Iran, iron, iron products, steel, steel products, iron sector of Iran, and steel sector of Iran. OFAC also is making conforming edits to § 561.301, relating to the effective date of applicable prohibitions, § 561.403, relating to facilitation, § 561.404, relating to determinations of significance, § 561.504, relating to an authorization for transactions related to closing a correspondent or payable-through account, and § 561.802, relating to the delegation of authority by the Secretary of the Treasury.

Changing the Heading of the Iranian Human Rights Regulations to the Iranian Sector and Human Rights Abuses Sanctions Regulations and Amending the Newly Renamed Regulations

OFAC is changing the heading of the Iranian Human Rights Abuses Regulations, 31 CFR part 562, to the Iranian Sector and Human Rights Abuses Sanctions Regulations (ISHR) and amending the renamed regulations to implement section 1 of E.O. 13871.

OFAC is adding a new § 562.204 to the ISHR to implement the blocking sanctions in section 1 of E.O. 13871. In subpart C of the ISHR, which defines key terms used throughout the ISHR, OFAC is adding new §§ 562.312 through 562.320 to provide definitions of aluminum, aluminum products, aluminum sector of Iran, copper, copper products, copper sector of Iran, iron, iron products, steel, steel products, iron sector of Iran, and steel sector of Iran. The definitions are the same as the corresponding definitions that are being added to the IFSR. In subpart D of the ISHR, which contains interpretive sections, OFAC is adding § 562.407 setting forth the types of factors that, as a general matter, the Secretary of the Treasury will consider in determining, for purposes of section 1(a)(ii) and 1(a)(iii) of Executive Order 13871, whether transactions are significant. OFAC also is making conforming edits to § 562.302, relating to the effective dates of applicable prohibitions, and § 562.802, relating to the delegation of authorities by the Secretary of the Treasury. Finally, the text of E.O. 13871 is being added to part 562 as appendix B. OFAC intends to supplement part 562 with a more comprehensive set of regulations, which may include additional interpretative and definitional guidance and additional general licenses and statements of licensing policy.

Public Participation

Because the amendment of the IFSR and the ISHR involves a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of Executive Order 13771, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to § 561.601 of the IFSR and to the ISHR are contained in OFAC's Reporting, Procedures and Penalties Regulations, 31 CFR part 501. Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget (OMB) under control number 1505–0164. The collection of information in section 561.504 of the IFSR has been approved by OMB under control number 1505–0243. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects

31 CFR Part 561

Administrative practice and procedure, Aluminum, Banks, banking, Copper, correspondent account, Foreign Financial Institution, Iran, Iron, Metals, Payable-through account, Sanctions, Steel.

31 CFR Part 562

Administrative practice and procedure, Aluminum, Banks, banking, Blocking of assets, Copper, Iran, Iron, Metals, Sanctions, Steel.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR chapter V as follows:

PART 561—IRANIAN FINANCIAL SANCTIONS REGULATIONS

■ 1. The authority citation for part 561 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111–195, 124 Stat. 1312 (22 U.S.C. 8501–8551); Pub. L. 112–81, 125 Stat. 1298 (22 U.S.C. 8513a); Pub. L. 112–158, 126 Stat. 1214 (22 U.S.C. 8701–8795); E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 13553, 75 FR 60567, 3 CFR, 2010 Comp., p. 253; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13846, 83 FR 38939; E.O. 13871, 84 FR 20761.

Subpart B—Prohibitions

§ 561.205 [Redesignated as § 561.220]

■ 2. Redesignate § 561.205 as § 561.220.

■ 3. Add new § 561.205 to read as follows:

§ 561.205 Metals-related sanctions on certain foreign financial institutions.

(a) *Imposition of sanctions.* Subject to the exemptions set forth in paragraph (d) of this section, upon a determination by the Secretary of the Treasury, in consultation with the Secretary of State, that a foreign financial institution has, on or after May 8, 2019, knowingly engaged in one or more of the activities described in paragraph (b) of this section, the Secretary of the Treasury may:

(1) Prohibit U.S. financial institutions from opening a correspondent account or a payable-through account in the United States for the foreign financial institution with respect to which the determination has been made; and either

(2)(i) Prohibit U.S. financial institutions from maintaining a correspondent account or a payable-through account in the United States for the foreign financial institution with respect to which the determination has been made; or

(ii) Impose one or more strict conditions on the maintaining of a correspondent account or payable-through account in the United States for the foreign financial institution with respect to which the determination has been made.

Note 1 to paragraph (a): The name of any foreign financial institution with respect to which a determination has been made pursuant to this paragraph (a), along with the relevant sanctions to be imposed (prohibition(s) and/or strict condition(s)), will be added to the List of Foreign Financial Institutions Subject to Correspondent Account or Payable-Through Account Sanctions (CAPTA List), which is maintained on the Office of Foreign Assets Control's website (*www.treasury.gov/ofac*), and published in the **Federal Register**.

Note 2 to paragraph (a): *See* § 561.203(b) for examples of strict conditions that might be imposed, pursuant to paragraph (a)(2)(ii) of this section, on the maintaining of a correspondent account or payable-through account for a foreign financial institution with respect to which the Secretary of the Treasury's determination has been made.

(b) *Sanctionable activity.* A foreign financial institution has engaged in an activity described in this paragraph if it knowingly conducted or facilitated, on or after May 8, 2019, any significant financial transaction:

(1) For the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran;

(2) For the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran; or

(3) For or on behalf of any person whose property and interests in property are blocked pursuant to Executive Order 13871.

(c) *Prohibitions.* (1) A U.S. financial institution shall not open a correspondent account or payable-through account in the United States for a foreign financial institution for which the opening of such an account is prohibited pursuant to paragraph (a)(1) of this section.

(2) A U.S. financial institution shall not maintain a correspondent account or payable-through account in the United States for a foreign financial institution for which the maintaining of such an account is prohibited pursuant to paragraph (a)(2)(i) of this section.

(3) A U.S. financial institution shall not maintain a correspondent account or payable-through account in the United States for a foreign financial institution in a manner that is inconsistent with any strict condition imposed and in effect pursuant to paragraph (a)(2)(ii) of this section.

(4) The prohibitions in paragraphs (c)(1) through (c)(3) of this section apply except to the extent provided by regulations, orders, directives, or licenses that may be issued pursuant to this part, and notwithstanding any contract entered into or any license or permit granted prior to the effective date.

(d) *Exempt activity.* Nothing in this section shall apply to transactions for the conduct of the official business of the Federal Government or the United Nations (including its specialized agencies, programmes, funds, and related organizations) by employees, grantees, or contractors thereof.

Subpart C—General Definitions

■ 4. In § 561.301, revise paragraph (a) and add new paragraph (d) to read as follows:

§ 561.301 Effective date.

(a) The effective date of a prohibition or condition imposed pursuant to §§ 561.201, 561.203, 561.204, or 561.205 on the opening or maintaining of a correspondent account or a payable-through account in the United States by a U.S. financial institution for a particular foreign financial institution is the earlier of the date the U.S. financial institution receives actual or constructive notice of such prohibition or condition.

* * * * *

(d) For the purposes of this section, *constructive notice* is the date that notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

■ 5. Add § 561.331 through § 561.337 to read as follows:

Sec.

* * * * *

561.331 Aluminum, Aluminum products.
561.332 Aluminum sector of Iran.
561.333 Copper, Copper products.
561.334 Copper sector of Iran.
561.335 Iron, Iron products, Steel, Steel products.
561.336 Iron sector of Iran.
561.337 Steel sector of Iran.

* * * * *

§ 561.331 Aluminum, Aluminum products.

The terms *aluminum* and *aluminum products* mean any raw, semi-fabricated, fabricated, or finished form of aluminum or aluminum alloy of all grades, sizes, and thicknesses, including in the following forms: Ores and concentrates (*e.g.,* bauxite and alumina); unwrought aluminum including ingots, slabs, and billets; powders and flakes; wrought aluminum including bars, rods, profiles, plates, sheets, strip, foil, tubes, and pipes; tube or pipe fittings; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings,

stampings, and forgings; waste and scrap, including slag, and any aluminum and aluminum products produced from the melting or recycling of aluminum scrap.

§ 561.332 Aluminum sector of Iran.

The term *aluminum sector of Iran* means the mining, refining, processing, or manufacturing of aluminum or aluminum products in Iran.

§ 561.333 Copper, Copper products.

The terms *copper* and *copper products* mean any raw, semi-fabricated, fabricated, or finished form of copper or copper alloy of all grades, sizes, and thicknesses, including in the following forms: Ores and concentrates; copper mattes, cement copper (precipitated copper); refined, unrefined, wrought, or unwrought copper; billets; cathodes; bars, rods, profiles, plates, sheets, strips, foil, tubes, and pipes; tube and pipe fittings; powders and flakes; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings, stampings, and forgings; and waste and scrap, including slag.

§ 561.334 Copper sector of Iran.

The term *copper sector of Iran* means the mining, refining, processing, or manufacturing of copper or copper products in Iran.

§ 561.335 Iron, Iron products, Steel, Steel products.

The terms *iron, iron products, steel,* and *steel products* mean any raw, semi-fabricated, fabricated, or finished form of iron, iron alloy, alloy steel, non-alloy steel, ferroalloys, pig iron, and spiegeleisen of all grades, sizes, and thicknesses, whether or not clad, plated, or coated, including in the following forms: Iron ores and concentrates including roasted iron pyrites; pigs and blocks; ferrous products obtained by direct reduction of iron ore and other spongy ferrous products, in lumps or pellets; granules and powders; ingots, blooms billets, slabs, and beam blanks; flat-rolled products (plates, sheets, strips, and foils) either cut-to-length or in coils; bars, and rods; structural profiles (beams, channels, angles, and other shapes); sheet piling; railway or tramway track construction materials; tubes, pipes, and hollow profiles; tube or pipe fittings; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings, stampings, and forgings; and ferrous waste and scrap, including slag.

§ 561.336 Iron sector of Iran.

The term *iron sector of Iran* means the mining, refining, processing, or manufacturing of iron or iron products in Iran.

§ 561.337 Steel sector of Iran.

The term *steel sector of Iran* means the iron-ore smelting, ferrous-scrap melting, refining, processing, or manufacturing of steel or steel products in Iran.

Subpart D—Interpretations

■ 6. Revise § 561.403 to read as follows:

§ 561.403 Facilitation of certain efforts, activities, or transactions by foreign financial institutions.

For purposes of §§ 561.201, 561.203, 561.204, and 561.205, the term *facilitate* or *facilitated* used with respect to certain efforts, activities, or transactions refers to the provision of assistance by a foreign financial institution for those efforts, activities, or transactions, including the provision of currency, financial instruments, securities, or any other transmission of value; purchasing; selling; transporting; swapping; brokering; financing; approving; guaranteeing; or the provision of other services of any kind; or the provision of personnel; or the provision of software, technology, or goods of any kind.

■ 7. In § 561.404, revise the introductory paragraph to read as follows:

§ 561.404 Significant transaction or transactions; significant financial services; significant financial transaction.

In determining, for purposes of paragraph (a)(5) of § 561.201, whether a transaction is significant, whether transactions are significant, or whether financial services are significant, or, for purposes of paragraph (a) of § 561.203, paragraph (b) of § 561.204, and paragraph (b) of § 561.205 whether a financial transaction is significant, the Secretary of the Treasury may consider the totality of the facts and circumstances. As a general matter, the Secretary may consider some or all of the following factors:

* * * * *

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 8. In § 561.504, revise the introductory paragraph to read as follows:

§ 561.504 Transactions related to closing a correspondent account or payable-through account.

(a) During the 10-day period beginning on the effective date of the prohibition in § 561.201(c), § 561.203(c)(2), § 561.204(c)(2), § 561.205(a), or § 561.205(c) on the maintaining of a correspondent account or a payable-through account for a foreign financial institution whose name is added to the List of Foreign Financial Institutions Subject to Correspondent Account or Payable-Through Account Sanctions (CAPTA List), which is maintained on the Office of Foreign Assets Control's website (*www.treasury.gov/ofac*), U.S. financial institutions that maintain correspondent accounts or payable-through accounts for the foreign financial institution are authorized to:

* * * * *

Subpart H—Procedures

■ 9. Revise § 561.802 to read as follows:

§ 561.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to subsections 104(c), (d), (h), or (i), or section 104A of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195) (22 U.S.C. 8501–8551), as amended by the Iran Threat Reduction and Syria Human Rights Act of 2012 (Pub. L. 112–158) (22 U.S.C. 8701–8795), pursuant to Executive Order 13553 of September 28, 2010 (75 FR 60567, October 1, 2010), Executive Order 13599 of February 5, 2012 (77 FR 6659, February 8, 2012), Executive Order 13846 of August 6, 2018 (83 FR 38939, August 7, 2018), Executive Order 13871 of May 8, 2019 (84 FR 20761, May 10, 2019), or any further Executive order relating to the national emergency declared in Executive Order 12957 of March 15, 1995, and any action of the Secretary of the Treasury described in this part, may be taken by the Director of the Office of Foreign Assets Control or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

PART 562—IRANIAN SECTOR AND HUMAN RIGHTS ABUSES SANCTIONS REGULATIONS

■ 10. Revise the heading of Part 562 to read as set forth above:

■ 11. The authority citation for part 562 is revised to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2332d; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111–195, 124 Stat. 1312 (22 U.S.C. 8501–8551); E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 13553, 75 FR 60567, October 1, 2010; E.O. 13871, 84 FR 20761, May 10, 2019.

Subpart B–Prohibitions

■ 12. Revise § 562.201 to read as follows:

§ 562.201 Prohibited transactions.

(a) All transactions prohibited pursuant to Executive Order 13553 are also prohibited pursuant to this part.

(b) All transactions prohibited pursuant to sections 1 and 6 of Executive Order 13871 are also prohibited pursuant to this part.

Note 1 to paragraph (b): Section 2 of Executive Order 13871 is implemented in section 561.205 of the Iranian Financial Sanctions Regulations, 31 CFR part 561.

Note 1 to § 562.201: The names of persons listed in or designated pursuant to Executive Order 13553, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into the Office of Foreign Assets Control's Specially Designated Nationals and Blocked Persons List (''SDN List'') with the identifier ''[IRAN–HR].'' The names of persons designated pursuant to section 1 of Executive Order 13871, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into the SDN List with the identifier ''[IRAN–EO13871].'' The SDN List is accessible through the following page on the Office of Foreign Assets Control's website: *http://www.treasury.gov/sdn.* Additional information pertaining to the SDN List can be found in appendix A to this chapter. *See* § 562.406 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 562.201: The International Emergency Economic Powers Act (50 U.S.C. 1701–1706), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to Executive Order 13553 also are published in the **Federal Register** and incorporated into the SDN List with the identifier ''[BPI–IRAN–HR].'' The names of persons whose property and interests in property are blocked pending investigation pursuant to Executive Order 13871 also are published in the **Federal Register** and incorporated into the SDN List with the identifier ''[BPI–IRAN–EO13871].''

Note 3 to § 562.201: Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

Subpart C—General Definitions

■ 13. Revise § 562.302 to read as follows:

§ 562.302 Effective date.

(a) The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(1) With respect to a person listed in the Annex to Executive Order 13553, 12:01 a.m. eastern daylight time, September 29, 2010;

(2) With respect to a person whose property and interests in property are otherwise blocked pursuant to Executive Order 13553, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked; and

(3) With respect to a person whose property and interests in property are blocked pursuant to Executive Order 13871, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

(b) For the purposes of this section, *constructive notice* is the date that a notice of the blocking of the relevant person's property and interests in property is published in the **Federal Register**.

■ 14. Add § 562.312 through § 562.318 to read as follows:

Sec.

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§ 562.312 Aluminum, Aluminum products.

The terms *aluminum* and *aluminum products* mean any raw, semi-fabricated, fabricated, or finished form of aluminum or aluminum alloy of all grades, sizes, and thicknesses, including in the following forms: Ores and concentrates (*e.g.,* bauxite and alumina); unwrought aluminum including ingots, slabs, and billets; powders and flakes; wrought aluminum including bars, rods, profiles, plates, sheets, strip, foil, tubes, and pipes; tube or pipe fittings; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings, stampings, and forgings; waste and scrap, including slag, and any aluminum and aluminum products produced from the melting or recycling of aluminum scrap.

§ 562.313 Aluminum sector of Iran.

The term *aluminum sector of Iran* means the mining, refining, processing, or manufacturing of aluminum or aluminum products in Iran.

§ 562.314 Copper, Copper products.

The terms *copper* and *copper products* mean any raw, semi-fabricated, fabricated, or finished form of copper or copper alloy of all grades, sizes, and thicknesses, including in the following forms: Ores and concentrates; copper mattes, cement copper (precipitated copper); refined, unrefined, wrought, or unwrought copper; billets; cathodes; bars, rods, profiles, plates, sheets, strips, foil, tubes, and pipes; tube and pipe fittings; powders and flakes; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings, stampings, and forgings; and waste and scrap, including slag.

§ 562.315 Copper sector of Iran.

The term *copper sector of Iran* means the mining, refining, processing, or manufacturing of copper or copper products in Iran.

§ 562.316 Iron, Iron products, Steel, Steel products.

The terms *iron, iron products, steel,* and *steel products* mean any raw, semi-fabricated, fabricated, or finished form of iron, iron alloy, alloy steel, non-alloy steel, ferroalloys, pig iron, and spiegeleisen of all grades, sizes, and thicknesses, whether or not clad, plated, or coated, including in the following forms: Iron ores and concentrates, including roasted iron pyrites; pigs and blocks; ferrous products obtained by direct reduction of iron ore and other spongy ferrous products, in lumps or pellets; granules and powders; ingots, blooms billets, slabs, and beam blanks; flat-rolled products (plates, sheets, strips, and foils) either cut-to-length or in coils; bars and rods; structural profiles (beams, channels, angles, and other shapes); sheet piling; railway or tramway track construction materials; tubes, pipes, and hollow profiles; tube or pipe fittings; reservoirs, tanks, vats, and similar containers; wire, stranded wire, ropes, cables, and plaited band; castings, stampings, and forgings; and ferrous waste and scrap, including slag.

§ 562.317 Iron sector of Iran.

The term *iron sector of Iran* means the mining, refining, processing, or manufacturing of iron or iron products in Iran.

§ 562.318 Steel sector of Iran.

The term *steel sector of Iran* means the iron-ore smelting, ferrous-scrap melting, refining, processing, or

manufacturing of steel or steel products in Iran.

Subpart D—Interpretations

■ 15. Add § 562.407 to read as follows:

§ 562.407 Significant transaction or transactions.

In determining, for purposes of section 1(a)(ii) and 1(a)(iii) of Executive Order 13871, whether a transaction is significant, the Secretary of the Treasury may consider the totality of the facts and circumstances. As a general matter, the Secretary may consider some or all of the following factors:

(a) *Size, number, and frequency.* The size, number, and frequency of transactions performed, over a period of time, including whether the transactions are increasing or decreasing over time and the rate of increase or decrease.

(b) *Nature.* The nature of the transaction(s), or the goods or services for sale, supply, or transfer, including the type, complexity, and commercial purpose of the transaction(s), or the goods or services for sale, supply, or transfer.

(c) *Level of Awareness; Pattern of Conduct.* (1) Whether the transaction(s) is performed with the involvement or approval of management or only by clerical personnel; and

(2) Whether the transaction(s) is part of a pattern of conduct or the result of a business development strategy.

(d) *Nexus.* The proximity between the person that engaged in the transaction(s) and the activity described in sections 1(a)(ii) and (iii) of Executive Order 13871.

(e) *Impact.* The impact of the transaction(s) on the objectives of Executive Order 13871, including the economic or other benefit conferred or attempted to be conferred on Iran or the iron, steel, aluminum, and copper sectors of Iran.

(f) *Deceptive practices.* Whether the transaction(s) involves an attempt to obscure or conceal the actual parties or true nature of the transaction(s), or to evade sanctions.

(g) *Other relevant factors.* Such other factors that the Secretary deems relevant on a case-by-case basis in determining the significance of a transaction(s) or the sale, supply, or transfer of goods or services.

Subpart H—Procedures

■ 16. Revise § 562.802 to read as follows:

§ 562.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13553 of September 28, 2010 (75 FR 60567, October 1, 2010), Executive Order 13871 of May 8, 2019 (84 FR 20761, May 10, 2019) and any further Executive orders relating to the national emergency declared in Executive Order 12957 of March 17, 1995, may be taken by the Director of Office of Foreign Assets Control or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

■ 17. Add appendix B to part 562 to read as follows:

Appendix B to Part 562—Executive Order 13871 of May 8, 2019

Executive Order 13871 of May 8, 2019

Imposing Sanctions With Respect to the Iron, Steel, Aluminum, and Copper Sectors of Iran

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, DONALD J. TRUMP, President of the United States of America, find that: It remains the policy of the United States to deny Iran all paths to both a nuclear weapon and intercontinental ballistic missiles, and to counter the totality of Iran's malign influence in the Middle East. It is also the policy of the United States to deny the Iranian government revenue, including revenue derived from the export of products from Iran's iron, steel, aluminum, and copper sectors, that may be used to provide funding and support for the proliferation of weapons of mass destruction, terrorist groups and networks, campaigns of regional aggression, and military expansion.

In light of these findings and in order to take further steps with respect to the national emergency declared in Executive Order 12957 of March 15, 1995, and to supplement the authorities provided in the Iran Freedom and Counter-Proliferation Act of 2012 (subtitle D of title XII of Public Law 112–239), I hereby order:

Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in: any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) To be operating in the iron, steel, aluminum, or copper sector of Iran, or to be a person that owns, controls, or operates an entity that is part of the iron, steel, aluminum, or copper sector of Iran;

(ii) to have knowingly engaged, on or after the date of this order, in a significant transaction for the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran;

(iii) to have knowingly engaged, on or after the date of this order, in a significant transaction for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran;

(iv) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of any person whose property and interests in property are blocked pursuant to this section; or

(v) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this section.

(b) The prohibitions in this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 2. (a) The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to impose on a foreign financial institution the sanctions described in subsection (b) of this section upon determining that the foreign financial institution has, on or after the date of this order, knowingly conducted or facilitated any significant financial transaction:

(i) For the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran;

(ii) for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran; or

(iii) for or on behalf of any person whose property and interests in property are blocked pursuant to this order.

(b) With respect to any foreign financial institution determined by the Secretary of the Treasury in accordance with this section to meet any of the criteria set forth in subsection (a)(i) through (a)(iii) of this section, the Secretary of the Treasury may prohibit the opening, and prohibit or impose strict conditions on maintaining, in the United States of a correspondent account or payable-through account by such foreign financial institution.

(c) The prohibitions in subsection (b) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 3. I hereby determine that the making of donations of the types of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order would seriously impair my ability to deal with the national emergency declared in Executive Order 12957, and I hereby prohibit such donations as provided by this section.

Sec. 4. The prohibitions in section 1 of this order include:

(a) The making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to subsection (a) of that section; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 5. The unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in subsection 1(a) of this order would be detrimental to the interests of the United States, and the entry of such persons into the United States, as immigrants or nonimmigrants, is therefore hereby suspended. Such persons shall be treated as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions).

Sec. 6. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 7. Nothing in this order shall apply to transactions for the conduct of the official business of the Federal Government or the United Nations (including its specialized agencies, programmes, funds, and related organizations) by employees, grantees, or contractors thereof.

Sec. 8. For the purposes of this order:

(a) The term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(b) the term ''foreign financial institution'' means any foreign entity that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes, but is not limited to, depository institutions, banks, savings banks, money service businesses, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and holding companies, affiliates, or subsidiaries of any of the foregoing. The term does not include the international financial institutions identified in 22 U.S.C. 262r(c)(2), the International Fund for Agricultural Development, the North American Development Bank, or any other international financial institution so notified by the Secretary of the Treasury;

(c) the term ''Government of Iran'' includes the Government of Iran, any political subdivision, agency, or instrumentality thereof, including the Central Bank of Iran, and any person owned or controlled by, or acting for or on behalf of, the Government of Iran;

(d) the term ''Iran'' means the Government of Iran and the territory of Iran and any other territory or marine area, including the exclusive economic zone and continental shelf, over which the Government of Iran claims sovereignty, sovereign rights, or jurisdiction, provided that the Government of Iran exercises partial or total de facto control over the area or derives a benefit from economic activity in the area pursuant to international arrangements;

(e) the term ''knowingly,'' with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result;

(f) the term ''person'' means an individual or entity; and

(g) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Sec. 9. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in Executive Order 12957, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 10. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including adopting rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to implement this order. The Secretary of the Treasury may, consistent with applicable law, redelegate any of these functions within the Department of the Treasury. All agencies shall take all appropriate measures within their authority to implement this order.

Sec. 11. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) The authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 12. The measures taken pursuant to this order are in response to actions of the Government of Iran occurring after the conclusion of the 1981 Algiers Accords, and are intended solely as a response to those later actions.

Donald J. Trump

THE WHITE HOUSE,
May 8, 2019.

Dated: August 1, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–16842 Filed 8–6–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 96

[Docket ID: DOD–2019–OS–0055]

RIN 0790–AK27

Acquisition and Use of Criminal History Record Information by the Military Services

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation addressing the acquisition and use of criminal history record information on potential applicants and recruits for the United States Armed Forces. That regulation articulated the Department's statutory authority to collect criminal background information from other government agencies including state and local governments, and it set forth internal standards for the use and protection of that information. Because that authority and those standards are set forth in current statute and internal policies, this part is not needed. Further, DoD utilizes a standardized form to request this criminal information, and any burden on the public attributable to the information collection is accounted for through the Paperwork Reduction Act process. Therefore, the regulation is unnecessary and can be removed from the CFR.

DATES: This rule is effective on August 7, 2019.

FOR FURTHER INFORMATION CONTACT: MAJ Maria Elizabeth Sanchez, 703–695–5527, *maria.e.sanchez48.mil@mail.mil.*

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is unnecessary since it is based on removing information that paraphrases existing law and DoD internal procedures. Title 5 U.S.C. 9101 authorizes the Department to collect and properly use criminal history record information on potential recruits. Internal policies can be found in DoD Instruction 1304.02, ''Accession

Processing Data Collection Forms,'' dated September 9, 2011, which can be located at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/130402p.pdf.* Further, DD Form 369, ''Police Records Check,'' is used to request local criminal history information and has been cleared under OMB Control Number 0704–0007. It can be found at the following web address: *https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd0369.pdf.*

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, the requirements of E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' do not apply.

List of Subjects in 32 CFR Part 96

Investigations, Privacy.

PART 96—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 96 is removed.

Dated: August 1, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–16785 Filed 8–6–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 311

[Docket ID: DOD–2019–OS–0049]

RIN 0790–AK57

Office of the Secretary of Defense and Joint Staff Privacy Program

AGENCY: Office of the Secretary of Defense/Joint Staff, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation concerning the Office of the Secretary of Defense and Joint Staff (OSD/JS) Privacy Program. On April 11, 2019, the Department of Defense published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide privacy program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also includes all DoD component exemption rules. Therefore, this part is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on August 7, 2019.

FOR FURTHER INFORMATION CONTACT: Mrs. Luz D. Ortiz at 571–372–0478.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The OSD/JS Privacy Program regulation at 32 CFR part 311, last updated on October 30, 2009 (74 FR 56114), is no longer required and may be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest because it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR 310, or are publically available on the Department's website. To the extent that OSD/JS internal guidance concerning the implementation of the Privacy Act within OSD/JS is necessary, it will continue to be published in Administrative Instruction 81, OSD/Joint Staff (JS) Privacy Program, *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/ai/a81p.pdf?ver=2019-02-25-104539-627.*

This rule is one of 20 separate component Privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department eliminated the need for component Privacy rules, thereby reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019 at 84 FR 14728.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' does not apply.

List of Subjects in 32 CFR Part 311

Privacy.

PART 311—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 311 is removed.

Dated: August 1, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–16775 Filed 8–6–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0660]

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone on the Milwaukee River, between the I–794 overpass to the confluence of the Kinnickinnic River in Milwaukee, WI for the Milwaukee Open Water Swim, also referred to as the ''Cream City Classic'' on August 10, 2019 to provide for the safety of life on navigable waterways during the event. During the enforcement period, vessels and persons are prohibited from transiting through, mooring, or anchoring within the safety zone without approval from the Captain of the Port (COTP) Lake Michigan or a designated representative.

DATES: The regulations in 33 CFR 165.929 Table 165.929(f)(18) will be enforced on August 10, 2019 from 6 a.m. to 12 noon.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Chief Petty Officer Kyle Weitzell, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email *Kyle.W.Weitzell@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone in 33 CFR 165.929 Table 165.929(f)(18) for the Milwaukee River Open Water Swim, also referred to as the ''Cream City Classic'' from 6 a.m. to 12 noon on August 10, 2019. This action is being taken to provide for the safety of life on navigable waterways of the Milwaukee River in Milwaukee, WI. This safety zone will encompass all waters of the Milwaukee River from the I–794 overpass to the confluence of the Milwaukee River and Kinnickinnic River. Pursuant to 33 CFR 165.929, entry into, transiting, or anchoring within the safety zone during an enforcement period is prohibited unless authorized by the COTP or their designated on-scene representative(s). Those seeking permission to enter the safety zone may request permission from the COTP via Channel 16, VHF–FM or by phone at 414–747–7182.

Vessels and persons granted permission to enter the safety zone shall obey the directions of the COTP or their designated representative(s) and all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice of enforcement is issued under the authority of 33 CFR 165.929 and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Captain of the Port Lake Michigan will also provide notice through other means, which will include Broadcast Notice to Mariners. Additionally, the COTP may notify representatives from the maritime industry through telephonic notifications, email notifications, or by direct communication from on scene patrol commanders. If the COTP or a designated representative determines that the regulated area does not need to be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area. The COTP or a designated on-scene representative may be contacted via Channel 16, VHF–FM or at (414) 747–7182.

Dated: July 31, 2019.

T.J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port Sector Lake Michigan.

[FR Doc. 2019–16793 Filed 8–6–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0674]

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce safety zones for the Fireworks at Pier Wisconsin in Milwaukee, WI and for the Sister Bay Marinafest Fireworks on August 31, 2019 from 8:30 p.m. through 10 p.m. to provide for the safety of life on navigable waterways during these events. During each enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Lake Michigan

DATES: The regulations in 33 CFR 165.929 Table 165.929 listed as (e)(46) and (g)(3) will be enforced from 8:30 p.m. through 10 p.m. on August 31, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Chief Petty Officer Kyle Weitzell, U.S. Coast Guard; telephone 414–747–7148, email *Kyle.W.Weitzell@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zones; Annual Events in the Captain of the Port Lake Michigan zone listed in 33 CFR 165.929 for the following events:

(1) *Fireworks at Pier Wisconsin, Milwaukee, WI;* The safety zone listed in Table 165.929(e)(46) will be enforced for all waters of Milwaukee Harbor including Lakeshore Inlet and the marina at Pier Wisconsin within the arc of a circle with a 300-foot radius from the fireworks launch site on Pier Wisconsin located in approximate position 43°02.178′ N, 087°53.625′ W from 8:30 p.m. through 10 p.m. on August 31, 2019.

(2) *Sister Bay Marinafest Fireworks, Sister Bay, WI;* The safety zone listed in Table 165.929(g)(3) will be enforced for all waters of Sister Bay within an 800-foot radius of position 45°11.585′ N, 087°07.392′ W from 8:30 p.m. through 10 p.m. on August 31, 2019.

This action is being taken to provide for the safety of life on navigable waterways during these annually recurring fireworks events. During the enforcement periods, as reflected in § 165.929(a)(3), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign. Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within the safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated representative. Those seeking permission to enter the safety zones may request permission from the Captain of Port Lake Michigan via channel 16, VHF–FM.

This notice of enforcement is issued under authority of 33 CFR 165.929 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Lake Michigan determines that the safety zone need not be enforced for the full duration stated in this notice he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: July 31, 2019.

T.J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port Sector Lake Michigan.

[FR Doc. 2019–16795 Filed 8–6–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0376]

RIN 1625–AA00

Safety Zone; Sabine River, Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX. This action is necessary to protect persons and vessels from hazards associated with a high-speed Jet Ski race competition in Orange, TX. Entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur or a designated representative.

DATES: This rule is effective from 6 a.m. on August 17, 2019 through 6 p.m. on August 18, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0376 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Scott Whalen, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409–719–5086, email *Scott.K.Whalen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Marine Safety Unit Port Arthur
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This safety zone must be established by August 17, 2019 and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone until after the dates of the high-speed races and compromise public safety.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Marine Safety Unit Port Arthur (COTP) has determined that the potential hazards associated with high-speed Jet Ski races are a safety concern for persons and vessels operating on the Sabine River. Possible hazards include risks of injury or death from near or actual contact among participant vessels and spectators or mariners traversing through the safety zone. This rule is needed to protect all waterway users, including event participants and spectators, before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 9 a.m. through 6 p.m. each day from August 17, 2019 through August 18, 2019. The safety zone covers all navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded by the Navy Pier One between latitude 30°05′50″ N and latitude 30°05′33″ N. The duration of the safety zone is intended to protect participants, spectators, and other persons and vessels, in the navigable waters of the Sabine River during high-speed Jet Ski races and will include breaks and opportunity for vessels to transit through the regulated area.

Entry of vessels or persons into this zone is prohibited unless authorized by the COTP or a designated representative. They may be contacted on VHF–FM channel 13 or 16, or by phone at by telephone at 409–719–5070. A designated representative may be a Patrol Commander (PATCOM). The PATCOM may be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM''. All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators. The ''official patrol vessels'' consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels assigned or approved by the COTP or a designated representative to patrol the regulated area. Spectator vessels desiring to transit the regulated area may do so only with prior approval of the Patrol Commander and when so directed by that officer will be operated at a minimum safe navigation speed in a manner which will not endanger participants in the regulated area or any other vessels. No spectator vessel shall anchor, block, loiter, or impede the through transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel. Any spectator vessel may anchor outside the regulated area, but may not anchor in, block, or loiter in a navigable channel. Spectator vessels may be moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event. Such mooring must be complete at least 30 minutes prior to the establishment of the regulated area and remain moored through the duration of the event.

The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both. The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

The COTP or a designated representative will terminate enforcement of the special local regulations at the conclusion of the event.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. This safety zone encompasses a less than half-mile stretch of the Sabine River for nine hours on each of two days. Moreover, the Coast Guard will issue Broadcast Notice to Mariners (BNMs) via VHF–FM marine channel 16 about the zone, daily enforcement periods will include breaks that will provide an opportunity for vessels to transit through the regulated area, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on vessel owners or operators.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental

jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 8 hours on each of two days that will prohibit entry on less than a one-half mile stretch of the Sabine River. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREA AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–376 to read as follows:

§ 165.T08–376 Safety Zone; Sabine River, Orange, Texas.

(a) *Location.* The following area is a safety zone: All navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded by the Navy Pier One between latitude 30°05′50″ N and latitude 30°05′33″ N.

(b) *Effective period.* This section is effective from 9 a.m. on August 17, 2019 through 6 p.m. on August 18, 2019.

(c) *Enforcement periods.* This section will be enforced from 9 a.m. through 6 p.m. daily. Breaks in the racing will occur during the enforcement periods, which will allow for vessels to pass through the safety zone. The Captain of the Port Marine Safety Unit Port Arthur (COTP) or a designated representative will provide notice of breaks as appropriate per paragraph (e) of this section.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry of vessels or persons into this zone is prohibited unless authorized by the COTP or a designated representative. They may be contacted on VHF–FM channel 13 or 16, or by phone at by telephone at 409–719–5070. A designated representative may be a Patrol Commander (PATCOM). The PATCOM may be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM''.

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators. The ''official patrol vessels'' consist of any Coast Guard, state, or local law enforcement and sponsor provided vessels assigned or approved by the COTP or a designated representative to patrol the regulated area.

(3) Spectator vessels desiring to transit the regulated area may do so only with prior approval of the Patrol Commander and when so directed by that officer will be operated at a minimum safe navigation speed in a manner which will not endanger participants in the regulated area or any other vessels.

(4) No spectator vessel shall anchor, block, loiter, or impede the through transit of participants or official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) Any spectator vessel may anchor outside the regulated area, but may not anchor in, block, or loiter in a navigable channel. Spectator vessels may be

moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event. Such mooring must be complete at least 30 minutes prior to the establishment of the regulated area and remain moored through the duration of the event.

(6) The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(7) The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(8) The COTP or a designated representative will terminate enforcement of the special local regulations at the conclusion of the event.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: July 15, 2019.

Jacqueline Twomey,

Captain, U.S. Coast Guard, Captain of the Port Marine Safety Unit Port Arthur.

[FR Doc. 2019–16731 Filed 8–6–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 38

RIN 2900–AQ35

Committal Services, Memorial Services and Funeral Honors

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule reflects current VA practices relative to respecting the expressed wishes of the personal representative when making arrangements for the committal or memorial service. The final rule clarifies the process for requesting committal or memorial services when requesting interment at VA national cemeteries and addresses access to public areas at VA national cemeteries. The final rule also addresses when committal services may be conducted at a gravesite rather than in a committal shelter and standardizes measures to implement the statutory requirement that VA notify the personal representative of the funeral honors available to the deceased veteran.

DATES: This final rule is effective September 6, 2019.

FOR FURTHER INFORMATION CONTACT: Melvin Gerrets, Office of the Director of Cemetery Operations, National Cemetery Administration (NCA), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: (202) 461–9646 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA published a proposed rule in the **Federal Register** on March 25, 2019 (84 FR 11037), to address committal or memorial services and funeral honors at VA national cemeteries, including current VA practices, under 38 U.S.C. 2404(h), relative to respecting the expressed wishes of the personal representative when making arrangements for the committal or memorial service. The amendments also clarified the process for requesting interment at VA national cemeteries, defined when a committal service may be conducted at a gravesite rather than in a committal shelter, and included measures to implement the statutory requirement that VA notify the personal representative of the funeral honors available to the deceased veteran. VA received no comments on the proposed rule during the comment period, which ended on May 25, 2019. Based on the rationale set forth in the **SUPPLEMENTARY INFORMATION** to the proposed rule, we are adopting the provisions of the proposed rule as a final rule without change.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement, unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi). This final rule contains provisions constituting collection of information at 38 CFR 38.619(a) and (b), and at 38 CFR 38.619(f)(5).

The information collection at § 38.619(a) and (b) is necessary to establish eligibility for national cemetery burial and to schedule and plan interments. This information collection is currently approved by OMB and has been assigned OMB control number 2900–0232. The burden of this information collection would remain unchanged.

This final rule also imposes new information collection requirements at 38 CFR 38.619(f)(5). This new information collection is a certification requirement for non-DoD funeral honors providers, that will help ensure the safety of cemetery visitors and staff and maintain the decorum of the national cemeteries by requiring that non-DoD funeral honors providers that perform funeral honors activities at VA national cemeteries certify to VA that they will comply with requirements set forth in the regulation. As required by 44 U.S.C. 3507(d), VA submitted the new information collection to OMB for its review. The Office of Management and Budget has assigned the information collection requirement in this section under control number 2900–0865. The information collection is pending OMB approval. VA will not collect information associated with the funeral honors providers certification until OMB approves the associated information collection.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Even to the extent some veterans service organizations that provide funeral honors could be viewed as ''small entities'' as defined in 5 U.S.C. 601(4), (6), this final rule will not have a significant economic impact on them because it concerns only the standards of conduct those groups must abide by when conducting funeral honors in national cemeteries. Therefore, pursuant to 5 U.S.C. 605(b), this final rule would be exempt from the initial and final

regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

VA has examined the economic, interagency, budgetary, legal, and policy implications of this final rule action and determined that the action is not a significant regulatory action under Executive Order 12866. This final rule is not a E.O. 13771 regulatory action because this final rule is not significant under E.O. 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.201 National Cemeteries; 64.202 Procurement of Headstones and Markers and/or Presidential Memorial Certificates; and, 64.203 State Cemetery Grants.

List of Subjects in 38 CFR Part 38

Administrative practice and procedure, Cemeteries, Veterans, Claims, Crime, Criminal offenses.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on August 1, 2019, for publication.

Dated: August 2, 2019.

Luvenia Potts,

Program Specialist, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 38 as follows:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 38 U.S.C. 107, 501, 512, 2306, 2402, 2403, 2404, 2407, 2408, 2411, 7105.

■ 2. Add § 38.619 to read as follows:

§ 38.619 Requests for interment, committal services or memorial services, and funeral honors.

(a) *Interment requests.* A personal representative, as defined in § 38.600, may request interment of an eligible decedent in a national cemetery by contacting the National Cemetery Scheduling Office (NCSO) at 1–800–535–1117.

(1) *Required information.* VA will request the following information from the decedent's personal representative at the time of the request for interment to allow VA to schedule the interment for the decedent:

(i) Documentation of the decedent's eligibility for national cemetery interment. If needed, VA will make reasonable efforts to assist the personal representative in obtaining such documentation;

(ii) Preferred date and time for the interment;

(iii) Whether a committal service is requested (a committal service is not required);

(iv) Whether the remains are in a casket or urn. For cremated remains, the personal representative will be advised to present a certificate of cremation or other documentation sufficient to identify the decedent at the time of interment.

(v) The size of the casket or urn.

(vi) The contact information for the personal representative.

(vii) Whether a private vault will be provided to the national cemetery or a government-furnished grave liner is required.

(viii) Whether the personal representative intends to have funeral honors during the committal service, if the decedent is a veteran.

(ix) Other relevant information necessary to establish or confirm eligibility of the decedent and/or for cemetery logistics and planning.

(2) [Reserved].

(b) *Memorial services requests.* The personal representative may request a memorial service for a decedent who is eligible for interment in a VA national cemetery. Memorial services may be conducted if the decedent's cremated remains will be scattered and will not be interred, or if the remains of the eligible individual are otherwise not available for interment, or were previously interred without a committal service. The personal representative may request the memorial service by contacting the National Cemetery Scheduling Office (NCSO) at 1–800–535–1117 and providing the following required information:

(1) Documentation of the decedent's eligibility for national cemetery interment. If needed, VA will make reasonable efforts to assist the personal representative in obtaining such documentation;

(2) Preferred date and time for the memorial service;

(3) The contact information for the personal representative;

(4) Whether the personal representative intends to have funeral honors services during the memorial service, if the decedent is a veteran;

(5) Other relevant information necessary to establish or confirm eligibility of the decedent and/or for cemetery logistics and planning.

(c) *Content of committal or memorial services.* VA will respect and defer to the expressed wishes of the personal representative for the content and conduct of a committal or memorial service, including the display of

religious or other symbols chosen by the family, the use of all appropriate public areas, and the selection of funeral honors providers, provided that the safety and security of the national cemetery and its visitors are not adversely affected.

(d) *Location of services.* Committal or memorial services at VA national cemeteries will be held in committal shelters located away from the gravesite to ensure accessibility and visitor safety, unless the cemetery director determines that a committal shelter is not available for logistical reasons, or the cemetery director approves a request from the personal representative for a gravesite service. A request for a gravesite service may be approved by the cemetery director if:

(1) The service is requested by the decedent's personal representative for religious reasons; and

(2) The request is made sufficiently prior to the scheduled committal service to ensure the gravesite is accessible; and

(3) The cemetery director has sufficient staffing resources for the gravesite service, and

(4) The site can be safely accessed on the day of the service.

(e) *Witnessing interment without additional services.* When scheduling the interment, the decedent's personal representative may request to witness the interment of the decedent's remains without additional services at the committal shelter. Approval of a request for witness-only interment is at the discretion of the cemetery director, and may be made only if:

(1) The timing of the request provides sufficient time to ensure the gravesite is accessible, and;

(2) The site can be safely accessed on the day of the interment. This determination may require limiting the number of individuals who may witness the interment and other logistics, such as distance from the gravesite, as the cemetery director finds necessary.

(f) *Funeral honors*—(1) *List of organizations providing funeral honors.* Each cemetery director will maintain a list of organizations that will, upon request, provide funeral honors at the cemetery at no cost to the family. Each list must include DoD funeral honors contacts. Non-DoD funeral honors providers who want to be included on the list must make a request to the cemetery director and meet the requirements of paragraph (f)(5) of this section.

(2) *Request required.* Funeral honors will be provided at a committal or memorial service for an eligible individual only if requested by the decedent's personal representative. When scheduling a committal or memorial service for a veteran or other eligible individual who served in the U.S. armed forces, the NCSO will make available to the personal representative the list of available funeral honors providers, as described in paragraph (f)(1) of this section, for the cemetery where interment or services are to be scheduled. The decedent's personal representative may choose any funeral honors provider(s) on the list provided by VA, and/or any other organization that provides funeral honors services.

(3) *Agreement.* Any agreement to provide funeral honors is exclusively between the organization(s) providing funeral honors and the decedent's personal representative. The composition of a funeral honors detail, as well as the specific content of the ceremony provided during a committal or memorial service is dependent on available resources of the providing organization(s). The Department of Defense (DoD) is responsible for determining eligibility for funeral honors provided by a DoD funeral honors detail. If funeral honors are provided by a combined detail that includes one or more funeral honors providers, all providers must provide services as requested by the personal representative.

(4) *Requirements for all funeral honors providers.* All organizations performing funeral honors at VA national cemeteries, including DoD organizations and any provider selected by the personal representative that is not on the list of providers provided by VA under paragraph (f)(1) of this section, must:

(i) Provide to the cemetery director the name and contact information of a representative for the organization who is accountable for funeral honors activities; and

(ii) Comply with VA security, safety, and law enforcement regulations under 38 CFR 1.218; and

(iii) Maintain and operate any equipment in a safe manner consistent with VA and DoD policies and regulations; and

(iv) Not solicit for or accept donations on VA property except as authorized under 38 CFR 1.218(a)(8).

(5) *Additional requirements for non-DoD funeral honors providers.* Non-DoD funeral honors providers, including any provider selected by the personal representative that is not on the list of providers provided by VA under paragraph (f)(1) of this section, must certify that:

(i) They will comply with the requirements in subparagraphs (f)(4) of this section;

(ii) They are conducting activities on federal property as an independent entity, not as an agent or employee of VA, unless registered as a VA volunteer;

(iii) Members of the organization who will conduct the funeral honors have completed training on funeral honors tasks and the safe use of funeral honors equipment; and

(iv) The funeral honors will be provided in accordance with the agreement in paragraph (f)(3) of this section between the personal representative and the funeral honors provider.

(g) *Public areas.* The cemetery director and cemetery staff will allow access to and use of appropriate public areas of the national cemetery by national cemetery visitors, as well as to families and funeral honors providers for service preparations, contemplation, prayer, mourning, or reflection, so long as the safety and security of the national cemetery and cemetery operations are not adversely affected. Appropriate public areas include, but are not limited to, committal shelters, rest areas, chapels, and benches. The cemetery director will ensure that signs adequately identify restricted or non-public areas in the national cemetery.

(h) *Gifts.* Nothing in this section prohibits or constrains any member of a funeral honors provider, a Veterans Service Organization, or the public from offering a gift or token to a family member of the decedent or any person at a committal or memorial service, provided that no compensation is requested, received, or expected in exchange for such gift or token. Committal or memorial service attendees may accept or decline any such gift or token, and may request that the offeror refrain from making any such offers to the service attendees.

(Authority: 38 U.S.C. 2402, 2404)

[FR Doc. 2019–16915 Filed 8–6–19; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2019–0218; FRL–9996–99–Region 1]

Air Plan Approval; Maine; Reasonably Available Control Technology for the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State

Implementation Plan (SIP) revisions submitted by the State of Maine for purposes of implementing the 2008 Ozone National Ambient Air Quality Standards (NAAQS). The revisions consist of a demonstration that Maine meets the requirements of reasonably available control technology (RACT) for volatile organic compounds (VOCs), set forth by the Clean Air Act (CAA or Act), with respect to the 2008 Ozone standards. Additionally, we are approving a related regulation that limits air emissions of VOCs from certain industrial sources that use organic solvents in cleaning activities, and withdrawing several previously approved source-specific RACT requirements for sources that have ceased operation. This action is being taken under the Clean Air Act.

DATES: This rule is effective on September 6, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2019–2018. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: David L. Mackintosh, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109–3912, tel. 617–918–1584, email *Mackintosh.David@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. Background and Purpose

On June 11, 2019 (84 FR 27046), EPA issued a notice of proposed rulemaking (NPRM) for the State of Maine. In the NPRM, EPA proposed approval of SIP revisions submitted by Maine on August 31, 2018. The SIP submittal included a certification that Maine has addressed its RACT requirements for the 2008 Ozone NAAQS, a request for EPA approval of 06–096 Code of Maine Rules (CMR) Chapter 166, ''Industrial Cleaning Solvents,'' to address EPA's 2006 CTG for Industrial Cleaning Solvents, and a request that EPA remove from the SIP several previously approved source-specific RACT requirements for facilities that no longer exist or, in one case, for a facility that no longer operates the process controlled by the source-specific requirements.

The NPRM provides the rationale for EPA's proposed approval, which will not be restated here.

II. Public Comment

EPA received one comment in response to the NPRM. The comment is outside the scope of a RACT SIP action, does not explain (or provide a legal basis for) how the proposed action should differ in any way, and makes no specific mention of the proposed action; it is not germane.

III. Final Action

EPA is approving 06–096 CMR Chapter 166, ''Industrial Cleaning Solvents,'' into the Maine SIP at 40 CFR 52.1020(c), ''EPA approved regulations.'' EPA is approving Maine's SIP revision on the basis that Maine has met the RACT requirements for the 2008 8-hour Ozone NAAQS as set forth by sections 182(b) and 184(b)(2) of the CAA. In addition, EPA is approving ''Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision Under the 2008 8-hour Ozone National Ambient Air Quality Standard (NAAQS),'' as having satisfied the 2008 8-hour NAAQS RACT requirements, and as an addition to the Maine SIP at 40 CFR 52.1020(e), ''Nonregulatory''.

EPA is withdrawing the following previously-approved source-specific RACT requirements for ''Prime Tanning Company, York County, Berwick, Maine'' (two approvals); ''JJ Nissen Baking Company, Cumberland County, Portland Maine''; ''Georgia Pacific Corporation, Washington County, Woodland, Maine''; ''Moosehead Manufacturing Company, Piscataquis County, Dover-Foxcroft, Maine''; ''Moosehead Manufacturing Company, Piscataquis County, Monson, Maine''; ''Dexter Shoe Company, Penobscot County, Dexter, Maine'' (two approvals); and ''McCain Foods USA, Inc., Tatermeal Facility'', and removing all entries for these facilities which are currently listed in 40 CFR 52.1020(d) ''EPA-approved State Source specific requirements.''

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Code of Maine Rules described in the amendments to 40 CFR part 52 set forth below. EPA is also removing provisions from the ''EPA-approved State Source specific requirements'' table from the Maine State Implementation Plan at 40 CFR 52.1020(d), which is incorporated by reference in accordance with the requirements of 1 CFR part 51. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

[1] 62 FR 27968 (May 22, 1997).

• This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 7, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 22, 2019.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart U—Maine

■ 2. Section 52.1020 is amended by:

■ i. In table (c) by adding a new state citation ''Chapter 166, Industrial Cleaning Solvents'' in numerical order,

■ ii. In table (d) by removing the entries for ''Prime Tanning Company, York County, Berwick, Maine'' (remove both entries), ''JJ Nissen Baking Company, Cumberland County, Portland Maine'', ''Georgia Pacific Corporation, Washington County, Woodland, Maine'', ''Moosehead Manufacturing Company, Piscataquis County, Dover-Foxcroft, Maine'', ''Moosehead Manufacturing Company, Piscataquis County, Monson, Maine'', ''Dexter Shoe Company, Penobscot County, Dexter, Maine'' (remove both entries), and ''McCain Foods USA, Inc., Tatermeal Facility''; and

■ iii. In table (e) by adding a new provision for ''Reasonably Available Control Technology (RACT) for the 2008 8-hour Ozone National Ambient Air Quality Standard'' to read as follows:

§ 52.1020 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MAINE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date EPA approval date and citation [1]	Explanations
*	* * *	*	* *	*
Chapter 166	Industrial Cleaning Solvents	8/22/2018	8/7/2019 [Insert **Federal Register** citation].	
*	* * *	*	* *	*

[1] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

* * * * * (e) * * *

MAINE NON REGULATORY

Name of non regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA approved date [3]	Explanations
* *	*	* *	*	*
Reasonably Available Control Technology (RACT) for the 2008 8-hour Ozone National Ambient Air Quality Standard.	Statewide	Submitted 9/4/2018	8/7/2019 [Insert **Federal Register** citation].	

[3] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

[FR Doc. 2019–16203 Filed 8–6–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0727; FRL–9996–44]

Autographa Californica Multiple Nucleopolyhedrovirus Strain FV#11; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 in or on all food commodities when used in accordance with label directions and good agricultural practices. Andermatt Biocontrol AG submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 in or on all food commodities under FFDCA.

DATES: This regulation is effective August 7, 2019. Objections and requests for hearings must be received on or before October 7, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0727, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0727 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 7, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0727, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of March 21, 2018 (83 FR 12311) (FRL–9974–76), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 7F8621) by Andermatt Biocontrol AG, Stahlermatten 6, CH–6146 Grossdietwil, Switzerland (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the insecticide *Autographa californica* multiple nucleopolyhedrovirus (AcMNPV) strain FV#11 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Andermatt Biocontrol AG and available in the docket via *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit III.C.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicological and exposure data on *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for *Autographa californica* Multiple Nucleopolyhedrovirus strain FV#11'' (Safety Determination). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES.**

The available data demonstrated that, with regard to humans, *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 is not anticipated to be toxic, pathogenic, or infective via any reasonably foreseeable route of exposure and when used in accordance with label directions and good agricultural practices. Baculoviruses, such as *Autographa californica* multiple nucleopolyhedrovirus strain FV#11, are ubiquitous in the environment and have been extensively studied with no adverse effects in mammals observed or known. Although there may be some exposure to residues when *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 is used on food commodities, there is not a concern due to the lack of potential for adverse effects when used in accordance with label directions and good agricultural practices. EPA also determined that retention of the Food Quality Protection Act safety factor was not necessary as part of the qualitative assessment conducted for *Autographa californica* multiple nucleopolyhedrovirus strain FV#11.

Based upon its evaluation in the Safety Determination, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 when used in accordance with label directions and good agricultural practices. Therefore, an exemption from the requirement of a tolerance is established for residues of *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Response to Comments

EPA received one comment on the notice of filing. Generally, the commenter acknowledged that pesticides are essential for food production and human exposure to them is likely but emphasized that these substances need to be regulated appropriately to, among other things, instill trust amongst the public with regard to pesticide use and protect human health. EPA agrees that pesticides must be regulated appropriately and therefore has evaluated the available information on *Autographa californica* multiple nucleopolyhedrovirus strain FV#11, including toxicological and potential exposure information, and concluded, in accordance with the statutory requirements of FFDCA, that the exemption would be safe. The commenter provided no basis for a different conclusion.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled

''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 24, 2019.

Richard Keigwin,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1369 to subpart D to read as follows:

§ 180.1369 *Autographa californica* multiple nucleopolyhedrovirus strain FV#11; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Autographa californica* multiple nucleopolyhedrovirus strain FV#11 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2019–16707 Filed 8–6–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2019–0003; Internal Agency Docket No. FEMA–8591]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not

participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/ cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region IV				
Georgia:				
Burke County, Unincorporated Areas ...	130022	January 13, 1976, Emerg; September 15, 1989, Reg; August 15, 2019, Susp.	Aug. 15, 2019 ...	Aug. 15, 2019.
DeKalb County, Unincorporated Areas	130065	June 5, 1970, Emerg; May 15, 1980, Reg; August 15, 2019, Susp.	.....do	Do.
Doraville, City of, DeKalb County	130069	November 27, 1973, Emerg; September 1, 1977, Reg; August 15, 2019, Susp.	.....do	Do.
Region V				
Michigan:				
Adrian, Charter Township of, Lenawee County.	260732	October 20, 1982, Emerg; November 16, 1990, Reg; August 15, 2019, Susp.	.....do	Do.
Adrian, City of, Lenawee County	260115	April 1, 1975, Emerg; July 19, 1982, Reg; August 15, 2019, Susp.	.....do	Do.
Blissfield, Village of, Lenawee County ..	260339	December 10, 1976, Emerg; July 19, 1982, Reg; August 15, 2019, Susp.	.....do	Do.
Deerfield, Township of, Lenawee County.	260717	December 21, 1978, Emerg; May 25, 1984, Reg; August 15, 2019, Susp.	.....do	Do.
Deerfield, Village of, Lenawee County ..	260438	September 20, 1976, Emerg; April 1, 1981, Reg; August 15, 2019, Susp.	.....do	Do.
Hudson, City of, Lenawee County	260116	June 20, 1975, Emerg; November 4, 1981, Reg; August 15, 2019, Susp.	.....do	Do.
Palmyra, Township of, Lenawee County	260737	June 10, 1983, Emerg; May 25, 1984, Reg; August 15, 2019, Susp.	.....do	Do.
Minnesota:				
Fillmore County, Unincorporated Areas	270124	April 16, 1974, Emerg; September 18, 1987, Reg; August 15, 2019, Susp.	.....do	Do.
Preston, City of, Fillmore County	270129	January 10, 1975, Emerg; August 1, 1979, Reg; August 15, 2019, Susp.	.....do	Do.
Whalan, City of, Fillmore County	270133	August 23, 1974, Emerg; March 2, 1981, Reg; August 15, 2019, Susp.	.....do	Do.
Ohio:				
Bay Village, City of, Cuyahoga County	390093	June 14, 1974, Emerg; December 1, 1977, Reg; August 15, 2019, Susp.	.....do	Do.

State and location	Community No.	Effective date authorization/ cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Bratenahl, Village of, Cuyahoga County	390734	June 9, 1975, Emerg; June 15, 1981, Reg; August 15, 2019, Susp.	.....do	Do.
Cleveland, City of, Cuyahoga County ...	390104	July 20, 1973, Emerg; August 1, 1978, Reg; August 15, 2019, Susp.	.....do	Do.
Euclid, City of, Cuyahoga County	390107	July 3, 1975, Emerg; August 17, 1981, Reg; August 15, 2019, Susp.	.....do	Do.
Lakewood, City of, Cuyahoga County ...	390112	March 30, 1973, Emerg; February 1, 1978, Reg; August 15, 2019, Susp.	.....do	Do.
Rocky River, City of, Cuyahoga County	395372	January 29, 1971, Emerg; September 17, 1971, Reg; August 15, 2019, Susp.	.....do	Do.
Region VI				
Texas:				
Clear Lake Shores, City of, Galveston County.	485461	July 31, 1970, Emerg; October 23, 1970, Reg; August 15, 2019, Susp.	.....do	Do.
Dickinson, City of, Galveston County	481569	April 8, 1971, Emerg; April 9, 1971, Reg; August 15, 2019, Susp.	.....do	Do.
Friendswood, City of, Galveston and Harris Counties.	485468	June 5, 1970, Emerg; March 3, 1972, Reg; August 15, 2019, Susp.	.....do	Do.
Hitchcock, City of, Galveston County	485479	June 19, 1970, Emerg; November 13, 1970, Reg; August 15, 2019, Susp.	.....do	Do.
La Marque, City of, Galveston County ..	485486	May 29, 1970, Emerg; October 16, 1970, Reg; August 15, 2019, Susp.	.....do	Do.
League City, City of, Galveston and Harris Counties.	485488	June 5, 1970, Emerg; November 20, 1970, Reg; August 15, 2019, Susp.	.....do	Do.
Santa Fe, City of, Galveston County	481562	April 8, 1971, Emerg; April 9, 1971, Reg; August 15, 2019, Susp.	.....do	Do.
Texas City, City of, Galveston County ..	485514	June 5, 1970, Emerg; November 20, 1970, Reg; August 15, 2019, Susp.	.....do	Do.
Region VIII				
Colorado:				
Aspen, City of, Pitkin County	080143	July 2, 1974, Emerg; December 4, 1985, Reg; August 15, 2019, Susp.	.....do	Do.
Boone, Town of, Pueblo County	080148	April 28, 1983, Emerg; July 15, 1985, Reg; August 15, 2019, Susp.	.....do	Do.
Lafayette, City of, Boulder County	080026	August 7, 1975, Emerg; March 18, 1980, Reg; August 15, 2019, Susp.	.....do	Do.
Louisville, City of, Boulder County	085076	March 3, 1972, Emerg; May 4, 1973, Reg; August 15, 2019, Susp.	.....do	Do.
Pueblo, City of, Pueblo County	085077	June 18, 1971, Emerg; August 24, 1973, Reg; August 15, 2019, Susp.	.....do	Do.
Pueblo County, Unincorporated Areas ..	080147	June 21, 1974, Emerg; September 29, 1989, Reg; August 15, 2019, Susp.	.....do	Do.
Rye, Town of, Pueblo County	080150	May 12, 2010, Emerg; N/A, Reg; August 15, 2019, Susp.	.....do	Do.
Superior, Town of, Boulder County	080203	July 15, 1975, Emerg; September 28, 1979, Reg; August 15, 2019, Susp.	.....do	Do.
Montana:				
Fairview, Town of, Richland County	300064	February 3, 1977, Emerg; May 15, 1986, Reg; August 15, 2019, Susp.	.....do	Do.
Sidney, City of, Richland County	300065	December 17, 1974, Emerg; December 4, 1985, Reg; August 15, 2019, Susp.	.....do	Do.

*-do- = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: July 31, 2019.

Eric Letvin,

Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2019–16806 Filed 8–6–19; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 61 and 69

[WC Docket Nos. 16–143, 05–25; GN Docket No. 13–5; RM 10593; FCC 19–66]

Business Data Services in an Internet Protocol Environment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission eliminates ex ante pricing regulation for lower speed time division multiplexing (TDM) transport services offered by price cap regulated carriers nationwide, finding there is widespread competition in the marketplace, and abundant support in the record for removing the Commission's pricing regulations.

DATES: This final rule is effective September 6, 2019.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: David Zesiger, Wireline Competition Bureau, Pricing Policy Division at (202) 418–1540 or via email at *David.Zesiger@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order on Remand, released on July 12, 2019. A full-text copy of this document may be obtained at the following internet address: *https://www.fcc.gov/document/removing-unnecessary-regulation-transport-services-and-facilities-0*.

I. Background

A. BDS TDM Transport Services

1. The term business data services refers to the ''dedicated point-to-point transmission of data at guaranteed speeds and service levels.'' BDS offerings are fundamentally important to modern communities and economies. Over the last several decades, the Commission has repeatedly recognized the increasing competition for BDS services in areas of the country served by price cap LECs. Competition has grown even more markedly in recent years as cable operators increasingly compete for all aspects of BDS, including TDM transport. In response, the Commission has worked consistently to streamline regulation of such services to reflect this evolution.

2. In so doing, the Commission has characterized TDM transport services, which ''involve carrying traffic from one point of traffic concentration to another,'' as ''low hanging fruit'' for competitors because they can more easily justify competitive investment and deployment. In 1999, recognizing that burdensome pricing regulation is unnecessary and counter-productive where competitive pressure exists, the Commission granted pricing flexibility to price cap carriers for their BDS offerings, including their TDM transport services. The Commission provided two levels of pricing flexibility to price cap LECs offering BDS, including TDM-based transport services, keyed to the presence of competitive providers collocated at a price cap LEC's wire centers. The Commission suspended further grants of pricing flexibility in 2012, pending the resolution of the BDS proceedings.

3. In 2017, after more than ten years of study and a massive data collection (the *2015 Collection*), the Commission adopted an order comprehensively addressing the pricing regulation of BDS in price cap LEC areas. In the *BDS Order,* the Commission found, among other things, that competition for BDS TDM transport services was sufficiently pervasive to justify elimination of ''all ex ante pricing regulation of price cap incumbent LEC provision of TDM transport and other transport (*i.e.,* non-end user channel termination)'' services. In support of this conclusion, the Commission looked to the record evidence showing that ''competitive providers have deployed competing transport networks in more than 95% of census blocks with [BDS] demand,'' which included ''about 99% of business establishments.'' It also found that ''in all price cap territories, 92.1 percent of buildings served were within a half mile of competitive fiber transport facilities'' and that, ''for all census blocks with business data services demand, 89.6 percent have at least one served building within a half mile of competitive LEC fiber.'' This half mile is significant because, as the Commission concluded, most BDS providers are willing and able to profitably invest in and deploy facilities within a half mile of existing competitive facilities. In addition, the Commission found that buildings with BDS demand that were served only by an incumbent LEC were on average only 364 feet from the closest competitive LEC fiber facility.

4. After the Eighth Circuit Court's partial remand of the *BDS Order,* finding that the Commission had not provided sufficient notice on the issue of eliminating ex ante pricing regulation for TDM transport, the Commission released the *Second Further Notice,* proposing to eliminate ex ante pricing regulation of price cap LECs' BDS TDM transport and other transport (*i.e.,* non-end user channel termination) services. The Commission received eight comments, six reply comments, and several filings memorializing various ex parte communications. Also, in the interest of ensuring a more complete analysis of competitive conditions affecting TDM transport services, the Commission conducted additional analysis of TDM transport services using data from the *2015 Collection.* That analysis is focused on measuring the proximity of incumbent LEC wire centers to competitive fiber and shows that the vast majority of locations with BDS demand in price cap areas are served by wire centers that are no more than a half mile from competitive fiber. The Wireline Competition Bureau (Bureau) made that additional analysis available for public review and sought and received an additional seven comments and six reply comments about those data tables (the *April Data Tables*). As a result of these two additional rounds of comments, we now have an even more robust record.

B. Forbearance Under Section 10 of the Act

5. Section 10 of the Communications Act of 1934 as amended by the Telecommunications Act of 1996 (the Act) requires the Commission to forbear from applying any requirement of the Act or of our regulations to a telecommunications carrier or telecommunications service if and only if the Commission determines that: (1) Enforcement of the requirement ''is not necessary to ensure that the charges, practices, classifications, or regulations by, for, or in connection with that telecommunications carrier or telecommunications service are just and reasonable and are not unjustly or unreasonably discriminatory;'' (2) enforcement of that requirement ''is not necessary for the protection of consumers;'' and (3) ''forbearance from applying that requirement is consistent with the public interest.'' Forbearance is warranted only if all three criteria are satisfied.

II. Eliminating Ex Ante Pricing Regulation of BDS TDM Transport Services Offered by Price Cap LECs (Report and Order on Remand)

6. After careful review of the record, we reaffirm the Commission's previous decision to eliminate ex ante pricing regulation of TDM transport services in areas served by price cap LECs. The current record, even more so than the record that was before the Commission in 2017, demonstrates that widespread and ever-increasing competition in the supply of BDS transport makes ex ante pricing regulation of TDM transport in price cap areas both unnecessary and unduly burdensome. We therefore grant nationwide relief from ex ante pricing regulation of BDS TDM transport services in price cap areas, forbear from applying Section 203 tariffing requirements to these services, and adopt permissive detariffing for price cap LECs' BDS TDM transport services for a transition period, followed by mandatory detariffing of these services.

A. Competition for BDS TDM Transport

7. In finding that there is widespread and increasing competition for BDS TDM transport services in price cap areas, we rely in part on the evidence and analysis that was before the Commission in 2017 and also on evidence and analysis added to the record through two additional rounds of public comment following the Eighth Circuit Court's remand. Indeed, the additional submissions to the record have substantiated the reasonableness of the Commission's previous findings, and nothing in those submissions would cause us to modify the conclusions the Commission previously made concerning the state of competition for TDM transport services. As the Commission did in 2017, we find particularly persuasive the data that shows that as of 2013: (1) ''competitive providers ha[d] deployed competing transport networks in more than 95% of census blocks with [BDS] demand'' which included ''about 99% of business establishments;'' (2) ''in all price cap territories, 92.1 percent of buildings served were within a half mile of competitive fiber transport facilities'' and that, ''for all census blocks with business data services demand, 89.6 percent have at least one served building within a half mile of competitive LEC fiber;'' and (3) buildings with BDS demand that were served only by an incumbent LEC were on average only 364 feet from the closest competitive LEC fiber facility.

8. We continue to find that competitive suppliers with nearby fiber put competitive pressure on transport prices. As the Commission previously found, the record demonstrates that providers actively compete for customers located within about a half mile from their networks. That is because wireline providers of BDS are commonly willing to extend their existing networks a half mile or further to meet demand. Thus, the fact that 92.1% of buildings served with business data services in price cap areas were within a half mile of competitive fiber transport facilities and that, 89.6% of census blocks with BDS demand in price cap areas had at least one served building within a half mile of competitive LEC fiber, demonstrates the widespread competitive pressure on TDM transport in price cap areas.

9. INCOMPAS disagrees and argues that the relevant measure of competition in the supply of TDM transport is the proximity of competitive fiber to incumbent LEC wire centers rather than the proximity of fiber to buildings with BDS demand. We find this argument to be misplaced. As the record demonstrates, while competitive LECs sometimes use transport links that are collocated at incumbent LEC wire centers, they often connect customers directly to their fiber facilities, effectively bypassing the incumbent LEC network. For example, cable operators compete with price cap incumbent LECs for transport services, but do not rely on interconnection with incumbent LEC wire centers to provide service. Commenters also observe competitors' increasing reliance on third party carrier hotels and data centers, which provide competitive LECs alternatives to incumbent LEC wire centers. Therefore, using the proximity of price cap LEC wire centers to competitive LEC fiber to measure the competitiveness of TDM transport would, by itself, understate the level of competition for TDM transport by failing to account for competition that bypasses incumbent LEC networks.

10. Moreover, we agree with commenters that argue that our decision to measure the proximity of buildings with BDS demand to competitive fiber is ''both more granular and more comprehensive'' than the competitive LECs' alternative proposal to measure the proximity of incumbent LEC wire centers to competitive fiber. Our metric assesses competition at approximately 1.2 million locations with BDS demand whereas there are fewer than 16,000 price cap incumbent LEC wire centers.

11. In the interest in having as complete a record as possible, however, earlier this year, using data from the *2015 Collection,* Commission staff included in the record the *April Data Tables* that show that the vast majority of locations with BDS demand are served by wire centers that were within a half mile of competitive fiber. More specifically, staff analysis demonstrates that, in 2013, 75.7% of price cap LEC wire center locations were within a half mile of competitive fiber. INCOMPAS's own analysis confirms this finding. Commission staff determined that only 5.6% of locations with BDS demand are likely served by incumbent LEC wire centers without competitive LEC fiber within a half mile. Staff further calculated that only 2.7% of all locations with BDS demand were either likely served by wire centers without nearby competitive fiber or were themselves not within a half mile of such fiber.

12. As CenturyLink explains, the ''tables confirm that competitors can connect to the vast majority of ILEC central offices, and particularly those with meaningful demand for business services, to supplement their own competitive networks.'' At the same time, the *April Data Tables* ''dramatically understate competition for these services, as cable companies and other competitors frequently bypass ILEC networks entirely, eliminating the need for them to connect to ILEC wire centers to reach end-user customers.'' Moreover, the *April Data Tables* reflect only the competitive fiber that existed in 2013; as the record demonstrates, however, competitive fiber providers have continued to build new fiber routes in part to compete with incumbent LECs' BDS offerings.

13. Commenters challenge the validity of the Commission's *April Data Tables* on various grounds. For example, INCOMPAS argues that without information about the distance between wire centers and the nearest splice point or interconnection point on the competitive provider's network, the *April Data Tables* understate the barriers to competitive entry. INCOMPAS cites Commission precedent regarding using the distance to splice points to measure competition, and notes the lack of splice point data in the record.

14. However, given the fact that fiber operators commonly install interconnection points at regular intervals on the fiber they deploy, measuring the distance to fiber is a reasonable proxy for measuring the distance to a splice point. As CenturyLink explains, installing an interconnection point on fiber is neither ''particularly burdensome [nor] otherwise unachievable . . . . If there is sufficient demand, carriers will

naturally install interconnection points nearby when they deploy fiber, and even if they do not, it is still possible to add new splice points.'' It further observes that ''[e]stablishing a splice point generally does not significantly increase the cost of adding a new customer location to CenturyLink's network . . . . As a result, the need for a new splice point typically does not negatively affect the business case for deploying a fiber lateral to serve a new customer . . . .'' These statements are unrebutted in the record. We believe the data on fiber locations represents the best data available to the Commission and find they provide a reasonable means by which to estimate competitive pressure generated by the proximity of competitive fiber.

15. We also find the suggestion that it is improper to include cable fiber in the *April Data Tables,* since cable providers do not collocate in incumbent LEC wire centers to sell transport, to be premised on an unnecessarily narrow and outdated view of competition that requires interconnection with the incumbent LEC. It misses the competitive pressure that nearby cable fiber exerts on the incumbent LEC regardless of whether it interconnects with the incumbent LEC. Competitive LEC fiber, including cable fiber, remains relevant to a competitive analysis regardless of whether competitors connect with incumbent facilities or bypass them.

16. We reaffirm the Commission's finding that the presence or reasonable proximity of a single competitor's facilities represents competition given the high sunk cost nature of BDS. At the same time, as some commenters have pointed out, there are major urban areas with as many as 28 competitive transport providers, and second tier metropolitan areas with more than a dozen separate competitive transport providers. While these data are discrete in nature, they are unquestionably relevant to our assessment of TDM transport competition. That some of these competitive providers may not *currently* ''offer a substitute for interoffice DS1 and DS3 facilities in the MSA'' is of limited relevance given our view that TDM transport services are competitive due in part to the *potential* for providers to deploy transport when competitive LEC fiber exists within a half mile of BDS demand. Moreover, the willingness of so many competitors to supply service in these markets is a general indicator of competitiveness and the increasing use of non-incumbent LEC networks for transport.

17. The *2015 Collection* and other data submitted into the record before the adoption of the *2017 BDS Order* necessarily do not account for competitive facilities deployed over the last several years. More recent record submissions show that competition for BDS transport services has continued to grow. The current record shows, for example, that cable operators have ''evolved from new entrants to established providers of BDS . . . .'' In the *BDS Order,* the Commission identified cable service as a substitute for BDS in areas with Metro Ethernet-enabled offerings and for lower speed TDM services but did not find ''broad substitution'' of cable best efforts services for BDS or ''substantial performance similarities'' between the two types of services. Cable now competes for the full range of BDS, and, since it almost always bypasses the incumbent LEC network when it provides service, displaces incumbent LEC transport offerings when it takes a customer. In recent years, cable operators have invested billions of dollars in their hybrid fiber coax (HFC) networks which are now available in most areas where there is BDS demand and which can be repurposed to provide various levels of BDS with only incremental investment. Comcast, for example, reports having invested billions of dollars ''to increase network capacity,'' resulting in ''the largest facilities-based last mile alternative to the phone company.'' Charter Spectrum reportedly spent over $1 billion in 2018 in new fiber infrastructure to increase the density of its national fiber network. Cox is reported to be planning to invest an additional $10 billion into its network over the next five years.

18. According to a recent industry analyst report, ''[c]able companies are leveraging [their] ubiquitous HFC and rapidly expanding fiber networks to gain share in the [BDS] market.'' It states that ''[a]ll major [cable operators] are focused on expanding their network footprints and speed offerings, and Comcast, Cox and other cable companies are working to increase the capacities of their Ethernet over HFC offerings.'' The report also projects that cable providers are ''expected to see share gains across markets, with continued expansion and upgrades of fiber and HFC footprint and focus on growing business and wholesale traction.''

19. As a result of this aggressive investment, cable's BDS revenues and share of BDS revenues have steadily increased. Cable operators' BDS revenues more than doubled from approximately $8 billion in 2013 to more than $18 billion in 2018 and could reach $20 billion by the end of 2019. Atlantic-ACM projects that from 2017 to 2023, cable operators' share of all BDS revenues will grow from 19.7% to an estimated 30.7%. In 2017 alone, cable BDS revenue growth was 10.6%.

20. Traditional competitive LEC's BDS offerings have also increased over the past two years. As one analyst report declares, ''CLECs are aggressively expanding their footprints via network builds or M&A while ILECs are attempting to remain competitive by making major investments to prepare their networks for 5G.'' Fiber-based competitive LECs such as Zayo and Uniti Fiber have deployed significant additional facilities and continue to grow their share of BDS revenues. Zayo reported a 38% increase in fiber route miles from December 2015 (95,000 miles) to November 2018 (131,100 miles). Moreover, as commenters have also observed the increased use of carrier-neutral facilities such as third-party carrier hotels and data centers that bypass incumbent LEC facilities, further suggesting competitive pressure from competitive LECs.

21. As the Commission did in the *BDS Order,* we consider packet-based transport services to be broadly substitutable for TDM-based transport services. Substitution between these two types of services is generally in one direction, and we find that ''circuit- and packet-switched business data services that offer similar speed, functionality, and quality of service characteristics fall within the same product markets'' for the purposes of the market analysis relevant here. Indeed, TDM transport services can be carried over fiber, so fiber providers can offer customers TDM services.

22. There is an ongoing steady decline in demand for TDM transport and increase in demand for packet-based alternatives. One analyst forecasts that legacy TDM transport will decline from $3.2 billion to $1.2 billion from 2017 to 2023. This forecast is supported by data submitted to the record by BDS providers. For example, according to CenturyLink, between 2015 and 2018, its incumbent LEC revenues for TDM transport dropped 9% annually and demand for DS1 and DS3 services ''has been declining for years as customers migrate to Ethernet and other packet-based services that are easily scalable to meet their growing bandwidth needs.'' Similarly, AT&T reports that its ''revenues for DS1 and D[S]3 transport have continued to decline substantially since 2015 due to the availability of competitive alternatives and the fact that many competitors (*e.g.,* cable companies) do not purchase much transport from ILECs at all.''

23. In light of the record of continued aggressive deployment by competitors of BDS-capable network facilities since the *BDS Order,* we find unpersuasive arguments that our analysis fails to sufficiently consider the barriers to supplying TDM transport and whether those barriers identified are significant enough to prevent robust competition. As the Commission previously explained, while entry barriers to BDS supply may seem high, competitors nonetheless frequently choose to make significant investment to enter these markets. And, given that transport services typically connect points of traffic aggregation and therefore offer relatively greater revenue opportunity than end user channel terminations, barriers to entry to supply transport are lower than for other types of BDS. Additionally, because fiber connections are a sunk cost, and it is efficient to deploy many more strands than are initially used, once competitors deploy facilities, they have every incentive to price competitively (as do the incumbents against whom they compete).

24. Some commenters' arguments about barriers to entry are based on an unjustifiably narrow view of BDS transport competition which is premised on competition that is interconnected with, and therefore dependent on, incumbent LEC infrastructure. This argument ignores substantial and growing evidence that competitors often bypass the incumbent LEC network entirely. Indeed, as the Commission has previously recognized, ''cable operators self-provision all aspects of their BDS, including transport functionality,'' and therefore do not rely on incumbent LEC central offices to offer competitive TDM transport services and competitive LECs are increasingly bypassing incumbent LEC infrastructure. As AT&T explains, ''CLECs do not need to collocate in ILEC central offices, or to replicate ILEC transport paths, in order to provide a competitive alternative that disciplines ILEC rates.''

25. Finally, we find unpersuasive the assertion by some commenters that incumbent LECs retain market power over DS1 and DS3 channel terminations, which they contend extends to TDM transport, thus rendering some TDM transport markets noncompetitive. As an initial matter, the Commission's competitive market test in the *BDS Order,* which was upheld on appeal by the Eighth Circuit, determined that 91.1% of locations with DS1 and DS3 end user channel termination demand were competitive. In support of their position, these commenters argue that the market analysis conducted by Dr. Marc Rysman on behalf of the Commission showed that incumbent LECs exercised some market power over DS1 and DS3 services. The conclusions they cite from the Rysman study, however, were specific to DS1 and DS3 channel terminations. Moreover, as the Commission explained in the *BDS Order,* the data used in Dr. Rysman's analysis were examined by peer reviewers and were found to be ''too noisy to draw any firm conclusions,'' and therefore the Commission chose not to rely on these to draw conclusions about markets for DS1 and DS3 services. Additionally, Dr. Rysman's analysis was based on pricing data for full circuit service which combined data for channel termination, transport, and other services. Dr. Rysman did not attempt to draw conclusions specific to TDM transport. In fact, Dr. Rysman removed from his study all data specific to standalone transport services ''because the cost structure behind providing transport is likely to be substantially different from providing service to end-user premises and therefore would make comparisons of prices less meaningful.''

B. Removing Ex Ante Pricing Regulation

26. Given our finding that the supply of TDM transport services is sufficiently competitive across the country that the continued application of ex ante pricing regulation would do more harm than good, and consistent with the recommendation made by numerous commenters, we reaffirm the Commission's decision in the *BDS Order* to remove ex ante pricing regulation of BDS TDM transport and other transport (*i.e.,* non-end user channel termination) services in price cap areas nationwide. The record does not support allegations made by some commenters that ''stark differences'' in competitive conditions in different areas preclude the nationwide removal of ex ante pricing regulation. It does demonstrate, as the Commission recognized in the *BDS Order,* that an extremely small percentage of buildings with BDS demand in price cap areas may face the prospect of no regulatory constraint on incumbent LEC prices for TDM transport and no immediate prospect of a competitive alternative. We believe, however, that the costs of imposing ex ante pricing regulation far exceed the benefits of continued regulation of price cap LECs' TDM transport services. Imposing inflexible and burdensome ex ante pricing regulation on TDM transport services would harm the dynamic competitive nature of these markets, could lead to a decrease in new entrants, and would likely delay the transition from TDM- to IP-based offerings. To the limited extent there remain locations where there is not an immediate competitive threat, the Commission has previously explained that we anticipate reasonably competitive outcomes in the short- to medium-term (*i.e.,* over several years) will discipline prices. As a result, we find that such locations do not preclude our adoption of a nationwide solution. Moreover, as the Commission previously recognized, ''our goal is not absolute mathematical precision but an administratively feasible approach that avoids imposing undue regulatory burdens on this highly competitive segment of the market.'' Refraining from pricing regulation for TDM transport services in price cap areas nationally achieves the proper balance between precision and administrability, particularly given the fact that parties continue to be able to file complaints with the Commission pursuant to section 208 of the Act.

27. As a result, we do not support proposals that we adopt a competitive market test for TDM transport services. The fact that the Commission adopted a competitive market test for TDM channel terminations in price cap areas does not compel the adoption of a competitive market test for TDM transport services. The Commission has always distinguished its analysis and regulation of these markets and presuming that a test for one set of services means that a competitive market test for the other is necessary or even possible, wrongly conflates the two. Indeed, commenters that support a competitive market test for TDM transport concede that a ''competitive market test for transport should be distinct from that used for channel termination given the differences between the two types of services.'' Moreover, they claim that the record ''does not[ ] contain data on the extent of competition by different transport service providers'' and urge the Commission to ''further develop the record.''

28. We see no benefit to prolonging this long-running proceeding to conduct a further data collection for TDM transport services. Given the very significant burdens and delays involved in the Commission's *2015 Collection,* the benefits of collecting additional data on TDM transport competition to develop a separate TDM transport competitive market test would need to be substantial to justify the burdens of such a collection. Commission staff analysis of the *2015 Collection* shows that only 2.7% of locations with BDS

demand in price cap areas in 2013 were neither served by a wire center that was within a half mile of competitive fiber nor were themselves within a half mile of competitive fiber. With competition this extensive, the burdens of a major data collection and of developing and administering a competitive market test for TDM transport services clearly outweigh the benefits.

29. This is particularly true because some commenters arguing for a competitive market test urge us to adopt a route-based test for TDM transport services based on transport routes connecting incumbent LEC wire centers. They argue that the relevant geographic market for TDM transport services is ''the route between two ILEC end offices and not the area within a given distance from a customer's location.'' The providers that suggest adoption of such a test do not explain—even in broad terms—how it would be structured, on what evidence it could be based, or how it could be feasibly administered. Neither do they acknowledge that the incumbent LEC-centric nature of such a test would not account for competitors that bypass incumbent LEC infrastructure. Nor do they take into account the fact that price cap LECs ''generally do not price their transport services on a route-by-route basis.'' Given the evidence of extensive and still growing competition for transport services in the vast majority of the areas served by price cap carriers where there is BDS demand, we cannot justify imposing burdensome new ex ante pricing regulation on BDS offerings based on the results of a test that will not actually be able to identify where there are failures in the transport market, but could inhibit investment in this dynamic marketplace.

30. We also reject arguments made by some commenters that nationwide deregulation of TDM transport will have secondary consequences for the pricing of channel terminations in those price cap counties that the *BDS Order* deemed insufficiently competitive to warrant removal of ex ante pricing regulation. These parties argue that eliminating pricing regulations for TDM transport would allow price cap LECs to evade the price caps that remain on channel terminations in areas deemed non-competitive by allowing them to impose offsetting rate increases on TDM transport services in those counties. We find this reasoning flawed. The argument assumes that, if a provider tried to charge supracompetitive rates on transport services to compensate for price-capped channel terminations, competitors would not respond to such increased transport prices with additional investment in transport facilities. However, given the evidence of widespread competitive entry for BDS transport, there is reason to believe that the likely result of a price cap LEC charging supracompetitive rates on transport services would be the entry of a competitor with the capacity to bypass facilities being added in response. The competitive LECs' view of the BDS marketplace ignores the evidence of competitive pressure in the record. Moreover, in the more than two years since the adoption of the *BDS Order,* ex ante pricing regulation of TDM transport has been largely removed in price cap areas, even in counties where the Commission retained price cap regulation over price cap LECs' DS1 and DS3 channel terminations. Yet, competitive LECs cite no instance where deregulating transport rates has undercut price cap regulation of channel terminations. In light of this experience, the competitive LECs' concern seems speculative.

31. Refraining from pricing regulation for TDM transport services nationwide achieves the proper balance between precision and administrability. It also avoids unnecessary disruption of existing BDS transport sales arrangements. And, as one commenter explains, the ''risks of overregulation of these services would outweigh any marginal benefit from'' reinstating ex ante pricing regulation ''in this highly competitive sector, by artificially tamping down TDM transport rates, thereby deterring competitive entry and slowing the IP migration.'' Instead, we believe that providing regulatory relief in this market segment will foster conditions that will continue to encourage competitive entry and provide incentive for further investment in fiber transport facilities.

32. Finally, as we previously observed in the *BDS Order,* price cap LECs' TDM transport services continue to be subject to sections 201, 202 and 208 of the Communications Act. These statutory provisions prohibit carriers from imposing rates, terms, and conditions that are unjust, unreasonable, or unreasonably discriminatory.

C. Forbearance From Tariffing

33. To effectuate the approach we take to TDM transport, and consistent with the approach the Commission took in the *BDS* Order, pursuant to section 10 of the Communications Act, we forbear from applying section 203 of the Act and our tariffing requirements to price cap incumbent LECs in their provision of BDS TDM transport services. This forbearance relieves price cap LECs of the requirement to file interstate tariffs for these services nationwide.

34. The Commission has a long history of granting price cap LECs forbearance from tariffing requirements for various of their BDS offerings. More than a decade ago, the Commission provided grants of forbearance to price cap LECs for their packet-switched and optical transmission BDS. Two years ago, in the *BDS Order,* the Commission granted price cap LECs forbearance from the Act's tariffing obligations with respect to the provision of packet-based and higher speed TDM BDS, lower speed TDM transport, and DS1 and DS3 end user channel termination services in counties deemed competitive by the Commission's competitive market test. Based on the record before us, we find that the statutory test for granting forbearance from tariffing obligations for price cap LECs' TDM transport services has been met.

35. First, we find that the widespread existence of competitive alternatives to incumbent LECs' BDS TDM transport offerings means that the application of section 203 of the Act is not necessary to ensure that the charges and practices for price cap LECs' transport services are just and reasonable and not unreasonably discriminatory. Congress enacted section 203 of the Act in an era when tariffs ''were required to protect consumers from unjust, unreasonable, and discriminatory rates in a virtually monopolistic market.'' Over time, the Commission progressively modified its regulation of price cap LECs' BDS to reflect increasing levels of competition in the supply of BDS, and therefore, the reduced need for the protections tariffs that provide. The record demonstrates that current market forces will better ensure that prices for TDM transport offered by price cap LECs are just and reasonable and not unreasonably discriminatory than (necessarily) blunt regulatory measures.

36. Second, for many of the same reasons, we find that enforcement of our tariffing requirements for price cap LECs' BDS TDM transport services is ''not necessary for the protection of consumers,'' and forbearance will benefit consumers. Widespread and increasing competition to BDS services will drive down prices and provide competitive alternatives to those services, which in turn benefits consumers. Moreover, forbearance from tariffing will allow price cap carriers to respond more quickly to competition and be more innovative in the services they offer, also benefitting consumers. Additionally, price cap LEC BDS TDM transport offerings will remain subject to sections 201, 202, and 208 of the Act

and to our enforcement of those provisions through the section 208 complaint process.

37. Third, we find that granting forbearance for price cap LECs' BDS TDM transport services from section 203 of the Act is consistent with the public interest and will promote competitive market conditions. As the Commission found in the *BDS Order,* forbearance from tariffing obligations for TDM transport will promote further BDS competition and deployment in price cap LEC areas. Moreover, tariffing can adversely impact competitive markets by reducing a carrier's incentives to offer price discounts, delaying and increasing the costs of innovation, and inhibiting a carrier from tailoring services to best meet customers' needs. Further, tariffing itself is not without its costs. Forbearing from section 203 and our tariffing rules will reduce unnecessary administrative costs, which can be significant, and allow carriers to redirect their resources to deploying service capabilities and providing service. We continue to adhere to our view that disparate forbearance treatment of carriers providing the same or similar services is not in the public interest, as it creates distortions in the marketplace that may harm consumers. Accordingly, the continued application of section 203 is unnecessary under sections 10(a)(3) and 10(b). Because we find that each of the elements of the section 10 forbearance analysis is satisfied, we must grant forbearance from section 203 tariffing requirements.

D. Transition to Mandatory Detariffing

38. To ensure an orderly transition to a fully detariffed regulatory regime for price cap LECs' TDM transport offerings, we adopt mechanisms that align with those the Commission adopted in the *BDS Order.* As in the *BDS Order,* we also require competitive LECs, which are subject to permissive detariffing, to detariff their remaining transport BDS offerings by the end of this transition. In so doing, we recognize that many price cap LECs have already detariffed their TDM transport in response to the *BDS Order* and these services have remained detariffed given the Eighth Circuit's temporary stay of its partial remand. For those price cap LECs that have not already detariffed their TDM transport, we adopt a new transition period that will begin on the effective date of this Order (which will be 30 days after publication of this Order in the **Federal Register**) and will end on August 1, 2020, the date of the transition period mandated by the *BDS Order* for mandatory detariffing.

39. During this transition, tariffing for TDM transport services by carriers will be permissive—we will accept new tariffs and revisions to existing tariffs for the affected services. Price cap LECs will no longer be required to comply with price cap regulation for their TDM transport services, and once these rules are effective, carriers that wish to continue filing tariffs under the permissive detariffing regime are free to modify such tariffs consistent with this Order. Carriers, including non-incumbent LECs, may remove the relevant portions of their tariffs for the affected services at any time during the transition. Once the transition ends, no price cap carrier may file or maintain any interstate tariffs for affected business data services.

40. Price cap incumbent LECs and competitive LECs may not file or maintain any interstate tariffs for affected business data services once the transition ends. This will prevent carriers from obtaining ''deemed lawful'' status for tariff filings that are not accompanied by cost support and invoking the filed-rate doctrine in contractual disputes with customers. Business data service providers will also be prevented from picking and choosing when they are able to invoke the protections of tariffs.

41. We do not intend our actions to disturb existing contractual or other long-term arrangements—a contract tariff remains a contract even if it is no longer tariffed. As we stated in the *BDS Order,* contract tariffs, term and volume discount plans, and individual circuit plans do not become void upon detariffing. All carriers are to act in good faith to develop solutions to ensure rates remain just and reasonable.

42. The rule amendments we adopt today relating to TDM transport are substantively the same as those the Commission adopted in the *BDS Order,* and as such, impose the same obligations on carriers as the existing rules. We make only minor clarifying changes to the rules. For example, we amend the rules to specify that competitive LECs must detariff their business data services by August 1, 2020.

III. Procedural Matters

43. *Paperwork Reduction Act Analysis*—This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

44. *Congressional Review Act*—The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

45. Final Regulatory Flexibility Analysis—As required by the Regulatory by the Regulatory Flexibility Act of 1980, as amended (RFA) an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the Second Further Notice of Proposed Rulemaking and Further Notice of Proposed Rulemaking (Second Further Notice) for the Time Division Multiplexing (TDM) transport business data services (BDS). The Commission sought written public comment on the proposals in the Second Further Notice, including comment on the IRFA. The Commission received no comments on the IRFA. Because the Commission amends its rules in this Report and Order, the Commission has included this Final Regulatory Flexibility Analysis (FRFA). This present FRFA conforms to the RFA.

A. Need for, and Objectives of, the Proposed Rules

46. In the Second Further Notice, the Commission proposed changes to, and sought comment on, the appropriate regulatory treatment of TDM transport BDS offerings offered by price cap local exchange carriers (LECs). The Commission proposed to remove ex ante pricing regulation from TDM transport business data services offered by price cap LECs. In this Order, we promote competition in the market for BDS TDM transport services by adopting a regulatory framework for those services that better reflects the dynamic competitive nature of price cap LECs' TDM transport markets.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

47. We analyze the market for TDM transport in areas served by price cap incumbent local exchange carriers and conclude that the record in this proceeding demonstrates widespread, significant and growing competition in this segment of the BDS market. We therefore grant nationwide relief from ex ante pricing regulation of these carriers' TDM transport services, forbear from applying Section 203 tariffing requirements to these services, and adopt permissive detariffing for price cap LECs' TDM transport services for a

transition period, followed by mandatory detariffing of these services.

48. The Commission did not receive comments specifically addressing the rules and policies proposed in the IRFA.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

49. The Chief Counsel did not file any comments in response to this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

50. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and by the rule revisions on which the FNPRMs seek comment, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

1. Total Small Entities

51. Small Businesses, Small Organizations, Small Governmental Jurisdictions. Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States which translates to 28.8 million businesses.

52. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of August 2016, there were approximately 356,494 small organizations based on registration and tax data filed by nonprofits with the Internal Revenue Service (IRS).

53. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2012 Census of Governments indicates that there were 90,056 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 37,132 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,184 special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2012 U.S. Census Bureau data for most types of governments in the local government category shows that the majority of these governments have populations of less than 50,000. Based on these data we estimate that at least 49,316 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

2. Broadband Internet Access Service Providers

54. Internet Service Providers (Broadband). Broadband internet service providers include wired (*e.g.,* cable, DSL) and VoIP service providers using their own operated wired telecommunications infrastructure fall in the category of Wired Telecommunication Carriers. Wired Telecommunications Carriers are comprised of establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. The SBA size standard for this category classifies a business as small if it has 1,500 or fewer employees. U.S. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, under this size standard the majority of firms in this industry can be considered small.

3. Wireline Providers

55. Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

56. Incumbent Local Exchange Carriers (Incumbent LECs). Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent LEC services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers as defined above. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 3,117 firms operated in that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by the rules and policies adopted. A total of 1,307 firms reported that they were incumbent local exchange service providers. Of this total, an estimated 1,006 have 1,500 or fewer employees.

57. Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers, as defined above. Under that size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 indicate that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Based on this data, the Commission concludes that the majority of Competitive LECS, CAPs, Shared-Tenant Service Providers, and Other

Local Service Providers, are small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. Also, 72 carriers have reported that they are Other Local Service Providers. Of this total, 70 have 1,500 or fewer employees. Consequently, based on internally researched FCC data, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities.

58. We have included small incumbent LECs in this present RFA analysis. As mentioned above, a ''small business'' under the RFA is one that, inter alia, meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

59. Interexchange Carriers (IXCs). Neither the Commission nor the SBA has developed a definition for Interexchange Carriers. The closest NAICS Code category is Wired Telecommunications Carriers as defined above. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 indicates that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. According to internally developed Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of this total, an estimated 317 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of IXCs are small entities that may be affected by our proposed rules.

60. Local Resellers. The SBA has developed a small business size standard for the category of Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities.

61. Toll Resellers. The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of this total, an estimated 857 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of toll resellers are small entities.

62. Other Toll Carriers. Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable NAICS Code category is for Wired Telecommunications Carriers as defined above. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by rules adopted pursuant to the Second Further Notice.

63. Operator Service Providers (OSPs). Neither the Commission nor the SBA has developed a small business size standard specifically for operator service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 33 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 31 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities.

4. Wireless Providers—Fixed and Mobile

64. Wireless Telecommunications Carriers (except Satellite). This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees

and 12 had employment of 1,000 employees or more. Thus under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

65. The Commission's own data—available in its Universal Licensing System—indicate that, as of October 25, 2016, there are 280 Cellular licensees that will be affected by our actions today. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service, and Specialized Mobile Radio Telephony services. Of this total, an estimated 261 have 1,500 or fewer employees, and 152 have more than 1,500 employees. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

66. Wireless Communications Services. This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions.

67. Wireless Telephony. Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As explained, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, a little less than one third of these entities can be considered small.

5. Cable Service Providers

68. Because section 706 requires us to monitor the deployment of broadband using any technology, we anticipate that some broadband service providers may not provide telephone service. Accordingly, we describe below other types of firms that may provide broadband services, including cable companies, MDS providers, and utilities, among others.

69. Cable and Other Subscription Programming. This industry comprises establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (*e.g.,* limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA has established a size standard for this industry stating that a business in this industry is small if it has 1,500 or fewer employees. The 2012 Economic Census indicates that 367 firms were operational for that entire year. Of this total, 357 operated with less than 1,000 employees. Accordingly, we conclude that a substantial majority of firms in this industry are small under the applicable SBA size standard.

70. Cable Companies and Systems (Rate Regulation). The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are currently 4,600 active cable systems in the United States. Of this total, all but eleven cable operators nationwide are small under the 400,000-subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

71. Cable System Operators (Telecom Act Standard). The Communications Act also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1% of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 52,403,705 cable video subscribers in the United States today. Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard. The Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

72. All Other Telecommunications. ''All Other Telecommunications'' is defined as follows: This U.S. industry is comprised of establishments that are primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing internet services or voice over internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for ''All Other Telecommunications,'' which consists of all such firms with gross annual receipts of $32.5 million or less. For this category, census data for 2012 show that there were 1,442 firms that operated for the entire year. Of these firms, a total of 1,400 had gross annual receipts of less than $25 million. Consequently, we estimate that the majority of All Other Telecommunications firms are small entities that might be affected by our action.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

73. The rule changes in the Order include reducing the unnecessary regulatory burdens and inflexibility of ex ante pricing regulation and tariffing requirements for price cap LECs' TDM

transport services since the Commission has found there is sufficient competition to justify reduced regulation. These rule changes provide additional incentives for competitive entry, network investment and the migration to IP-based network technologies and services.

74. The transition period for detariffing price cap LECs' TDM transport services will begin on the effective date of this Order (thirty (30) days after **Federal Register** publication). Given our desire to align the transition periods we adopt here with those the Commission already adopted in the BDS Order, the transition periods for detariffing TDM transport services will end on the same date that the transition period mandated by the BDS Order for price cap LECs' other BDS services is scheduled to end—August 1, 2020.

75. Specifically, the Order eliminates ex ante pricing regulation and tariffing requirements for price cap LECs' TDM transport BDS. This will eliminate reporting, recordkeeping, and other compliance requirements for any price cap LEC.

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

76. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

77. The rule changes in this Order reduce the economic impact of the Commission's rules on price cap LECs by freeing price cap LECs from ex ante pricing regulation for their TDM transport offerings, including the requirement to tariff their TDM transport services. These rule changes will significantly minimize the economic impact of our rules on price cap LECs.

G. Report to Congress

78. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Order and FRFA (or summaries thereof) will also be published in the **Federal Register**. Final Regulatory Flexibility Analysis.

79. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the Second Further Notice of Proposed Rulemaking and Further Notice of Proposed Rulemaking (Second Further Notice) for the Time Division Multiplexing (TDM) transport business data services (BDS). The Commission sought written public comment on the proposals in the Second Further Notice, including comment on the IRFA. The Commission received no comments on the IRFA. Because the Commission amends its rules in this Report and Order, the Commission has included this Final Regulatory Flexibility Analysis (FRFA). This present FRFA conforms to the RFA.

A. Need for, and Objectives of, the Proposed Rules

80. In the Second Further Notice, the Commission proposed changes to, and sought comment on, the appropriate regulatory treatment of TDM transport BDS offerings offered by price cap local exchange carriers (LECs). The Commission proposed to remove ex ante pricing regulation from TDM transport business data services offered by price cap LECs. In this Order, we promote competition in the market for BDS TDM transport services by adopting a regulatory framework for those services that better reflects the dynamic competitive nature of price cap LECs' TDM transport markets.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

81. We analyze the market for TDM transport in areas served by price cap incumbent local exchange carriers and conclude that the record in this proceeding demonstrates widespread, significant and growing competition in this segment of the BDS market. We therefore grant nationwide relief from ex ante pricing regulation of these carriers' TDM transport services, forbear from applying Section 203 tariffing requirements to these services, and adopt permissive detariffing for price cap LECs' TDM transport services for a transition period, followed by mandatory detariffing of these services.

82. The Commission did not receive comments specifically addressing the rules and policies proposed in the IRFA.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

83. The Chief Counsel did not file any comments in response to this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

84. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and by the rule revisions on which the FNPRMs seek comment, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

1. Total Small Entities

85. Small Businesses, Small Organizations, Small Governmental Jurisdictions. Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States which translates to 28.8 million businesses.

86. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of August 2016, there were approximately 356,494 small organizations based on registration and tax data filed by nonprofits with the Internal Revenue Service (IRS).

87. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data

from the 2012 Census of Governments indicates that there were 90,056 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 37,132 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,184 special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2012 U.S. Census Bureau data for most types of governments in the local government category shows that the majority of these governments have populations of less than 50,000. Based on these data we estimate that at least 49,316 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

2. Broadband Internet Access Service Providers

88. Internet Service Providers (Broadband). Broadband internet service providers include wired (*e.g.,* cable, DSL) and VoIP service providers using their own operated wired telecommunications infrastructure fall in the category of Wired Telecommunication Carriers. Wired Telecommunications Carriers are comprised of establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. The SBA size standard for this category classifies a business as small if it has 1,500 or fewer employees. U.S. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, under this size standard the majority of firms in this industry can be considered small.

3. Wireline Providers

89. Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

90. Incumbent Local Exchange Carriers (Incumbent LECs). Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent LEC services. The closest applicable size standard under SBA rules is for the category Wired Telecommunications Carriers as defined above. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 3,117 firms operated in that year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by the rules and policies adopted. A total of 1,307 firms reported that they were incumbent local exchange service providers. Of this total, an estimated 1,006 have 1,500 or fewer employees.

91. Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers. Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers, as defined above. Under that size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 indicate that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Based on this data, the Commission concludes that the majority of Competitive LECS, CAPs, Shared-Tenant Service Providers, and Other Local Service Providers, are small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. Also, 72 carriers have reported that they are Other Local Service Providers. Of this total, 70 have 1,500 or fewer employees. Consequently, based on internally researched FCC data, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities.

92. We have included small incumbent LECs in this present RFA analysis. As mentioned above, a ''small business'' under the RFA is one that, inter alia, meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

93. Interexchange Carriers (IXCs). Neither the Commission nor the SBA has developed a definition for Interexchange Carriers. The closest NAICS Code category is Wired Telecommunications Carriers as defined above. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 indicates that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. According to internally developed Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of this total, an estimated 317 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of IXCs are small entities that may be affected by our proposed rules.

94. Local Resellers. The SBA has developed a small business size standard for the category of Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity

from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities.

95. Toll Resellers. The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of this total, an estimated 857 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of toll resellers are small entities.

96. Other Toll Carriers. Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable NAICS Code category is for Wired Telecommunications Carriers as defined above. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by rules adopted pursuant to the Second Further Notice.

97. Operator Service Providers (OSPs). Neither the Commission nor the SBA has developed a small business size standard specifically for operator service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 33 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 31 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities.

4. Wireless Providers—Fixed and Mobile

98. Wireless Telecommunications Carriers (except Satellite). This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1,000 employees or more. Thus under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

99. The Commission's own data—available in its Universal Licensing System—indicate that, as of October 25, 2016, there are 280 Cellular licensees that will be affected by our actions today. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service, and Specialized Mobile Radio Telephony services. Of this total, an estimated 261 have 1,500 or fewer employees, and 152 have more than 1,500 employees. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

100. Wireless Communications Services. This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these definitions.

101. Wireless Telephony. Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As explained, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, a little less than one third of these entities can be considered small.

5. Cable Service Providers

102. Because section 706 requires us to monitor the deployment of broadband using any technology, we anticipate that some broadband service providers may not provide telephone service. Accordingly, we describe below other types of firms that may provide broadband services, including cable companies, MDS providers, and utilities, among others.

103. Cable and Other Subscription Programming. This industry comprises establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (*e.g.,* limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA has established a size standard for this industry stating that a business in this industry is small if it has 1,500 or fewer employees. The 2012 Economic Census indicates that 367 firms were operational for that entire year. Of this total, 357 operated with less than 1,000 employees. Accordingly, we conclude that a substantial majority of firms in this industry are small under the applicable SBA size standard.

104. Cable Companies and Systems (Rate Regulation). The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are currently 4,600 active cable systems in the United States. Of this total, all but eleven cable operators nationwide are small under the 400,000-subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

105. Cable System Operators (Telecom Act Standard). The Communications Act also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1% of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 52,403,705 cable video subscribers in the United States today. Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard. The Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

106. All Other Telecommunications. ''All Other Telecommunications'' is defined as follows: This U.S. industry is comprised of establishments that are primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing internet services or voice over internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for ''All Other Telecommunications,'' which consists of all such firms with gross annual receipts of $32.5 million or less. For this category, census data for 2012 show that there were 1,442 firms that operated for the entire year. Of these firms, a total of 1,400 had gross annual receipts of less than $25 million. Consequently, we estimate that the majority of All Other Telecommunications firms are small entities that might be affected by our action.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

107. The rule changes in the Order include reducing the unnecessary regulatory burdens and inflexibility of ex ante pricing regulation and tariffing requirements for price cap LECs' TDM transport services since the Commission has found there is sufficient competition to justify reduced regulation. These rule changes provide additional incentives for competitive entry, network investment and the migration to IP-based network technologies and services.

108. The transition period for detariffing price cap LECs' TDM transport services will begin on the effective date of this Order (thirty (30) days after **Federal Register** publication). Given our desire to align the transition periods we adopt here with those the Commission already adopted in the BDS Order, the transition periods for detariffing TDM transport services will end on the same date that the transition period mandated by the BDS Order for price cap LECs' other BDS services is scheduled to end—August 1, 2020.

109. Specifically, the Order eliminates ex ante pricing regulation and tariffing requirements for price cap LECs' TDM transport BDS. This will eliminate reporting, recordkeeping, and other compliance requirements for any price cap LEC.

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

110. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

111. The rule changes in this Order reduce the economic impact of the Commission's rules on price cap LECs by freeing price cap LECs from ex ante pricing regulation for their TDM transport offerings, including the requirement to tariff their TDM transport services. These rule changes will significantly minimize the economic impact of our rules on price cap LECs.

G. Report to Congress

112. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Order and FRFA (or

summaries thereof) will also be published in the **Federal Register**.

IV. Ordering Clauses

113. *Accordingly, it is ordered* that, pursuant to sections 1, 2, 4(i)–(j), 10, 201(b), 202(a), 403, of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i)–(j), 160, 201(b), 202(a), 403, 1302, this Report and Order on Remand in WC Docket No. 16–143, GN Docket No. 13–5, WC Docket No. 05–25, and RM–10593 *is adopted* and *shall be effective* thirty (30) days after publication in the **Federal Register**.

114. *It is further ordered* that Parts 61 and 69 of the Commission's rules, 47 CFR parts 61 and 69, *are amended* as set forth in Appendix A, and that such rule amendments *shall be effective* thirty (30) days after publication of this Report and Order on Remand in the **Federal Register**.

115. *It is further ordered* that, pursuant to sections 402 and 405 of the Communications Act, 47 U.S.C. 402, 405, the date of ''public notice'' with respect to this Report and Order on Remand of all actions taken herein shall be the date that a summary of this Report and Order on Remand is published in the **Federal Register**. The period for filing petitions for reconsideration or petitions for judicial review of all actions taken herein shall commence on that date. Section 1.4 of the Commission's rules, 47 CFR 1.4, is hereby waived to the extent inconsistent with this paragraph.

116. *It is further ordered* that the Commission's Consumer & Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order on Remand to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

117. *It is further ordered,* that the Commission's Consumer & Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order on Remand, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 61

Communications, Common carriers, Reporting and recordkeeping requirements, Telephone.

47 CFR Part 69

Communications, Common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons set forth in the preamble, the Federal Communications Commission amends parts 61 and 69 of title 47 of the CFR, as follows:

PART 61—TARIFFS

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 201–205, 403, unless otherwise noted.

■ 2. Section 61.201 is amended by revising paragraph (a)(3) to read as follows:

§ 61.201 Detariffing of price cap local exchange carriers.

(a) * * *

(3) Any transport services as defined in § 69.801(j) of this chapter;

* * * * *

■ 3. Section 61.203 is amended by revising paragraph (b) to read as follows:

§ 61.203 Detariffing of competitive local exchange carriers.

* * * * *

(b) The detariffing must be completed by August 1, 2020.

PART 69—ACCESS CHARGES

■ 4. The authority citation for part 69 continues to read as follows:

Authority: 47 U.S.C. 154, 201, 202, 203, 205, 218, 220, 254, 403, unless otherwise noted.

■ 5. Section 69.807 is amended by revising paragraph (a) to read as follows:

§ 69.807 Regulatory relief.

(a) Price cap local exchange carrier TDM transport, end user channel terminations in markets deemed competitive, and end user channel terminations in grandfathered markets for a price cap local exchange carrier that was granted Phase II pricing flexibility prior to June 2017, are granted the following regulatory relief:

(1) Elimination of the rate structure requirements contained in subpart B of this part;

(2) Elimination of price cap regulation; and

(3) Elimination of tariffing requirements as specified in § 61.201 of this chapter.

* * * * *

[FR Doc. 2019–16897 Filed 8–6–19; 8:45 a.m.]

BILLING CODE 6712–01–P

SURFACE TRANSPORTATION BOARD

49 CFR Part 1002

[Docket No. EP 542 (Sub-No. 27)]

Regulations Governing Fees for Services Performed in Connection With Licensing and Related Services—2019 Update

AGENCY: Surface Transportation Board.

ACTION: Final rule.

SUMMARY: The Surface Transportation Board (Board) updates for 2019 the fees that the public must pay to file certain cases and pleadings with the Board. Pursuant to this update, 93 of the Board's 135 fees will be increased and 42 fees will be maintained at their current levels.

DATES: This final rule is effective September 6, 2019.

FOR FURTHER INFORMATION CONTACT: David T. Groves at (202) 245–0327, or Andrea Pope-Matheson at (202) 245–0363. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board's regulations at 49 CFR 1002.3 provide for an annual update of the Board's entire user-fee schedule. Fees are generally revised based on the cost study formula set forth at 49 CFR 1002.3(d), which looks to changes in salary costs, publication costs, and Board overhead cost factors. Additional information is contained in the Board's decision, available at *www.stb.gov.*

List of Subjects in 49 CFR Part 1002

Administrative practice and procedure, Common carriers, and Freedom of information.

Decided: July 31, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Aretha Laws-Byrum,

Clearance Clerk.

For the reasons set forth in the preamble, title 49, chapter X, part 1002, of the Code of Federal Regulations is amended as follows:

PART 1002—FEES

■ 1. The authority citation for part 1002 continues to read as follows:

Authority: 5 U.S.C. 552(a)(4)(A), (a)(6)(B), and 553; 31 U.S.C. 9701; and 49 U.S.C. 1321. Section 1002.1(f)(11) is also issued under 5 U.S.C. 5514 and 31 U.S.C. 3717.

■ 2. Section 1002.1 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1002.1 Fees for records search, review, copying, certification, and related services.

* * * * *

(a) Certificate of the Records Officer, $21.00.

(b) Services involved in examination of tariffs or schedules for preparation of certified copies of tariffs or schedules or extracts therefrom at the rate of $46.00 per hour.

* * * * *

■ 3. Section 1002.2 is amended by revising paragraph (f) to read as follows:

* * * * *

(f) *Schedule of filing fees.*

Type of proceeding	Fee
PART I: Non-Rail Applications or Proceedings to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(1) An application for the pooling or division of traffic	$5,500.
(2) (i) An application involving the purchase, lease, consolidation, merger, or acquisition of control of a motor carrier of passengers under 49 U.S.C. 14303.	$2,500.
(ii) A petition for exemption under 49 U.S.C. 13541 (other than a rulemaking) filed by a non-rail carrier not otherwise covered.	$3,900.
(iii) A petition to revoke an exemption filed under 49 U.S.C. 13541(d)	$3,200.
(3) An application for approval of a non-rail rate association agreement. 49 U.S.C. 13703	$34,300.
(4) An application for approval of an amendment to a non-rail rate association agreement:	
(i) Significant amendment	$5,600.
(ii) Minor amendment	$100.
(5) An application for temporary authority to operate a motor carrier of passengers. 49 U.S.C. 14303(i)	$600.
(6) A notice of exemption for transaction within a motor passenger corporate family that does not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with motor passenger carriers outside the corporate family.	$2,000.
(7)–(10) [Reserved]	
PART II: Rail Licensing Proceedings other than Abandonment or Discontinuance Proceedings:	
(11) (i) An application for a certificate authorizing the extension, acquisition, or operation of lines of railroad. 49 U.S.C. 10901.	$9,000.
(ii) Notice of exemption under 49 CFR 1150.31–1150.35	$2,100.
(iii) Petition for exemption under 49 U.S.C. 10502	$15,600.
(12) (i) An application involving the construction of a rail line	$92,700.
(ii) A notice of exemption involving construction of a rail line under 49 CFR 1150.36	$2,000.
(iii) A petition for exemption under 49 U.S.C. 10502 involving construction of a rail line	$92,700.
(iv) A request for determination of a dispute involving a rail construction that crosses the line of another carrier under 49 U.S.C. 10902(d).	$350.
(13) A Feeder Line Development Program application filed under 49 U.S.C. 10907(b)(1)(A)(i) or 10907(b)(1)(A)(ii)	$2,600.
(14) (i) An application of a class II or class III carrier to acquire an extended or additional rail line under 49 U.S.C. 10902	$7,600.
(ii) Notice of exemption under 49 CFR 1150.41–1150.45	$2,100.
(iii) Petition for exemption under 49 U.S.C. 10502 relating to an exemption from the provisions of 49 U.S.C. 10902	$8,100.
(15) A notice of a modified certificate of public convenience and necessity under 49 CFR 1150.21–1150.24	$2,000.
(16) An application for a land-use-exemption permit for a facility existing as of October 16, 2008 under 49 U.S.C. 10909	$7,400.
(17) An application for a land-use-exemption permit for a facility not existing as of October 16, 2008 under 49 U.S.C. 10909.	$26,200.
(18)–(20) [Reserved]	
PART III: Rail Abandonment or Discontinuance of Transportation Services Proceedings:	
(21) (i) An application for authority to abandon all or a portion of a line of railroad or discontinue operation thereof filed by a railroad (except applications filed by Consolidated Rail Corporation pursuant to the Northeast Rail Service Act [Subtitle E of Title XI of Pub. L. 97–35], bankrupt railroads, or exempt abandonments).	$27,500.
(ii) Notice of an exempt abandonment or discontinuance under 49 CFR 1152.50	$4,400.
(iii) A petition for exemption under 49 U.S.C. 10502	$7,800.
(22) An application for authority to abandon all or a portion of a line of a railroad or operation thereof filed by Consolidated Rail Corporation pursuant to Northeast Rail Service Act.	$550.
(23) Abandonments filed by bankrupt railroads	$2,300.
(24) A request for waiver of filing requirements for abandonment application proceedings	$2,200.
(25) An offer of financial assistance under 49 U.S.C. 10904 relating to the purchase of or subsidy for a rail line proposed for abandonment.	$1,900.
(26) A request to set terms and conditions for the sale of or subsidy for a rail line proposed to be abandoned	$28,100.
(27) (i) Request for a trail use condition in an abandonment proceeding under 16 U.S.C. 1247(d)	$350.
(ii) A request to extend the period to negotiate a trail use agreement	$550.
(28)–(35) [Reserved]	
PART IV: Rail Applications to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(36) An application for use of terminal facilities or other applications under 49 U.S.C. 11102	$23,500.
(37) An application for the pooling or division of traffic. 49 U.S.C. 11322	$12,600.
(38) An application for two or more carriers to consolidate or merge their properties or franchises (or a part thereof) into one corporation for ownership, management, and operation of the properties previously in separate ownership. 49 U.S.C. 11324:	
(i) Major transaction	$1,852,800.
(ii) Significant transaction	$370,500.
(iii) Minor transaction	$8,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$2,000.
(v) Responsive application	$8,900.

Type of proceeding	Fee
(vi) Petition for exemption under 49 U.S.C. 10502	$11,600.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$6,800.
(39) An application of a non-carrier to acquire control of two or more carriers through ownership of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	$1,852,800.
(ii) Significant transaction	$370,500.
(iii) Minor transaction	$8,900.
(iv) A notice of an exempt transaction under 49 CFR 1180.2(d)	$1,500.
(v) Responsive application	$8,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$11,600.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$6,800.
(40) An application to acquire trackage rights over, joint ownership in, or joint use of any railroad lines owned and operated by any other carrier and terminals incidental thereto. 49 U.S.C. 11324:	
(i) Major transaction	$1,852,800.
(ii) Significant transaction	$370,500.
(iii) Minor transaction	$8,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,400.
(v) Responsive application	$8,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$11,600.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$6,800.
(41) An application of a carrier or carriers to purchase, lease, or contract to operate the properties of another, or to acquire control of another by purchase of stock or otherwise. 49 U.S.C. 11324:	
(i) Major transaction	$1,852,800.
(ii) Significant transaction	$370,500.
(iii) Minor transaction	$8,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,600.
(v) Responsive application	$8,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$8,100.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$6,800.
(42) Notice of a joint project involving relocation of a rail line under 49 CFR 1180.2(d)(5)	$2,800.
(43) An application for approval of a rail rate association agreement. 49 U.S.C. 10706	$86,800.
(44) An application for approval of an amendment to a rail rate association agreement. 49 U.S.C. 10706:	
(i) Significant amendment	$16,000.
(ii) Minor amendment	$100.
(45) An application for authority to hold a position as officer or director under 49 U.S.C. 11328	$900.
(46) A petition for exemption under 49 U.S.C. 10502 (other than a rulemaking) filed by rail carrier not otherwise covered	$9,900.
(47) National Railroad Passenger Corporation (Amtrak) conveyance proceeding under 45 U.S.C. 562	$350.
(48) National Railroad Passenger Corporation (Amtrak) compensation proceeding under Section 402(a) of the Rail Passenger Service Act.	$350.
(49)–(55) [Reserved]	
PART V: Formal Proceedings:	
(56) A formal complaint alleging unlawful rates or practices of carriers:	
(i) A formal complaint filed under the coal rate guidelines (Stand-Alone Cost Methodology) alleging unlawful rates and/or practices of rail carriers under 49 U.S.C. 10704(c)(1).	$350.
(ii) A formal complaint involving rail maximum rates filed under the Simplified-SAC methodology	$350.
(iii) A formal complaint involving rail maximum rates filed under the Three Benchmark methodology	$150.
(iv) All other formal complaints (except competitive access complaints)	$350.
(v) Competitive access complaints	$150.
(vi) A request for an order compelling a rail carrier to establish a common carrier rate	$350.
(57) A complaint seeking or a petition requesting institution of an investigation seeking the prescription or division of joint rates or charges. 49 U.S.C. 10705.	$11,000.
(58) A petition for declaratory order:	
(i) A petition for declaratory order involving a dispute over an existing rate or practice which is comparable to a complaint proceeding.	$1,000.
(ii) All other petitions for declaratory order	$1,400.
(59) An application for shipper antitrust immunity. 49 U.S.C. 10706(a)(5)(A)	$8,700.
(60) Labor arbitration proceedings	$350.
(61) (i) An appeal of a Surface Transportation Board decision on the merits or petition to revoke an exemption pursuant to 49 U.S.C. 10502(d).	$350.
(ii) An appeal of a Surface Transportation Board decision on procedural matters except discovery rulings	$450.
(62) Motor carrier undercharge proceedings	$350.
(63) (i) Expedited relief for service inadequacies: A request for expedited relief under 49 U.S.C. 11123 and 49 CFR part 1146 for service emergency.	$350.
(ii) Expedited relief for service inadequacies: A request for temporary relief under 49 U.S.C. 10705 and 11102, and 49 CFR part 1147 for service inadequacy.	$350.
(64) A request for waiver or clarification of regulations except one filed in an abandonment or discontinuance proceeding, or in a major financial proceeding as defined at 49 CFR 1180.2(a).	$700.
(65)–(75) [Reserved]	

Type of proceeding	Fee
PART VI: Informal Proceedings:	
(76) An application for authority to establish released value rates or ratings for motor carriers and freight forwarders of household goods under 49 U.S.C. 14706.	$1,500.
(77) An application for special permission for short notice or the waiver of other tariff publishing requirements	$150.
(78) (i) The filing of tariffs, including supplements, or contract summaries	$1 per page. ($30 min. charge.)
(ii) The filing of water carrier annual certifications	$30.
(79) Special docket applications from rail and water carriers:	
(i) Applications involving $25,000 or less	$75.
(ii) Applications involving over $25,000	$150.
(80) Informal complaint about rail rate applications	$750.
(81) Tariff reconciliation petitions from motor common carriers:	
(i) Petitions involving $25,000 or less	$75.
(ii) Petitions involving over $25,000	$150.
(82) Request for a determination of the applicability or reasonableness of motor carrier rates under 49 U.S.C. 13710(a)(2) and (3).	$300.
(83) Filing of documents for recordation. 49 U.S.C. 11301 and 49 CFR 1177.3(c)	$51 per document.
(84) Informal opinions about rate applications (all modes)	$300.
(85) A railroad accounting interpretation	$1,400.
(86) (i) A request for an informal opinion not otherwise covered	$1,800.
(ii) A proposal to use on a voting trust agreement pursuant to 49 CFR 1013 and 49 CFR 1180.4(b)(4)(iv) in connection with a major control proceeding as defined at 49 CFR 1180.2(a).	$6,300.
(iii) A request for an informal opinion on a voting trust agreement pursuant to 49 CFR 1013.3(a) not otherwise covered.	$650.
(87) Arbitration of certain disputes subject to the statutory jurisdiction of the Surface Transportation Board under 49 CFR 1108:	
(i) Complaint	$75.
(ii) Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(iii) Third Party Complaint	$75.
(iv) Third Party Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(v) Appeals of Arbitration Decisions or Petitions to Modify or Vacate an Arbitration Award	$150.
(88) Basic fee for STB adjudicatory services not otherwise covered	$350.
(89)–(95) [Reserved]	
PART VII: Services:	
(96) Messenger delivery of decision to a railroad carrier's Washington, DC, agent	$40 per delivery.
(97) Request for service or pleading list for proceedings	$30 per list.
(98) Processing the paperwork related to a request for the Carload Waybill Sample to be used in an STB or State proceeding that:.	
(i) Annual request does not require a **Federal Register** (FR) notice:	
(A) Set cost portion	$200.
(B) Sliding cost portion	$58 per party.
(ii) Annual request does require a FR notice:	
(A) Set cost portion	$450.
(B) Sliding cost portion	$58 per party.
(iii) Quarterly request does not require a FR notice:	
(A) Set cost portion	$50.
(B) Sliding cost portion	$14 per party.
(iv) Quarterly request does require a FR notice:	
(A) Set cost portion	$231.
(B) Sliding cost portion	$14 per party.
(v) Monthly request does not require a FR notice:	
(A) Set cost portion	$16.
(B) Sliding cost portion	$4 per party.
(vi) Monthly request does require a FR notice:	
(A) Set cost portion	$177.
(B) Sliding cost portion	$4 per party.
(99) (i) Application fee for the STB's Practitioners' Exam	$200.
(ii) Practitioners' Exam Information Package	$25.
(100) Carload Waybill Sample data:	
(i) Requests for Public Use File for all years prior to the most current year Carload Waybill Sample data available, provided on CD–R.	$250 per year.
(ii) Specialized programming for Waybill requests to the Board	$125 per hour.

* * * * *

[FR Doc. 2019–16738 Filed 8–6–19; 8:45 am]

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Proposed Rules

Federal Register
Vol. 84, No. 152
Wednesday, August 7, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 190726–0005]

RIN 0691–AA89

Direct Investment Surveys: BE–10, Benchmark Survey of U.S. Direct Investment Abroad

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the 2019 BE–10, Benchmark Survey of U.S. Direct Investment Abroad (''BE–10 survey''). The BE–10 survey is conducted every five years; the prior survey covered 2014. The BE–10 survey covers the universe of U.S. direct investment abroad and is BEA's most comprehensive survey of such investment. For the 2019 BE–10 survey, BEA proposes changes in data items collected, the design of the survey forms, and the reporting requirements for the survey to satisfy changing data needs and improve data quality and the effectiveness and efficiency of data collection.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before 5:00 p.m. October 7, 2019.

ADDRESSES: You may submit comments, identified by RIN 0691–AA89 and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. For Keyword or ID, enter ''EAB–2019–0002.''
- *Email: ricardo.limes@bea.gov.*
- *Mail:* Multinational Operations Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–69, Washington, DC 20233.
- *Hand Delivery/Courier:* Multinational Operations Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–69, 4600 Silver Hill Road, Suitland, MD 20746.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent to both BEA through any of the methods above and to the Office of Management and Budget (OMB), OIRA, Paperwork Reduction Project 0608–0049, Attention PRA Desk Officer for BEA, via email at *OIRA_Submission@omb.eop.gov,* or by FAX at 202–395–7245.

Public Inspection: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. Personal identifying information voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments (enter N/A in required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Ricardo Limes, Chief, Multinational Operations Branch (BE–69), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20233; telephone number: (301) 278–9659; email: *ricardo.limes@bea.gov.*

SUPPLEMENTARY INFORMATION: The BE–10, Benchmark Survey of U.S. Direct Investment Abroad, is a mandatory survey and is conducted once every five years by BEA under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The BE–10 survey covers the U.S. direct investment abroad universe and is BEA's most comprehensive survey of such investment. U.S. direct investment abroad is defined as the ownership or control, directly or indirectly, by one U.S. person of 10 percent or more of the voting securities of an incorporated foreign business enterprise or an equivalent interest in an unincorporated foreign business enterprise, including a branch.

The purpose of the BE–10 survey is to obtain universe data on the financial and operating characteristics of, and on positions and transactions between, U.S. parent companies and their foreign affiliates. The data are needed to measure the size and economic significance of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. Such data are generally found in enterprise-level accounting records of respondent companies. The benchmark data provide a baseline for subsequent sample-based estimates in non-benchmark years. In particular, they serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions, international investment position, and national income and product accounts, and for annual estimates of the U.S. direct investment abroad position and of the activities of U.S. multinational enterprises.

This proposed rule would amend 15 CFR part 801 to set forth the reporting requirements for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad. Under this proposed rule, persons subject to the reporting requirements of the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, would be required to respond, whether or not they are contacted by BEA.

The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520 (PRA).

Description of Changes

The proposed changes would amend the regulations and the survey forms for the BE–10 survey. These amendments include changes in data items collected, the design of the survey forms, and the reporting requirements for the survey.

BEA proposes to change the reporting requirements for certain private funds that file the BE–10 survey. BEA, in cooperation with the U.S. Department of the Treasury, proposes to instruct reporters of investments in private funds that meet the definition of direct investment (that is, ownership by one person of 10 percent or more of the voting interest of a business enterprise) but display characteristics of portfolio investment (specifically, investors who

do not intend to control or influence the management of an operating company) to report through the Treasury International Capital (TIC) reporting system. Reporting through TIC is more efficient because other related portfolio investments are already being reported there. Such private funds should not report on the BE–10 survey and BEA's other direct investment surveys. Direct investment in operating companies, including investment by and through private funds, will continue to be reported to BEA. This change has already been implemented on BEA's other surveys of U.S. direct investment abroad: The BE–577, Quarterly Survey of U.S. Direct Investment Abroad; and the BE–11, Annual Survey of U.S. Direct Investment Abroad. Additional information on the change in reporting requirements for investments in private funds can be found in the *Direct Investment Surveys: BE–577, Quarterly Survey of U.S. Direct Investment Abroad-Transactions of U.S. Reporter With Foreign Affiliate, and Changes to Private Fund Reporting on Direct Investment Surveys* **Federal Register** notice issued in 2016 (81 FR 33658).

BEA proposes to add, delete, and modify some items on the BE–10 survey forms. Most of the additions are proposed in response to suggestions from data users and to provide more information about U.S. direct investment abroad. The following items would be added to, or modified on, the BE–10 survey:

(1) The form of organization question for the U.S. reporter (item 2 on the BE–10A form, the form that collects information on the domestic operations of U.S. parent companies) will be modified to include more options: Corporations (except for S corporations); partnerships; S corporations; limited liability companies (LLCs); individual, estate, or trust; and other (specify). This information will help BEA to produce economic statistics by sector.

(2) A question will be added to collect the 20-digit Legal Entity Identifier of each U.S. parent and foreign affiliate on the BE–10A, BE–10B, and BE–10C forms (the BE–10B and BE–10C forms collect information on foreign affiliate operations). This information will assist in matching entities across databases, enabling better verification of data and linking to other surveys and publicly available data.

(3) For each publicly traded company, the stock exchange on which it is listed and the ticker symbol will be collected on the BE–10A form. This information will assist in matching entities across databases, enabling better verification of data and linking to other surveys and publicly available data.

(4) The income statement item on income from equity investments (item 44) on the BE–10A form will be modified to separately collect income from unconsolidated U.S. investments and from foreign investments. This will aid in resolving discrepancies between the BE–10 and the BE–577 surveys.

(5) Item 73 on the BE–10A and item 127 on the BE–10B forms collect the amount of restatement in a company's property, plant, and equipment. This question will be modified to separately collect restatement due to ''change in entity'' and due to ''change in accounting methods or principles.'' A checkbox question will be added to the BE–10A and BE–10B forms asking if the change due to accounting methods or principles is due in whole or in part to implementation of FASB ASU No. 2016–02, Leases (Topic 842). This information will allow BEA to assess the impact on BEA's statistics of the change in accounting standards on leases.

(6) Questions will be added to collect sales, employment, and costs and expenses (excluding compensation) on the BE–10A form, and sales on the BE–10B form, related to the provision of selected services generally recognized as prevalent in the digital economy. These selected services are (1) cloud computing, (2) digital intermediation services on both the BE–10A and BE–10B forms, and (3) advertising on the BE–10B form. In addition, checkboxes will be added to the BE–10A and BE–10B forms to collect the percentage of the respondent's sales of services delivered remotely, sales of services that were digitally ordered, and sales of goods that were digitally ordered, along with checkboxes to identify if this information was sourced from accounting records or from recall/general knowledge. These questions will contribute to BEA's efforts to measure the digital economy.

(7) A checkbox question will be added to the BE–10B and BE–10C forms to capture whether the affiliate serves as a regional headquarters. This information will support research into the role and impact of regional headquarters in the operations of multinational enterprises.

(8) A checkbox question will be added to the BE–10B forms to collect information on the value of R&D performed by the U.S. parent for the foreign affiliate under a collaborative R&D agreement, such as a cost-sharing agreement. This question will help BEA follow the production and use of intellectual property in global value chains and their impacts on economic statistics.

(9) A section will be added to the BE–10 Claim for Not Filing to report affiliates that do not meet the survey reporting requirements. This section will make it easier for reporters to indicate to BEA which affiliates should be removed from the survey.

a. The section would include a private funds exemption option. This is a change to prior reporting requirements described above.

b. There would also be an option to select if the U.S. reporter no longer owns the foreign affiliate and if this was due to the affiliate being sold or liquidated, or because the U.S. reporter's ownership interest in the affiliate fell below 10 percent.

BEA also proposes to eliminate or consolidate the following items from the BE–10 survey:

(1) Item 8 on the BE–10A, which asks if the U.S. reporter is a bank, will be removed. This question was used in the past when reporting requirements for direct investment surveys were different for banks than other *industries* but is no longer needed.

(2) Questions on contract manufacturing services will be deleted (items 33–35 on the BE–10A form). The data collected have been burdensome for companies to provide and have not been widely used by data users. Alternative methods are being developed to measure and study contract manufacturing.

(3) The petroleum and mining exploration and development expenditures item will be removed from the BE–10A form (item 80) and BE–10B form (item 135). This item was used to calculate the current cost adjustment to the direct investment statistics in the international transactions accounts (ITAs) but is not used in the current methodology.

(4) The trade in goods by world region questions (items 99–104 and 109–114) on the BE–10A form will be removed. The data collected have been burdensome for companies to provide and have not been widely used by data users. BEA is exploring alternative methods to produce geographical detail on trade by U.S. multinational companies.

(5) Option 2 of item 11 on the BE–10B form and item 8 on the BE–10C form, which collect information on why the affiliate will no longer report on the survey, will be removed. This information will now be captured on the BE–10 Claim for Not Filing (as discussed in item 9 of the additions and modifications section above). U.S. reporters will no longer be required to complete the rest of the BE–10B or BE–10C form with partial year information

for foreign affiliates that were sold, merged, reorganized, liquidated, seized, or otherwise ceased to exist at some point during, but before the end of, their fiscal year that ended in the calendar year covered by the BE–10 survey.

(6) Items 18 and 19 on the BE–10B form, and 14 and 15 on the BE–10C form, which collect the direct ownership interest held by ''foreign persons in this affiliate's country of location'' and by ''all other foreign persons,'' will be combined into one item on each of the forms.

(7) Questions collecting information on sales by world region (items 105–110) and on sales to the top five countries outside of the country of location of the affiliate (items 111–116) on the BE–10B form will be removed. The data collected have been burdensome for companies to provide and have not been widely used by data users. BEA will continue to collect items 101–104, which allow sales to be disaggregated into goods and services and by whether the sales are to the United States, to the host country, or to other foreign countries. These items are more widely used.

(8) Several items of Part V of the BE–10B form and Part III of the BE–10C form will be removed, except for the items noted below. These data were used to validate the information collected on the quarterly survey, but data reported elsewhere in the BE–10 forms are sufficient for this purpose. The following items will be retained:

a. A question on reverse investment (item 167 on the BE–10B form).

b. Intercompany debt balances (items 63–65 on the BE–10C form) for foreign affiliates with less than $60 million in assets, sales, or net income.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This proposed rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the PRA. The requirement will be submitted to OMB for approval as a reinstatement, with change, of a previously approved collection under OMB control number 0608–0049.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection displays a currently valid OMB control number.

The BE–10 survey, as proposed, is expected to result in the filing of reports from approximately 18,000 respondents. A complete response includes a BE–10A form for the U.S. parent's domestic operation and one or more BE–10B, BE–10C, or BE–10D forms for its foreign affiliates. BEA estimates that U.S. parents will submit 18,000 BE–10A forms, 19,100 BE–10B forms, 14,500 BE–10C forms, 18,000 BE–10D forms, and 2,000 BE–10 Claims for Not Filing. Total annual burden is calculated by multiplying the estimated number of submissions of each form by the average hourly burden per form, which is 10 hours for the BE–10A form, 19 hours for the BE–10B form, 6 hours for the BE–10C form, 3 hours for the BE–10D form, and 0.5 hours for the BE–10 Claim for Not Filing. The estimated total respondent burden for this survey is estimated at 684,900 hours. The respondent burden for this collection of information is expected to vary considerably among respondents because of differences in company structure, size, and complexity. The burden includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The average respondent burden is 38 hours per response (684,900 hours/18,000 respondents), compared to an average burden of 144 hours and total burden of 561,100 hours for the previous (2014) BE–10 survey. The increase in the estimated total respondent burden reflects an increase in the respondent universe of U.S. and foreign entities that are required to file the BE–10 survey. The average burden decreased because the newer respondents on average file fewer and more abbreviated forms and because BEA is proposing a net decrease in the amount of information collected on the survey.

Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent to both BEA and OMB following the instructions given in the **ADDRESSES** section above.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities. The changes proposed in this rule are discussed in the preamble and are not repeated here.

A BE–10 report is required of any U.S. company that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, including a branch—at the end of the U.S. company's 2019 fiscal year. U.S. companies that have direct investments abroad tend to be large. To qualify as a small business, the multinational enterprise as a whole must be evaluated when determining if the business meets the size standards set by the Small Business Administration (SBA), *i.e.* the size determination takes into account the sizes of both the U.S. parents and their foreign operations. BEA estimates that approximately 20 percent of the U.S. multinational enterprises that will be required to respond to the BE–10 survey are small businesses according to the standards established by the SBA. The number of items required to be reported for a U.S. parent and its foreign affiliates is determined by the size of each in terms of assets, sales, and net income. In the BE–10 survey, for the smallest foreign affiliates—those with assets, sales or gross operating revenues, and net income (loss) less than or equal to $25 million (positive or negative)—only a few selected items would be reported on a schedule-type form, Form BE–10D. To further ease the reporting burden on smaller U.S. companies, U.S. reporters with total assets, sales or gross operating revenues, and net income (loss) less than or equal to $300 million (positive or negative) are required to report a subset of items on the BE–10A form for U.S. reporters, in addition to forms they may be required to file for their foreign

affiliates. BEA expects that virtually all small businesses filing the BE–10 will complete an abbreviated BE–10A and BE–10D. The proposed changes represent a net decrease in the amount of information collected on the survey, further reducing the economic impact on small businesses required to file the survey.

Because relatively few small businesses are impacted by this rule, and because those small businesses that are impacted are subject to only minimal recordkeeping burdens, the Chief Counsel for Regulation certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 801

Economic statistics, International transactions, Multinational companies, Penalties, Reporting and recordkeeping requirements, U.S. direct investment abroad.

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA proposes to amend 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.8 to read as follows:

§ 801.8 Rules and regulations for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad.

A BE–10, Benchmark Survey of U.S. Direct Investment Abroad will be conducted every five years and covers years ending in 4 and 9. All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 through 801.2 and §§ 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–10 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, contained in this section, whether or not they are contacted by BEA. Also, a person, or their agent, contacted in writing by BEA about reporting in this survey must respond by filing a properly completed BE–10 report (BE–10A and BE–10B, BE–10C, BE–10D, and/or BE–10 Claim for Not Filing);

(b) *Who must report.* A BE–10 report is required of any U.S. person that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, including a branch—at the end of the U.S. person's fiscal year that ended in the calendar year covered by the survey. Foreign affiliates that are private funds and meet certain criteria are exempt from the BE–10 survey. Specifically, if a foreign affiliate meets ALL of the following 3 criteria, the U.S. reporter is not required to file a BE–10 form for that affiliate except to indicate exemption from the survey if contacted by BEA: (1) The foreign affiliate is a private fund; AND (2) the private fund foreign affiliate does not own, directly or indirectly through another business enterprise, an ''operating company''—*i.e.,* a business enterprise that is not a private fund or a holding company—in which the consolidated U.S. reporter owns at least 10 percent of the voting interest; AND (3) if the U.S. reporter owns the private fund indirectly (through one or more other business enterprises), there are no ''operating companies'' between the consolidated U.S. reporter and the indirectly-owned foreign private fund.

(c) *Forms to be filed.* (1) Form BE–10A must be completed by a U.S. reporter. Form BE–10A is required to cover the fully consolidated U.S. domestic business enterprise. It must also file Form(s) BE–10B, BE–10C, and/or BE–10D for its foreign affiliates, whether held directly or indirectly.

(2) Form BE–10B must be filed for each majority-owned foreign affiliate (for purposes of this survey, a ''majority-owned'' foreign affiliate is one in which the combined direct and indirect ownership interest of all U.S. parents of the foreign affiliate exceeds 50 percent) for which any of the following three items (not just the U.S. reporter's share) was greater than $80 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey:

(i) Total assets (without netting liabilities);

(ii) Sales or gross operating revenues, excluding sales taxes; or

(iii) Net income after provision for foreign income taxes.

(3) Form BE–10C must be filed:

(i) For each majority-owned foreign affiliate for which any one of the three items listed in paragraph (c)(2) of this section was greater than $25 million but for which none of these items was greater than $80 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey, and

(ii) For each minority-owned foreign affiliate (for purposes of this survey, a ''minority-owned'' foreign affiliate is one in which the combined direct and indirect ownership interest of all U.S. parents of the foreign affiliate is 50 percent or less) for which any one of the three items listed in paragraph (c)(2) of this section was greater than $25 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(4) Form BE–10D must be filed for majority- or minority-owned foreign affiliates for which none of the three items listed in paragraph (c)(2) of this section was greater than $25 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey. Form BE–10D is a schedule; a U.S. reporter would submit one or more pages of the form depending on the number of affiliates that are required to be filed on this form.

(5) BE–10 Claim for Not Filing will be provided for response by:

(i) Persons that are not subject to the reporting requirements of the BE–10 survey but have been contacted by BEA concerning their reporting status; or

(ii) U.S. reporters that have been contacted by BEA concerning their reporting status for foreign affiliates that are no longer subject to the reporting requirements of the BE–10 survey.

(d) *Due date.* A fully completed and certified BE–10 report comprising Form BE–10A and Form(s) BE–10B, BE–10C, BE–10D, and/or BE–10 Claim for Not Filing (as required) is due to be filed with BEA not later than May 31 of the year after the year covered by the survey, for those U.S. reporters filing fewer than 50, and June 30, for those U.S. reporters filing 50 or more, foreign affiliate Forms BE–10B, BE–10C, and/or BE–10D.

[FR Doc. 2019–16628 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–06–P

Notices

Federal Register
Vol. 84, No. 152
Wednesday, August 7, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0075]

Verdeca LLC; Determination of Nonregulated Status of Soybean Genetically Engineered for Yield Increase and Resistance to Glufosinate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the new plant variety HB4 soybean designated as event IND–00410–5, which has been genetically engineered for increased yield and resistance to the herbicide glufosinate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Verdeca LLC in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: This change in regulatory status will be recognized August 7, 2019.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

Supporting documents are also available on the APHIS website at *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS Petition 17–223–01p.

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737–1236; (301) 851–3901; email: *subray.hegde@usda.gov.* To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851–3892, email: *cynthia.a.eck@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 17–223–01p) from Verdeca LLC (Verdeca), seeking a determination of nonregulated status for the new plant variety called HB4 soybean (*Glycine max*) designated as event IND–00410–5 (also OECD unique identifier IND–00410–5), which has been genetically engineered for increased yield. The Verdeca petition states that information collected during field trials and laboratory analyses indicates that HB4 soybean is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process [1] for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice [2] published in the **Federal Register** on November 15, 2017 (82 FR 52873–52874, Docket No. APHIS–2017–0075), APHIS announced the availability of the Verdeca petition for public comment. APHIS solicited comments on the petition for 60 days ending on January 16, 2018, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received five comments on the petition (a sixth comment addressing an entirely different topic was erroneously submitted). Of the five comments, four were opposed to the deregulation and one comment was in support. In May 2018, Verdeca provided supplemental information to APHIS informing us that its HB4 soybean variety also had field-level resistance to the herbicide glufosinate. APHIS reviewed the supplemental information and included it in its analyses in the draft plant pest risk assessment (PPRA) and draft environmental assessment (EA).

APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS is following Approach 2, where we first solicit written comments from the public on a draft EA and a draft PPRA for a 30-day comment period through the publication of a **Federal Register** notice. Then, after reviewing and evaluating the comments on the draft EA and the draft PPRA and other information, APHIS revises the draft

[1] On March 6, 2012, we published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms (see *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129*).

[2] To view the notice, the petition, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075*.

PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) finding document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA, draft PPRA, and the supplemental information provided by Verdeca from March 13, 2019, to April 12, 2019.[3] APHIS solicited comments on those documents and whether the subject soybean is likely to pose a plant pest risk. APHIS received three comments on the petition and supporting documents, all of which opposed a decision of nonregulated status for HB4 soybean. Those comments are addressed in our final EA.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and draft PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of HB4 soybean. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of HB4 soybean).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Verdeca, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that HB4 soybean is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of August 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–16920 Filed 8–6–19; 8:45 am]

BILLING CODE 3410–34–P

[3] 84 FR 9077–9078.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0014]

BASF Plant Science, LP; Determination of Nonregulated Status of Canola Genetically Engineered for Altered Oil Profile and Resistance to an Imidazolinone Herbicide

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that canola designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids, including eicosapentaenoic acid and docosahexaenoic acid, from oleic acid in canola seed, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by BASF Plant Science, LP, in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: This change in regulatory status will be recognized August 7, 2019.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS website at *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS Petition 17–321–01p.

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737–1236; (301) 851–3901; email: *subray.hegde@usda.gov.* To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851–3892, email: *cynthia.a.eck@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 17–321–01p) from BASF Plant Science, LP, of Florham Park, NJ (BASF), seeking a determination of nonregulated status of canola (*Brassica napus* L.) designated as event LBFLFK, which has been genetically engineered to allow for the synthesis of long chain omega-3 polyunsaturated fatty acids (LC–PUFAs), including eicosapentaenoic acid (EPA) and docosahexaenoic acid

(DHA), from oleic acid in canola seed. The canola has also been genetically engineered for resistance to an imidazolinone herbicide. The BASF petition states that information collected during field trials and laboratory analyses indicates that LBFLFK canola is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process [1] for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice [2] published in the **Federal Register** on March 30, 2018 (83 FR 13722–13723, Docket No. APHIS–2018–0014), APHIS announced the availability of the BASF petition for public comment. APHIS solicited comments on the petition for 60 days ending on May 29, 2018, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received eight comments on the petition. Three of the comments were from individuals, three were from the canola industry, one was from a public interest group, and one was from a State government. APHIS evaluated the issues raised during the comment period and, where appropriate, provided a discussion of those issues in our draft environmental assessment (EA).

APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS is following Approach 2, where we first solicit written comments from the public on a draft EA and a draft plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a **Federal Register** notice. Then, after reviewing and evaluating the comments on the draft EA and the draft PPRA and other information, APHIS revises the draft PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) finding document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and draft PPRA from April 4, 2019, to May 6, 2019.[3] APHIS solicited comments on those documents and whether the subject canola is likely to pose a plant pest risk. APHIS received three comments on the petition and supporting documents, one of which opposed and two of which supported a decision of nonregulated status for LBFLFK canola. Those comments are addressed in our final EA.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and draft PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of LBFLFK canola. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of LBFLFK canola).

Determination

Based on APHIS' analysis of field and laboratory data submitted by BASF, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that LBFLFK canola is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of August 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–16921 Filed 8–6–19; 8:45 am]

BILLING CODE 3410–34–P

[1] On March 6, 2012, we published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms (see *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129*).

[2] To view the notice, the petition, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0014.*

[3] 84 FR 13243–13244.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0095]

Addition of Scotland to the List of Regions Classified as Having Controlled Risk for Bovine Spongiform Encephalopathy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Scotland, a region within the United Kingdom, to our list of regions classified as having controlled risk for bovine spongiform encephalopathy (BSE) and have removed Scotland from our list of regions considered negligible risk for BSE. We are taking this action because of the confirmation of classical C-type BSE in an indigenous cow in Scotland.

DATES: The case of BSE in Scotland was confirmed on October 18, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Gordon, Import Risk Analyst, Strategy and Policy, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855–7741; email: *Rebecca.K.Gordon@usda.gov.*

SUPPLEMENTARY INFORMATION:

The regulations in 9 CFR part 92 subpart B, ''Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard To Bovines'' (referred to below as the regulations), set forth the process by which the Animal

and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.* The list can also be obtained by writing to APHIS at Strategy and Policy, 4700 River Road Unit 38, Riverdale, MD 20737.

Under § 92.5(c)(2) of the regulations, if APHIS at any time determines that a region no longer meets the criteria for the risk classification it had previously received, APHIS will remove the region from its list of regions so classified. If the World Organization for Animal Health (OIE) determines the region no longer meets the criteria for the risk classification it had previously received, APHIS may concur with the OIE determination or may request updated information from the region and determine whether to concur with the OIE decision.

On October 19, 2018, the veterinary authority of the United Kingdom reported that Scotland had a case of classical C-type BSE in a 5 year-old indigenous cow; the BSE case was confirmed on October 18, 2018. As a result of this finding, the OIE suspended Scotland's negligible risk status effective October 2, 2018.

Therefore, in accordance with the regulations in § 92.5(c)(2) and in concurrence with the OIE's suspension of Scotland's negligible risk status, we have removed Scotland from our list of regions considered to be negligible risk for BSE and added Scotland to the list of regions classified by APHIS as having controlled risk for BSE.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 31st day of July 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–16902 Filed 8–6–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the national average payments, the amount of money the Federal Government provides States for lunches, afterschool snacks, and breakfasts served to children participating in the National School Lunch and School Breakfast Programs; to the maximum reimbursement rates, the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products. Further adjustments are made to these rates to reflect higher costs of providing meals in Alaska, Hawaii and Puerto Rico. The payments and rates are prescribed on an annual basis each July.

Overall, reimbursement rates this year for the National School Lunch, Breakfast Programs and the Special Milk Program either remained the same or increased compared to last year. Of note, the performance-based reimbursement for lunches certified as meeting the meal pattern increased from 6 cents to 7 cents.

DATES: These rates are effective from July 1, 2019 through June 30, 2020.

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, VA 22302–1594.

SUPPLEMENTARY INFORMATION:

Background

Special Milk Program for Children—Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

National School Lunch and School Breakfast Programs—Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor.

Lunch Payment Levels—Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C.1759 (a)) provides special cash

assistance payments to aid schools in providing free and reduced price lunches. The section 11 National Average Payment Factor for each reduced price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

Performanced-based Reimbursement—In addition to the funding mentioned above, school food authorized certified as meeting the meal pattern and nutrition standard requirements set forth in 7 CFR parts 210 and 220 are eligible to receive performance-based cash assistance for each reimbursable lunch served (an additional seven cents per lunch available beginning July 1, 2019, increased by inflation from six cents to seven cents, and will continue to be adjusted and rounded down to the nearest whole cent).

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced price and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced price, and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced price breakfasts served in schools determined to be in ''severe need'' because they serve a high percentage of needy children.

Adjusted Payments

The following specific section 4, section 11, and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2019 through June 30, 2020. Due to a higher cost of living, the average payments and maximum reimbursements for Alaska, Puerto Rico and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which schools receive as additional assistance for each meal served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Adjustments to the national average payment rates for all lunches served under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

Special Milk Program Payments

For the period July 1, 2019 through June 30, 2020, the rate of reimbursement for a half-pint of milk served to a non-needy child in a school or institution that participates in the Special Milk Program is 21.50 cents reflecting an increase of 1 cent from the School Year (SY) 2018–2019 level. This change is based on the 3.92 percent increase in the Producer Price Index for Fluid Milk Products from May 2018 to May 2019.

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half-pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half-pints) for each half-pint served to an eligible child.

National School Lunch Program Payments

Overall, payments for the National School Lunch Program and the Afterschool Snack Program either remained the same or increased from last years payments due to a 2.94 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2019 through June 30, 2020 in the Consumer Price Index for All Urban Consumers for the food away from home series during the 12-month period May 2018 to May 2019 (from a level of 275.307 in May 2017, as previously published in the **Federal Register** to 283.394 in May 2019).

These changes are reflected below.

Section 4 National Average Payment Factors—In school food authorities that served less than 60 percent free and reduced price lunches in School Year (SY) 2017–2018, the payments for meals served are: *Contiguous States:* Paid rate—32 cents (1 cent increase from the SY 2018–2019 level), free and reduced price rate—32 cents (1 cent increase), maximum rate—40 cents (1 cent increase); *Alaska:* Paid rate—53 cents (2 cents increase), free and reduced price rate—53 cents (2 cents increase), maximum rate—63 cents (2 cents increase); *Hawaii and Puerto Rico:* Paid rate—38 cents (1 cent increase), free and reduced price rate—38 cents (1 cent increase), maximum rate—46 cents (1 cent increase).

In school food authorities that served 60 percent or more free and reduced price lunches in School Year 2017–2018, payments are: *Contiguous States:* Paid rate—34 cents (1 cent increase from the SY 2018–2019 level), free and reduced price rate—34 cents (1 cent increase), maximum rate—40 cents (1 cent increase); *Alaska:* Paid rate—55 cents (2 cents increase), free and reduced price rate—55 cents (2 cents increase), maximum rate—63 cents (2 cents increase); *Hawaii and Puerto Rico:* Paid rate—40 cents (1 cent increase), free and reduced price rate—40 cents (1 cent increase), maximum rate—46 cents (1 cent increase).

Beginning this year, School food authorities certified to receive the performance-based cash assistance will receive an additional 7 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—Contiguous States: Free lunch—3 dollars and 9 cents (9 cents increase from the SY 2018–2019 level), reduced price lunch—2 dollars and 69 cents (9 cents increase); *Alaska:* Free lunch—5 dollars and 1 cent (14 cents increase), reduced price lunch—4 dollars and 61 cents (14 cents increase); *Hawaii and Puerto Rico:* Free lunch—3 dollars and 62 cents (11 cents increase), reduced price lunch—3 dollars and 22 cents (11 cents increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: *Contiguous States:* Free snack—94 cents (3 cents increase from the SY 2018–2019 level), reduced price snack—47 cents (2 cents increase), paid snack—8 cents (no change); *Alaska:* Free snack—1 dollar and 52 cents (4 cents increase), reduced price snack—76 cents (2 cents increase), paid snack—13 cents (no change); *Hawaii and Puerto Rico:* Free snack—1 dollar and 10 cents (4 cents increase), reduced price snack—55 cents (2 cent increase), paid snack—10 cents (1 cent increase).

School Breakfast Program Payments

Overall, payments for the National School Breakfast Program either remained the same or increased from last years payments due to a 2.94 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2019 through June 30, 2020 in the Consumer Price Index for

All Urban Consumers in the Food Away from Home series during the 12-month period May 2018 to May 2019 (from a level of 275.307 in May 2018, as previously published in the **Federal Register** to 283.394 in May 2019).

These changes are reflected below.

For schools ''not in severe need'' the payments are: *Contiguous States:* Free breakfast—1 dollar and 84 cents (5 cents increase from the SY 2018–2019 level), reduced price breakfast—1 dollar and 54 cents (5 cents increase), paid breakfast—31 cents (no change); *Alaska:* Free breakfast—2 dollars and 95 cents (8 cents increase), reduced price breakfast—2 dollars and 65 cents (8 cents increase), paid breakfast—47 cents (1 cent increase); *Hawaii and Puerto Rico:* Free breakfast—2 dollars and 15 cents (6 cents increase), reduced price breakfast—1 dollar and 85 cents (6 cents increase), paid breakfast—36 cents (1 cent increase).

For schools in ''severe need'' the payments are: *Contiguous States:* Free breakfast—2 dollars and 20 cents (6 cents increase from the SY 2018–2019 level), reduced price breakfast—1 dollar and 90 cents (6 cents increase), paid breakfast—31 cents (no change); *Alaska:* Free breakfast—3 dollars and 53 cents (10 cents increase), reduced price breakfast—3 dollars and 23 cents (10 cents increase), paid breakfast—47 cents (1 cent increase); *Hawaii and Puerto Rico:* Free breakfast—2 dollars and 57 cents (7 cents increase), reduced price breakfast—2 dollars and 27 cents (7 cents increase), paid breakfast—36 cents (1 cent increase).

Payment Chart

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including severe need schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia, Virgin Islands, and Guam are those specified for the contiguous States.

BILLING CODE 3410–30–P

SCHOOL PROGRAMS

MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES

Expressed in Dollars or Fractions Thereof

Effective from: July 1, 2019 - June 30, 2020

NATIONAL SCHOOL LUNCH PROGRAM[1]		LESS THAN 60%	LESS THAN 60% + 7 cents[2]	60% OR MORE	60% or MORE + 7 cents[2]	MAXIMUM RATE	MAXIMUM RATE + 7 cents[2]
CONTIGUOUS STATES	PAID	0.32	0.39	0.34	0.41	0.40	0.47
	REDUCED PRICE	3.01	3.08	3.03	3.10	3.18	3.25
	FREE	3.41	3.48	3.43	3.50	3.58	3.65
ALASKA	PAID	0.53	0.60	0.55	0.62	0.63	0.70
	REDUCED PRICE	5.14	5.21	5.16	5.23	5.38	5.45
	FREE	5.54	5.61	5.56	5.63	5.78	5.85
HAWAII and PUERTO RICO	PAID	0.38	0.45	0.40	0.47	0.46	0.53
	REDUCED PRICE	3.60	3.67	3.62	3.69	3.78	3.85
	FREE	4.00	4.07	4.02	4.09	4.18	4.25

SCHOOL BREAKFAST PROGRAM		NON-SEVERE NEED	SEVERE NEED
CONTIGUOUS STATES	PAID	0.31	0.31
	REDUCED PRICE	1.54	1.90
	FREE	1.84	2.20
ALASKA	PAID	0.47	0.47
	REDUCED PRICE	2.65	3.23
	FREE	2.95	3.53
HAWAII and PUERTO RICO	PAID	0.36	0.36
	REDUCED PRICE	1.85	2.27
	FREE	2.15	2.57

SPECIAL MILK PROGRAM	ALL MILK	PAID MILK	FREE MILK
PRICING PROGRAMS WITHOUT FREE OPTION	0.2150	N/A	N/A
PRICING PROGRAMS WITH FREE OPTION	N/A	0.2150	Average Cost Per 1/2 Pint of Milk
NONPRICING PROGRAMS	0.2150	N/A	N/A

AFTERSCHOOL SNACKS SERVED IN AFTERSCHOOL CARE PROGRAMS		
CONTIGUOUS STATES	PAID	0.08
	REDUCED PRICE	0.47
	FREE	0.94
ALASKA	PAID	0.13
	REDUCED PRICE	0.76
	FREE	1.52
HAWAII and PUERTO RICO	PAID	0.10
	REDUCED PRICE	0.55
	FREE	1.10

[1] Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds

[2] Performance-based cash reimbursement (adjusted annually for inflation)

BILLING CODE 3410–30–C

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507),

no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This rule has been determined to be not significant by the Office of Management and Budget in conformance with Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

National School Lunch, School Breakfast, and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553, and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

Authority: Sections 4, 8, 11, and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773(b)).

Dated: August 1, 2019.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2019–16903 Filed 8–6–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Child and Adult Care Food Program: National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period July 1, 2019 Through June 30, 2020

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the annual adjustments to the national average payment rates for meals and snacks served in child care centers, outside-school-hours care centers, at-risk afterschool care centers, and adult day care centers; the food service payment rates for meals and snacks served in day care homes; and the administrative reimbursement rates for sponsoring organizations of day care homes, to reflect changes in the Consumer Price Index. Further adjustments are made to these rates to reflect the higher costs of providing meals in Alaska and Hawaii. The adjustments contained in this notice are made on an annual basis each July, as required by the laws and regulations governing the Child and Adult Care Food Program.

DATES: These rates are effective from July 1, 2019 through June 30, 2020.

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to sections 4, 11, and 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753, 1759a and 1766), section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) and 7 CFR 226.4, 226.12 and 226.13 of the Program regulations, notice is hereby given of the new payment rates for institutions participating in the Child and Adult Care Food Program (CACFP). As provided for under the law, all rates in the CACFP must be revised annually, on July 1, to reflect changes in the Consumer Price Index (CPI), published by the Bureau of Labor Statistics of the United States Department of Labor, for the most recent 12-month period. These rates are in effect during the period July 1, 2019 through June 30, 2020.

Adjusted Payments

The following national average payment factors and food service payment rates for meals and snacks are in effect from July 1, 2019 through June 30, 2020. All amounts are expressed in dollars or fractions thereof. Due to a higher cost of living, the reimbursements for Alaska and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, Puerto Rico, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each lunch or supper served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Adjustments to the national average payment rates for all meals served under the Child and Adult Care Food Program are rounded down to the nearest whole cent.

National Average Payment Rates for Centers

The changes in the national average payment rates for centers reflect a 2.94 percent increase during the 12-month period from May 2018 to May 2019 (from 275.307 in May 2018, as previously published in the **Federal Register**, to 283.394 in May 2019) in the food away from home series of the CPI for All Urban Consumers.

Payments for breakfasts served are: *Contiguous States:* Paid rate—31 cents (no change from 2018–2019 annual level), reduced price rate—1 dollar and 54 cents (5 cents increase), free rate—1 dollar and 84 cents (5 cents increase); *Alaska:* Paid rate—47 cents (1 cent increase), reduced price rate—2 dollars and 65 cents (8 cents increase), free rate—2 dollars and 95 cents (8 cents increase); *Hawaii:* Paid rate—36 cents (1 cent increase), reduced price rate—1 dollar and 85 cents (6 cents increase), free rate—2 dollars and 15 cents (6 cents increase).

Payments for lunch or supper served are: *Contiguous States:* Paid rate—32 cents (1 cent increase from 2018–2019 annual level), reduced price rate—3 dollars and 1 cent (10 cents increase), free rate—3 dollars and 41 cents (10 cents increase); *Alaska:* Paid rate—53 cents (2 cents increase), reduced price rate—5 dollars and 14 cents (16 cents increase), free rate—5 dollars and 54 cents (16 cents increase); *Hawaii:* Paid rate—38 cents (1 cent increase), reduced price rate—3 dollars and 60 cents (12 cents increase), free rate—4 dollars (12 cents increase).

Payments for snack served are: *Contiguous States:* Paid rate—8 cents (no change from 2018–2019 annual level), reduced price rate—47 cents (2 cent increase), free rate—94 cents (3 cents increase); *Alaska:* Paid rate—13 cents (no change), reduced price rate—76 cents (2 cents increase), free rate—1 dollar and 52 cents (4 cents increase); *Hawaii:* Paid rate—10 cents (1 cent increase), reduced price rate—55 cents (2 cent increase), free rate—1 dollar and 10 cents (4 cents increase).

Food Service Payment Rates for Day Care Homes

The changes in the food service payment rates for day care homes reflect a 1.19 percent increase during the 12-month period from May 2018 to May 2019 (from 239.287 in May 2018, as previously published in the **Federal Register**, to 242.145 in May 2019) in the food at home series of the CPI for All Urban Consumers.

Payments for breakfast served are: *Contiguous States:* Tier I—1 dollar and

33 cents (2 cent increase from 2018–2019 annual level) and tier II—48 cents (no change); *Alaska:* Tier I—2 dollars and 12 cents (3 cent increase) and tier II—75 cents (1 cent increase); *Hawaii:* Tier I—1 dollar and 54 cents (1 cent increase) and tier II—56 cents (1 cent increase).

Payments for lunch and supper served are: *Contiguous States:* Tier I—2 dollars and 49 cents (3 cent increase from 2018–2019 annual level) and tier II—1 dollar and 50 cents (2 cent increase); *Alaska:* Tier I—4 dollars and 4 cents (5 cent increase) and tier II—2 dollars and 44 cents (3 cent increase); *Hawaii:* Tier I—2 dollars and 92 cents (4 cent increase) and tier II—1 dollar and 76 cents (2 cents increase).

Payments for snack served are: *Contiguous States:* Tier I—74 cents (1 cent increase from 2018–2019 annual level) and tier II—20 cents (no change); *Alaska:* Tier I—1 dollar and 20 cents (1 cent increase) and tier II—33 cents (no change); *Hawaii:* Tier I—87 cents (1 cent increase) and tier II—24 cents (1 cent increase).

Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes

The changes in the administrative reimbursement rates for sponsoring organizations of day care homes reflect a 1.79 percent increase during the 12-month period, May 2018 to May 2019 (from 251.588 in May 2018, as previously published in the **Federal Register**, to 256.092 in May 2019) in the series for all items of the CPI for All Urban Consumers.

Monthly administrative payments to sponsors for each sponsored day care home are: *Contiguous States:* Initial 50 homes—120 dollars (2 dollar increase from 2018–2019 annual level), next 150 homes—91 dollars (1 dollar increase), next 800 homes—71 dollars (1 dollar increase), each additional home—63 dollars (1 dollar increase); *Alaska:* Initial 50 homes—194 dollars (3 dollar increase), next 150 homes—148 dollars (3 dollar increase), next 800 homes—115 dollars (2 dollar increase), each additional home—102 dollars (2 dollar increase); *Hawaii:* Initial 50 homes—140 dollars (2 dollar increase), next 150 homes—107 dollars (2 dollar increase), next 800 homes—83 dollars (1 dollar increase), each additional home—73 dollars (1 dollar increase).

Payment Chart

The following chart illustrates the national average payment factors and food service payment rates for meals and snacks in effect from July 1, 2019 through June 30, 2020.

BILLING CODE 3410–30–P

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)

Per Meal Rates in Whole or Fractions of U.S. Dollars

Effective from July 1, 2019 - June 30, 2020

CENTERS		BREAKFAST	LUNCH AND SUPPER[1]	SUPPLEMENT
CONTIGUOUS STATES	PAID	0.31	0.32	0.08
	REDUCED PRICE	1.54	3.01	0.47
	FREE	1.84	3.41	0.94
ALASKA	PAID	0.47	0.53	0.13
	REDUCED PRICE	2.65	5.14	0.76
	FREE	2.95	5.54	1.52
HAWAII	PAID	0.36	0.38	0.10
	REDUCED PRICE	1.85	3.60	0.55
	FREE	2.15	4.00	1.10

DAY CARE HOMES	BREAKFAST		LUNCH AND SUPPER		SUPPLEMENT	
	TIER I	TIER II	TIER I	TIER II	TIER I	TIER II
CONTIGUOUS STATES	1.33	0.48	2.49	1.50	0.74	0.20
ALASKA	2.12	0.75	4.04	2.44	1.20	0.33
HAWAII	1.54	0.56	2.92	1.76	0.87	0.24

ADMINISTRATIVE REIMBURSEMENT RATES FOR SPONSORING ORGANIZATIONS OF DAY CARE HOMES *Per Home/Per Month Rates in U.S. Dollars*	Initial 50	Next 150	Next 800	Each Additional
CONTIGUOUS STATES	120	91	71	63
ALASKA	194	148	115	102
HAWAII	140	107	83	73

[1] These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the *Federal Register*.

BILLING CODE 3410–30–C

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has been determined to be exempt under Executive Order 12866.

CACFP is listed in the Catalog of Federal Domestic Assistance under No. 10.558 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

This rule has been determined to be not significant by the Office of Management and Budget (OMB) in conformance with Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

This notice imposes no new reporting or recordkeeping provisions that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518).

Authority: Sections 4(b)(2), 11a, 17(c) and 17(f)(3)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753(b)(2), 1759a, 1766(f)(3)(B)) and section 4(b)(1)(B) of the Child Nutrition Act of 1966 (42 U.S.C. 1773(b)(1)(B)).

Dated: August 1, 2019.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2019–16907 Filed 8–6–19; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wyoming Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of web conference meeting regarding civil

rights concerns related to hate incidents in Wyoming.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Wyoming Advisory Committee (Committee) will hold a meeting via web conference on Thursday, August 29, 2019, from 12:00 p.m.—2:00 p.m. Mountain Time.

Public Call Information: (audio only) Dial: (866) 740–1260; Access Code: 7550833.

Web Access Information: (visual only) The online portion of the meeting may be accessed through the following link: *https://cc.readytalk.com/r/dj5cec7tim0r&eom.* To participate, please access webinar *and* call into conference line.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll-free number (audio only) and web access link (visual only). Please use both the call-in number and the web access link in order to follow the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.* Please click on the ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

Panel Presentations (12:00 p.m.–1:30 p.m.)

- Jack McDevitt, Director, Northeastern University, Institute on Race and Justice
- Brian Levin, Director, CSU San Bernardino, Center for the Study of Hate and Extremism co-presenting with Lisa Nakashima, Legal Fellow

Q & A (1:30 p.m.–1:45 p.m.)

Open Public Comment (1:45 p.m.–2:00 p.m.)

Dated: August 2, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–16868 Filed 8–6–19; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–840]

Carbon and Alloy Steel Threaded Rod From Thailand: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that carbon and alloy steel threaded rod (steel threaded rod) from Thailand is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 7, 2019.

FOR FURTHER INFORMATION CONTACT: Eliza Siordia, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3878.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 19, 2019.[1] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[2] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are steel threaded rods from Thailand. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[3] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product

[1] *See Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 10034 (March 19, 2019) (*Initiation Notice*).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Carbon and Alloy Steel Threaded Rod from Thailand,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

coverage (*i.e.,* scope).[4] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[5] Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available, with adverse inferences, for the mandatory respondent, Tycoons Worldwide Group (Thailand) Co. Ltd. (Tycoons), because this respondent did not timely respond to Commerce's antidumping duty questionnaire. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances exist for Tycoons, and for all other producers and exporters. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. We cannot apply the methodology described in section 735(c)(5)(A) of the Act to calculate the all-others rate because the sole margin in this preliminary determination was derived pursuant to section 776 of the Act. In cases where no weighted-average dumping margin other than margins that are zero, *de minimis,* or those determined entirely under section 776 of the Act has been established for individually examined entities, in accordance with section 735(c)(5)(B) of the Act, Commerce averages the margins calculated by the petitioners in the petition and applies the result to all other entities not individually examined.[6]

In the Petition, the petitioner calculated only one margin.[7] Therefore, we assigned as the all-others rate the only margin in the Petition, which is 20.83 percent.[8]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists during the period January 1, 2018 through December 31, 2018:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Tycoons Worldwide Group (Thailand) Co. Ltd	20.83
All Others	20.83

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise produced or exported by Tycoons and all others. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of shipments of subject merchandise from the producer(s) or exporter(s) identified in this paragraph that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the individually examined company, Tycoons, in this investigation, in accordance with section 776 of the Act, and the applied AFA rate is based solely on the petition, there are no calculations to disclose.

[4] *See Initiation Notice.*

[5] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from India, Taiwan, Thailand, and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated July 22, 2019.

[6] *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2.

[7] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties: Carbon and Alloy Steel Threaded Rod from the People's Republic of China, India, Taiwan, and Thailand,'' dated February 21, 2019 (the Petition).

[8] *See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Purified Carboxymethylcellulose from Sweden,* 69 FR 77213, 77215–16 (December 27, 2004), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Purified Carboxymethylcellulose from Sweden,* 70 FR 28278 (May 17, 2005).

Verification

Because the examined respondents in this investigation did not provide information requested by Commerce, and Commerce preliminarily determines that the examined respondent has been uncooperative, we will not conduct verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 50 days after the date of publication of the preliminary determination, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[9] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Final Determination

Section 735(a)(1) of the Act and 19 CFR 351.210(b)(1) provide that Commerce will issue the final determination within 75 days after the date of its preliminary determination. Accordingly, Commerce will make its final determination no later than 75 days after the signature date of this preliminary determination.

[9] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: July 30, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by the scope of these investigations is carbon and alloy steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon or alloy steel, having a solid, circular cross section of any diameter, in any straight length. Steel threaded rod is normally drawn, cold-rolled, threaded, and straightened, or it may be hot-rolled. In addition, the steel threaded rod, bar, or studs subject to these investigations are non-headed and threaded along greater than 25 percent of their total actual length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Steel threaded rod is normally produced to American Society for Testing and Materials (ASTM) specifications ASTM A36, ASTM A193 B7/B7m, ASTM A193 B16, ASTM A307, ASTM A320 L7/L7M, ASTM A320 L43, ASTM A354 BC and BD, ASTM A449, ASTM F1554–36, ASTM F1554–55, ASTM F1554 Grade 105, American Society of Mechanical Engineers (ASME) specification ASME B18.31.3, and American Petroleum Institute (API) specification API 20E. All steel threaded rod meeting the physical description set forth above is covered by the scope of these investigations, whether or not produced according to a particular standard.

Subject merchandise includes material matching the above description that has been finished, assembled, or packaged in a third country, including by cutting, chamfering, coating, or painting the threaded rod, by attaching the threaded rod to, or packaging it with, another product, or any other finishing, assembly, or packaging operation that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the threaded rod.

Carbon and alloy steel threaded rod are also included in the scope of these investigations whether or not imported attached to, or in conjunction with, other parts and accessories such as nuts and washers. If carbon and alloy steel threaded rod are imported attached to, or in conjunction with, such non-subject merchandise, only the threaded rod is included in the scope.

Excluded from the scope of these investigations are: (1) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total actual length; and (2) stainless steel threaded rod, defined as steel threaded rod containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with our without other elements.

Excluded from the scope of the antidumping investigation on steel threaded rod from the People's Republic of China is any merchandise covered by the existing antidumping order on Certain Steel Threaded Rod from the People's Republic of China. *See Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009).

Specifically excluded from the scope of these investigations is threaded rod that is imported as part of a package of hardware in conjunction with a ready-to-assemble piece of furniture.

Steel threaded rod is currently classifiable under subheadings 7318.15.5051, 7318.15.5056, and 7318.15.5090 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 7318.15.2095 and 7318.19.0000 of the HTSUS. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–16888 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; NIST Invention Disclosure and Inventor Information Collection

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before October 7, 2019.

ADDRESSES: Direct all written comments to Elizabeth Reinhart, Management Analyst, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20889- 1710, (or via the internet at *docpra@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Technology Partnerships Office, 100 Bureau Ave. MS 2200, Gaithersburg, Maryland 301–975–2522, and *donald.archer@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The NIST DN–45 Invention Disclosure Form is used to collect information pertaining to inventions created by Federal employees or by non-Federally employed individuals who have created an invention using NIST laboratory facilities as NIST Associates. The collection of this information is required to protect the United States rights to inventions created using Federal resources. The information collected on the form allows the Government to determine: (1) If an invention has been created; (2) the status of any statutory bar that pertains to the potential invention or that may pertain to the invention in the future. The information collected may allow the Government to begin a patent application process.

The Inventor Information Sheet is used to collect from individuals who have been named as potential inventors on a NIST Invention Disclosure Form. The collection of this information is used for multiple purposes:

(1) Some of the information may be required to file a patent application, if NIST seeks to protect a federally owned invention, pursuant to 35 U.S.C. 207.

(2) The form, in part, is a statement made by the respondent declaring whether the respondent considers herself/himself to be an inventor.

(3) Some of the information is needed for NIST to determine potential assignees with which NIST would potentially negotiate consolidation of rights and other patent related matters.

(4) Some of the information helps NIST determine under which statutory authority NIST may consolidate rights in an invention with other potential assignees.

(5) Country citizenship information is required to determine whether a Scientific and Technology agreement or treaty with the respondent's country may impact the U.S. Government's rights to the invention.

The information is collected by the Technology Partnerships Office and shared with the Office of Chief Counsel at NIST. The information may also be shared with non-Governmental entities that may have ownership rights to the potential invention. The Government collects this information to execute the policy and objective of the Congress expressed at 35 U.S.C. 200. 35 U.S.C. 207 authorizes Federal agencies to apply for, obtain, and maintain patents or other forms of protection . . . on inventions in which the Federal Government owns a right, title, or interest. 35 U.S.C. 207 also authorizes each Federal agency to undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal government. The information collected through the NIST DN–45 is necessary for NIST to execute the authority granted at 35 U.S.C. 207.

II. Method of Collection

Information is collected by completing the NIST DN–45 form which is a template created in Microsoft Word.

III. Data

OMB Control Number: New Collection 0693–XXXX.

Form Number(s): NIST DN–45.

Type of Review: Regular submission.

Affected Public: Individuals.

Estimated Number of Respondents: Invention Disclosure Form—10 per year. Inventor Information Form—100 per year.

Estimated Time per Response: Invention Disclosure Form: 3 hours. Inventor Information Form: 30 minutes.

Estimated Total Annual Burden Hours: Invention Disclosure Form: 30 hours. Inventor Information Form: 50 hours.

Estimated Total Annual Cost to Public: $500.

IV. Request for Comments

NIST invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–16882 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; Baldrige Performance Excellence Program Team Leader Consensus and Site Visit Information Collections

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before October 7, 2019.

ADDRESSES: Direct all written comments to Maureen O'Reilly, Management Analyst, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20889–1710, (or via the internet at *docpra@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Dawn Bailey, Baldrige Performance Excellence Program, 100 Bureau Drive, Stop 1020, Gaithersburg, MD 20899, 301–975–3074, *dawn.bailey@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Public Law 100–107 (The Malcolm Baldrige National Quality Improvement Act of 1987), which established the Baldrige Performance Excellence Program and its Malcolm Baldrige National Quality Award (MBNQA), stipulates that organizational applicants for the award (see OMB Control #0693–0006) receive ''an intensive evaluation by a competent board of examiners which shall review the evidence submitted by the organization and, through a site visit, verify the accuracy of the quality improvements claimed.''

Per the statute, ''the Director of the National Bureau of Standards shall rely upon'' these examiners, as they are in essence the external workforce of the Baldrige Performance Excellence Program. Baldrige Program staff members *manage and improve* the award and all of its processes, but the examiners actually do the objective review of MBNQA applicants.

The Team Leader Consensus and Site Visit Surveys will be one key way that Baldrige staff members can communicate with and seek feedback from the external workforce (Baldrige Examiners). To manage these voluntary examiners (some private citizens, some government and military personnel), the Baldrige Program needs the ability to ask them of their preferences for the sector in which they will do their application review (*e.g.,* do they want to review a health care applicant, manufacturing applicant), their availability to conduct reviews, their ability to travel on a site visit and about all of their logistical needs (*e.g.,* dietary restrictions, cannot review an organization from a certain state due to conflicts in that state), their ability to perform particular MBNQA roles such as technical editor or team leader, their conflicts with a particular organization, etc. The Baldrige Program also needs to survey them to obtain qualitative information on performance, as being a Baldrige Examiner is a very competitive selection.

The Baldrige Program could not perform the intensive evaluation called for in the law without surveying its own workforce about their unique needs in relation to the MBNQA process (and its subprocesses). In fact, these volunteer examiners expect to be asked their preferences, as well as given the ability to give their feedback to improve processes.

II. Method of Collection

Surveys are typically conducted via email or through a secure NIST file-sharing system if any MBNQA organization-specific information needs to be shared. Surveys can also be conducted over the phone if the number of examiners who need to be asked about a particular role or need is less than about 20. Often, a personal phone call is the best way to survey a subset of examiners, as maintaining positive relationships with examiners is very important to the program.

III. Data

OMB Control Number: 0693–0079.

Form Number(s): None.

Type of Review: Extension and revision of a current information collection.

Affected Public: Individuals, including private citizens. All must be U.S. citizens (proof of citizenship is required prior to Baldrige Examiner training).

Estimated Number of Respondents: 350 per year.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 88 hours.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

NIST invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–16883 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

BroadbandUSA Webinar Series

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meetings—Monthly webinars.

SUMMARY: The National Telecommunications and Information Administration (NTIA), as part of its BroadbandUSA program, promotes innovation and economic growth by supporting efforts to expand broadband access and meaningful use across America. BroadbandUSA serves local and state governments, industry and nonprofits that seek to expand broadband connectivity and promote digital inclusion. BroadbandUSA will host a series of webinars on a monthly basis to engage the public and stakeholders with information to accelerate broadband connectivity, improve digital inclusion, strengthen policies and support local priorities. The Practical Broadband Conversations webinar series will provide an ongoing source of information on a range of topics and issues being addressed by BroadbandUSA, including but not limited to best practices for improving broadband deployment, digital inclusion, workforce skills, smart communities, and economic development.

DATES: BroadbandUSA will hold the webinars from 2 p.m. to 3 p.m. Eastern Time on the third Wednesday of every month, beginning October 16, 2019 and continuing through September 16, 2020, with the exception of December 2019 and August 2020.

ADDRESSES: This is a virtual meeting. NTIA will post the registration information on its BroadbandUSA website, *https://broadbandusa.ntia.doc.gov* under Events.

FOR FURTHER INFORMATION CONTACT: Elaine Sloan, National Telecommunications and Information Administration, U.S. Department of Commerce, Room 4872, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8231; email: *BroadbandUSAwebinars@ntia.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email *press@ntia.gov.*

SUPPLEMENTARY INFORMATION: NTIA's BroadbandUSA program serves as a trusted and neutral strategic advisor,

collaborating with federal, state and local government, and industry leaders working to advance smart city and broadband initiatives designed to attract new employers, create quality jobs, improve educational opportunities, increase health outcomes and advance public safety.

BroadbandUSA convenes workshops on a regular basis to bring stakeholders together to discuss ways to improve broadband policies, share best practices, and connect state and local stakeholders to other federal agencies and funding sources for the purpose of expanding broadband infrastructure and adoption throughout America. Experts from NTIA's BroadbandUSA program are available to provide technical assistance and to connect stakeholders with additional resources, such as best practices, guides and program models.

NTIA's BroadbandUSA team convenes events around the country to bring together government, industry and non-profit personnel working to expand broadband connectivity and improve digital inclusion and workforce skills. These webinars are among the events BroadbandUSA uses to share broadband information with the public, broadband stakeholders, tribal, local and state governments and federal programs.

Details on specific webinar topics and webinar registration information will be posted on the BroadbandUSA website, *https://broadbandusa.ntia.doc.gov* under Events. These webinars are subject to change. Webinar time changes will be posted on the BroadbandUSA website, *https://broadbandusa.ntia.doc.gov* under Events, at least thirty days in advance of the webinar. Any webinar cancellation will also be posted on the same website. Any date changes will be published in a new **Federal Register** notice and posted on the website. The presentation, transcript, and recording of each webinar will be posted on the BroadbandUSA website within 7 days following the live webinar.

The public is invited to participate in these webinars. General questions and comments are welcome at any time during webinars via email to *BroadbandUSAwebinars@ntia.gov.* The webinars are open to the public and press. Pre-registration is recommended. NTIA asks each registrant to provide their first and last name, city, state, zip code, job title, organization and email address for both registration purposes and to receive any updates on the BroadbandUSA program via email at *BroadbandUSA@ntia.gov.* Information on webinar content and how to register for one or more webinars will be available on NTIA's website at *https://broadbandusa.ntia.doc.gov* under Events. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify the NTIA contact listed above at least seven (7) business days before the meeting.

Dated: August 2, 2019.

Kathy Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2019–16890 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process on Promoting Software Component Transparency

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene a meeting of a multistakeholder process on promoting software component transparency on September 5, 2019.

DATES: The meeting will be held on September 5, 2019, from 10:00 a.m. to 4:00 p.m., Eastern Time.

ADDRESSES: The meeting will be held at the American Institute of Architects, 1735 New York Ave. NW, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Allan Friedman, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4725, Washington, DC 20230; telephone: (202) 482–4281; email: *afriedman@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs: (202) 482–7002; email: *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background: This National Telecommunications and Information Administration cybersecurity multistakeholder process focuses on promoting software component transparency. Most modern software is not written completely from scratch, but includes existing components, modules, and libraries from the open source and commercial software world. Modern development practices such as code reuse, and a dynamic IT marketplace with acquisitions and mergers, make it challenging to track the use of software components. The Internet of Things compounds this phenomenon, as new organizations, enterprises, and innovators take on the role of software developer to add ''smart'' features or connectivity to their products. While the majority of libraries and components do not have known vulnerabilities, many do, and the sheer quantity of software means that some software products ship with vulnerable or out-of-date components.

The first meeting of this multistakeholder process was held on July 19, 2018, in Washington, DC.[1] Stakeholders presented multiple perspectives, and identified several inter-related work streams: Understanding the Problem, Use Cases and State of Practice, Standards and Formats, and Healthcare Proof of Concept. Since then, stakeholders have been discussing key issues and developing products such as guidance documents. NTIA acts as the convener, but stakeholders drive the outcomes. Success of the process will be evaluated by the extent to which broader findings on software component transparency are implemented across the ecosystem.

The main objectives of the September 5, 2019, meeting are to review drafts provided by the working groups, discuss how they complement each other, and hear feedback from the broader stakeholder community. Stakeholders will also identify next steps in this effort, how progress can be made on extending the basic model, collecting tooling, and promoting awareness and adoption of stakeholder work. More information about stakeholders' work is available at: *https://www.ntia.doc.gov/SoftwareTransparency.*

Time and Date: NTIA will convene the next meeting of the multistakeholder process on Software Component Transparency on September 5, 2019, from 10:00 a.m. to 4:00 p.m. Eastern Time. Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency,* for the most current information.

Place: The meeting will be held at the American Institute of Architects, 1735 New York Ave. NW, Washington, DC 20006. The location of the meeting is subject to change. Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency,* for the most current information.

Other Information: The meeting is open to the public and the press on a first-come, first-served basis. Space is limited.

[1] Notes, presentations, and a video recording of the July 19, 2018, kickoff meeting are available at: *https://www.ntia.doc.gov/SoftwareTransparency.*

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Allan Friedman at (202) 482–4281 or *afriedman@ntia.doc.gov* at least seven (7) business days prior to each meeting. The meetings will also be webcast. Requests for real-time captioning of the webcast or other auxiliary aids should be directed to Allan Friedman at (202) 482–4281 or *afriedman@ntia.doc.gov* at least seven (7) business days prior to each meeting. There will be an opportunity for stakeholders viewing the webcast to participate remotely in the meetings through a moderated conference bridge, including polling functionality. Access details for the meetings are subject to change. Please refer to NTIA's website, *https://www.ntia.doc.gov/SoftwareTransparency,* for the most current information.

Dated: August 2, 2019.

Kathy Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2019–16891 Filed 8–6–19; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Business Board; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Chief Management Officer, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Business Board (''the Board'') will take place.

DATES: Closed to the public Wednesday, August 7, 2019 from 7:55 a.m. to 3 p.m.

ADDRESSES: The closed meeting will be in Room 3E869 in the Pentagon, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Roma Laster, (703) 695–7563 (Voice), (703) 614–4365 (Facsimile), *roma.k.laster.civ@mail.mil* (Email). Mailing address is Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155. Website: *http://dbb.defense.gov/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense (DoD) and the Designated Federal Officer, the Defense Business Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning the August 7, 2019 meeting of the Defense Business Board. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: To obtain, review, and evaluate information related to the Board's mission in advising the Secretary of Defense on overall DoD management and governance on (a) issues central to strategic DoD planning; (b) policy implications of U.S. force structure and force modernization and on DoD's ability to execute U.S. defense strategy; (c) U.S. regional defense policies; and (d) other research and analysis of topics raised by the Secretary of Defense, Deputy Secretary of Defense, or Chief Management Officer (CMO) to allow the Board to provide informed, independent advice reflecting an outside private sector perspective of proven and effective best practices that can be applied to the DoD.

Agenda: The meeting will begin on August 7, 2019 at 7:55 a.m. with opening remarks by Ms. Roma Laster, the Designated Federal Officer, and Mr. Atul Vashistha, Interim Board Chairman. The day's presentations will begin with a series of panel discussions featuring DoD officials and private sector experts that will inform the Board's advice and recommendations to be provided on the CMO's ongoing reform efforts. Panels scheduled are:

—*Human Capital and Talent Management Reform Panel* with senior executives from Goldman Sachs, Activision, Ernst & Young, and Yale School of Management along with representatives from the Office of the Under Secretary of Defense for Acquisitions and Sustainment, Office of the Under Secretary of Defense for Personnel and Readiness, and the Office of the Deputy Assistant Secretary of Defense for Civilian Personnel Policy.

—*Data Management Strategy Reform Panel* with a senior executive from Activision along with representatives from the Office of the Under Secretary of Defense (Comptroller), DoD's Office of the Chief Information Officer, DoD's Office of the Chief Data Officer, and the Office of CMO Business Systems.

—*Shared Services Reform Panel* with senior executives from PepsiCo and United Parcel Service along with representatives from the Defense Logistics Agency, Defense Counterintelligence and Security Agency, and Washington Headquarters Service. Panel participants will provide information on current issues and challenges, and engage in discussions involving commercial or financial information that is privileged or confidential.

Mr. James Baker, Director, Office of Net Assessment (ONA) and Mr. David Ochmanek will provide a classified briefing on current and future strategic challenges to DoD. The meeting will adjourn at 3:00 p.m.

Meeting Accessibility: In accordance with section 10(d) of the FACA and 41 CFR 102–3.155, the DoD has determined that the Board's meeting will be closed to the public. Specifically, the CMO, after consultation with the DoD Office of General Counsel, has determined in writing that the meeting will be closed as it will consider commercial or financial information obtained from a person that is privileged or confidential covered by 5 U.S.C. 552b(4), as well as classified information covered by 5 U.S.C. 552b(c)(1). The 5 U.S.C. 552b(4) determination is based on the consideration that it is expected panel discussions will involve the sharing of commercial or financial information that is privileged or confidential by the private sector participants. The 5 U.S.C. 552b(c)(1) determination is based on the consideration that the ONA briefing is classified and it is expected that discussions throughout the briefing will involve classified matters of national security concern. Such privileged and proprietary information and classified material are so intertwined with the unclassified material that the sessions cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meeting. To permit the meeting to be open to the public would preclude any substantive discussion of such matters and would serve to greatly diminish the ultimate utility of the Board's findings and recommendations to the Secretary of Defense, the Deputy Secretary of Defense, and to the CMO.

Written Statements: Written comments may be submitted to the Designated Federal Officer via email to mailbox address: *osd.pentagon.odam.mbx.defense-business-board@mail.mil* in either Adobe Acrobat or Microsoft Word format. Please note that because the Board operates under the provisions of

the FACA, all submitted comments will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Dated: August 2, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–16875 Filed 8–6–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Board of Visitors of Marine Corps University

AGENCY: Department of the Navy, DoD.

ACTION: Notice of open meeting.

SUMMARY: The Board of Visitors of the Marine Corps University (BOV MCU) will meet to review, develop and provide recommendations on all aspects of the academic and administrative policies of the University; examine all aspects of professional military education operations; and provide such oversight and advice, as is necessary, to facilitate high educational standards and cost effective operations. The Board will be focusing primarily on the internal procedures of Marine Corps University. All sessions of the meeting will be open to the public.

DATES: The meeting will be held on Thursday, September 19, 2019, from 8:00 a.m. to 4:30 p.m. and Friday, September 20, 2019, from 8:00 a.m. to 12:30 p.m. Eastern Time Zone.

ADDRESSES: The meeting will be held at Marine Corps University in Quantico, Virginia. The address is: 2076 South Street, Quantico, VA 22134.

FOR FURTHER INFORMATION CONTACT: Dr. Kim Florich, Director of Faculty Development and Outreach, Marine Corps University Board of Visitors, 2076 South Street, Quantico, Virginia 22134, 703–432–4837.

Dated: August 2, 2019.

M.S. Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–16869 Filed 8–6–19; 8:45 am]

BILLING CODE 3810–FF–P

DENALI COMMISSION

Denali Commission Fiscal Year 2020 Draft Work Plan

AGENCY: Denali Commission.

ACTION: Notice.

SUMMARY: The Denali Commission (Commission) is an independent Federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission was created in 1998 with passage of the October 21, 1998 Denali Commission Act (Act). The Act requires that the Commission develop proposed work plans for future spending and that the annual work plan be published in the **Federal Register**, providing an opportunity for a 30-day period of public review and written comment. This **Federal Register** notice serves to announce the 30-day opportunity for public comment on the Denali Commission Draft Work Plan for Federal Fiscal Year 2020 (FY 2020).

DATES: Comments and related material to be received by September 2, 2019.

ADDRESSES: Submit comments to the Denali Commission, Attention: Elinda Hetami, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Elinda Hetami, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–3415. Email: *ehetemi@denali.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Denali Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to build and ensure the operation and maintenance of Alaska's basic infrastructure, and to develop a well-trained labor force employed in a diversified and sustainable economy.

By creating the Commission, Congress mandated that all parties involved partner together to find new and innovative solutions to the unique infrastructure and economic development challenges in America's most remote communities. Pursuant to the Act, the Commission determines its own basic operating principles and funding criteria on an annual federal fiscal year (October 1 to September 30) basis. The Commission outlines these priorities and funding recommendations in an annual work plan. The FY 2020 Work Plan was developed in the following manner.

- A workgroup comprised of Denali Commissioners and Commission staff developed a preliminary draft work plan.
- The preliminary draft work plan was published on *Denali.gov* for review by the public in advance of public testimony.
- A public hearing was held to record public comments and recommendations on the preliminary draft work plan.
- Written comments on the preliminary draft work plan were accepted for another ten days after the public hearing.
- All public hearing comments and written comments were provided to Commissioners for their review and consideration.
- Commissioners discussed the preliminary draft work plan in a public meeting and then voted on the work plan during the meeting.
- The Commissioners forwarded their recommended work plan to the Federal Co-Chair, who then prepared the draft work plan for publication in the **Federal Register** providing a 30-day period for public review and written comment. During this time, the draft work plan will also be disseminated to Commission program partners including, but not limited to, the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), Department of Agriculture—Rural Utilities Service (USDA/RUS), and the State of Alaska.
- At the conclusion of the **Federal Register** Public comment period Commission staff provides the Federal Co-Chair with a summary of public comments and recommendations, if any, on the draft work plan.
- If no revisions are made to the draft, the Federal Co-Chair provides notice of approval of the work plan to the Commissioners, and forwards the work plan to the Secretary of Commerce for approval; or, if there are revisions the Federal Co-Chair provides notice of modifications to the Commissioners for their consideration and approval, and upon receipt of approval from Commissioners, forwards the work plan to the Secretary of Commerce for approval.
- The Secretary of Commerce approves the work plan.
- The Federal Co-Chair then approves grants and contracts based upon the approved work plan.

FY 2020 Appropriations Summary

The Commission has historically received federal funding from several sources. The two primary sources at this time include the Energy & Water Appropriation Bill (''base'' or ''discretionary'' funds) and an annual allocation from the Trans-Alaska Pipeline Liability (TAPL) fund. The proposed FY 2020 Work Plan assumes the Commission will receive $15,000,000 of base funds, which is the

amount referenced in the reauthorization of the Commission passed by Congress in 2016 (ref: Pub. L. 114–322), and a $2,917,000 TAPL allocation based on discussions with the Office of Management and Budget (OMB). Approximately $2,500,000 of the base funds will be used for administrative expenses and non-project program support, leaving $12,500,000 available for program activities. The total base funding shown in the Work Plan also includes an amount typically available from project closeouts and other de-obligations that occur in any given year. Approximately $117,000 of the TAPL funds will be utilized for administrative expenses and non-project program support, leaving $2,800,000 available for program activities. Absent any new specific direction or limitations provided by Congress in the current Energy & Water Appropriations Bill, these funding sources are governed by the following general principles, either by statute or by language in the Work Plan itself:

- Funds from the Energy & Water Appropriation are eligible for use in all programs.
- TAPL funds can only be used for bulk fuel related projects and activities.
- Appropriated funds may be reduced due to Congressional action, rescissions by OMB, and other federal agency actions.
- All Energy & Water and TAPL investment amounts identified in the work plan, are ''up to'' amounts, and may be reassigned to other programs included in the current year work plan, if they are not fully expended in a program component area or a specific project.
- Energy & Water and TAPL funds set aside for administrative expenses that subsequently become available, may be used for program activities included in the current year work plan.

Denali Commission FY2020 funding summary

Source	Available for program activities
Energy & Water Funds:	
FY 2020 Energy & Water Appropriation [1]	$12,500,000
Prior Year Funds	2,000,000
Subtotal	14,500,000
TAPL Funds:	
FY 2020 Annual Allocation	2,800,000
Grand Total	17,300,000

Notes:
[1.] If the final appropriation is less than $15 million the Federal Co-Chair shall reduce investments to balance the FY 2020 Work Plan.

	Base	TAPL	Total
Energy Reliability and Security:			
Diesel Power Plants and Interties	$3,800,000	.....	$3,800,000
Wind, Hydro, Biomass, Other Proven Renewables and Emerging Technologies	1,000,000	.....	1,000,000
Audits, TA, & Community Energy Efficiency Improvements	500,000	.....	500,000
RPSU Maintenance and Improvement Projects	1,200,000	.....	1,200,000
Subtotal	6,500,000	.....	6,500,000
Bulk Fuel Safety and Security:			
New/Refurbished Facilities	.....	$1,500,000	1,500,000
Maintenance and Improvement Projects	.....	700,000	700,000
Subtotal	0	2,200,000	2,200,000
Village Infrastructure Protection:			
Mertarvik	150,000	.....	150,000
Shishmaref	150,000	.....	150,000
Shaktoolik	150,000	.....	150,000
Kivalina	150,000	.....	150,000
Program Support	400,000	.....	400,000
Subtotal	1,000,000	.....	1,000,000
Transportation	1,000,000	.....	1,000,000
Sanitation:			
Village Water, Wastewater and Solid Waste	2,000,000	.....	2,000,000
Subtotal	2,000,000	.....	2,000,000
Health Facilities	1,000,000	.....	1,000,000
Housing	500,000	.....	500,000
Broadband	1,000,000	.....	1,000,000
Workforce Development:			
Energy and Bulk Fuel	500,000	600,000	1,100,000
Other	1,000,000	.....	1,000,000
Subtotal	1,500,000	600,000	2,100,000
Totals	14,500,000	2,800,000	17,300,000

Energy, Bulk Fuel, Transportation, Sanitation, Health Facilities, Housing, Broadband, Workforce Development

In FY 2020 the Commission is moving in a new direction to work closely with other Federal Agencies, the State of Alaska and regional/local entities with the goal of identifying projects with funding gaps that will allow the Commission to use its small amount of funding to move forward a large number of projects. The Commission has already begun to have conversations with many of our Federal partners and intends to prioritize shovel-ready projects where the Commission can leverage its funds. If the Commission is unable to fully utilize its funding by April of 2020 then it will use any remaining funds to fund Energy and Bulk Fuel projects consistent with a needs-based list established in partnership with the State of Alaska.

Mertarvik, Shishmaref, Shaktoolik and Kivalina

In FY 2020 the Commission will continue to provide support to these communities by funding the relocation coordinator positions. These coordinators will assist the communities in applying for grants and coordinating relocation efforts.

Program Development

The $400,000 referenced above for this line item in the Workplan will be used to fund the ETC Grant Writing Center of Excellence at the Alaska Native Tribal Health Consortium.

Chad Stovall,

Chief Operating Officer.

[FR Doc. 2019–16914 Filed 8–6–19; 8:45 am]

BILLING CODE 3300–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—Technical Assistance and Dissemination Center for the Development and Implementation of High-Quality Instruction, Interventions, and Services for Children With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation. As such, the Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2019 for a Technical Assistance and Dissemination Center for the Development and Implementation of High-Quality Instruction, Interventions, and Services for Children with Disabilities, Catalog of Federal Domestic Assistance (CFDA) number 84.326C. This Center will develop knowledge, curate resources, and disseminate information related to (1) enabling children with disabilities to make progress toward meeting challenging goals and objectives in light of each child's circumstances, and (2) supporting local educational agencies (LEAs), charter management organizations (CMOs), private school associations, and schools in developing and implementing high-quality individualized educational programming. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: August 7, 2019.

Deadline for Transmittal of Applications: September 6, 2019.

Pre-Application Webinar Information: No later than August 12, 2019, OSERS will post pre-recorded informational webinars designed to provide technical assistance to interested applicants. The webinars may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

Pre-Application Q & A Blog: No later than August 12, 2019, OSERS will open a blog where interested applicants may post questions about the application requirements for this competition and where OSERS will post answers to the questions received. OSERS will not respond to questions unrelated to the application requirements for this competition. The blog may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html* and will remain open until August 26, 2019. After the blog closes, applicants should direct questions to the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: David E. Emenheiser, U.S. Department of Education, 400 Maryland Avenue SW, Room 5134, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7556. Email: *David.Emenheiser@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing TA, supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

Priority: This competition includes one absolute priority. In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1463 and 1481(d)).

Absolute Priority: For FY 2019 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Technical Assistance and Dissemination Center for the Development and Implementation of High-Quality Instruction, Interventions, and Services for Children with Disabilities (Center).

Background:

The Individuals with Disabilities Education Act (IDEA) entitles all eligible children with disabilities to a free appropriate public education (FAPE) that emphasizes special education and related services designed to meet their unique needs and prepare them for further education, employment, and independent living. (20 U.S.C. 1400(d)(1)(A)). The individualized education program (IEP) is the primary vehicle through which FAPE is delivered to those eligible children and is the foundation for each

eligible child's special education programming.

The 2017 U.S. Supreme Court's unanimous decision in *Endrew F.* v. *Douglas County School District Re-1,* 137 S. Ct. 988, stated that ''a school must offer an IEP reasonably calculated to enable a child to make progress appropriate in light of the child's circumstances,'' *id.* at 999, and that ''every child should have the chance to meet challenging objectives,'' *id.* at 1000. As the Supreme Court noted, ''The adequacy of a given IEP turns on the unique circumstances of the child for whom it was created.'' *Id.* at 1001. The Court's opinion reiterated that an adequate special education program includes development of challenging objectives in the IEP designed to enable the child with disabilities to make progress. School personnel must ''be able to offer a cogent and responsive explanation for their decisions that shows the IEP is reasonably calculated to enable the child to make progress appropriate in light of his circumstances.'' [1] *Id.* at 1002.

After the Court's ruling, some LEAs and schools requested TA for setting and meeting these high standards. This Center will disseminate to the field knowledge and best practices developed through research and provide intensive TA to a group of LEAs, CMOs, and schools that are examining and testing the features, activities, and relationships that ensure that the broadest set of children with disabilities have access to high-quality IEPs and the provision of a FAPE consistent with the *Endrew F.* decision as articulated by the Court.[2] This Center must be operated in a manner consistent with nondiscrimination requirements contained in the U.S. Constitution and Federal civil rights laws.

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a Technical Assistance and Dissemination Center for the Development and Implementation of High-Quality Instruction, Interventions, and Services for Children with Disabilities (Center). This Center will develop knowledge, disseminate strategies and products, and provide TA for LEAs, CMOs, private school associations, and schools to develop and implement high-quality special education programs that enable children with disabilities to make progress toward meeting challenging objectives in light of each child's circumstances.

The Center must achieve, at a minimum, the following expected outcomes:

(a) Design and refinement of a framework that incorporates theories, knowledge base, and effective policies, procedures, practices, and tools that can be used in a variety of settings [3] to develop and implement high-quality IEPs and the provision of a FAPE consistent with the *Endrew F.* decision by showing positive impact on the achievement of challenging objectives by children with disabilities;

(b) Increased knowledge of the practices that support high expectations and the achievement of challenging goals and objectives tailored to children's individual circumstances;

(c) Increased knowledge of how to improve students' access to appropriate, effective, and individualized instruction and services that enable appropriate developmental, social, academic, and functional progress and achievement; and

(d) Increased use of evidence-based [4] knowledge, tools, and products demonstrated to increase the capacity of LEAs, CMOs, and schools to develop and implement high-quality IEPs and the provision of a FAPE consistent with the *Endrew F.* decision and to have a positive impact on the progress toward meeting and the achievement of challenging objectives by children with disabilities.

In addition to meeting the programmatic requirements in this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how the proposed project will—

(1) Identify and address the current and emerging needs of LEAs, CMOs, and school personnel to develop and implement high-quality IEPs reasonably calculated to enable children to make progress based on challenging goals and objectives and high expectations in light of each child's circumstances. To meet this requirement, the applicant must—

(i) Present applicable national, State, regional, or local research demonstrating significant features, components, and practices of IEP development and implementation on student progress and achievement of challenging objectives;

(ii) Demonstrate knowledge of current educational issues and policy initiatives, including disability policy initiatives, that identify and address the particular and ongoing capacity needs of LEA, CMO, and school personnel, and school personnel in a variety of settings, and how they are likely to change, translate, and expand the general and special education approach to programming and implementing instruction and related services for students with disabilities;

(iii) Present information about how school leaders and practitioners access and utilize knowledge, tools, and products, which are developed based on evidence of their ability to impact progress and achievement of students with disabilities; and

(2) Improve the knowledge and use of the features of IEP development and implementation that have been shown to be positively related to progress and achievement of challenging goals and objectives by children with disabilities in rural, suburban, and urban communities, as well as those living in poverty or attending a high-need school,[5] and indicate the likely

[1] On December 7, 2017, the Department issued questions and answers (Q&A) that provided useful background on the *Endrew F.* decision and set out the Department's views on how schools may meet the standards the Court articulated. The Q&A are available at *https://sites.ed.gov/idea/questions-and-answers-qa-on-u-s-supreme-court-case-decision-endrew-f-v-douglas-county-school-district-re-1/#.*

[2] It is the Court, of course, and not this Center that established the standard in the *Endrew F.* decision, and working with the Center does not mean that the TA recipient is in compliance with that standard.

[3] For the purposes of this priority, ''settings'' include general education classrooms; special education classrooms; elementary, middle, and secondary schools; private schools, including faith-based schools; home education; after school programs; juvenile justice facilities; and settings other than those listed above in which students may receive services under IDEA.

[4] For the purposes of this priority, ''evidence-based'' means the proposed project component is supported, at a minimum, by evidence that demonstrates a rationale (as defined in 34 CFR 77.1), where a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

[5] For the purposes of this priority, ''high-need school'' refers to a public elementary or secondary school that is: (1) An LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children are from families with incomes below the poverty line; (2) a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA); (3) a school identified for comprehensive support and improvement by a State under section 1111(c)(4)(D) of the ESEA that includes (a) not less than the lowest performing 5 percent of all schools in the State receiving funds under Title I, Part A of the ESEA; (b) all public high schools in the State failing to graduate one third or more of their students; and (c) public schools in the State described under section 1111(d)(3)(A)(i)(II) of the ESEA; or (4) a school identified for targeted support and improvement by a State that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system as defined in section 1111(d)(2) of the ESEA.

magnitude or importance of the improvements.

(b) Demonstrate, in the narrative section of the application under ''Quality of project services,'' how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that services and products meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model [6] by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals and how they will be measured, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: *www.osepideasthatwork.org/logicModel* and *www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.*

(4) Be based on current research and make use of evidence-based practices (EBPs). To meet this requirement, the applicant must describe—

(i) The research methods for determining the salient IEP development and implementation of EBPs that are most closely related to ensuring children with disabilities are offered IEPs that are reasonably calculated to enable a child to make progress appropriate in light of the child's circumstances, as outlined in the IDEA, the *Endrew F.* decision, and current practices in rural, suburban, and urban communities, as well as those living in poverty or attending a high-need school;

(ii) The current research about adult learning principles and implementation science that will inform the proposed TA; and

(iii) How the proposed project will incorporate current research and practices in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base of:

(A) The relationships among IEP development, service delivery, parent engagement, and individual student outcomes; and

(B) The ways in which improved implementation of instructional practices and related services guided by the IEPs lead to improved student outcomes;

(ii) Its proposed approach to intensive, sustained TA,[7] which must identify—

(A) The intended recipients, including the type and number of recipients from a variety of settings and geographic distribution, that will receive the products and services designed to impact student progress and achievement based on the improved development and implementation of IEPs;

(B) The proposed measures and instruments used to show fidelity of implementation of the identified salient IEP development and implementation features as well as the impact on student progress and achievement;

(C) Its proposed approach to the selection of TA recipients, including how it will measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their need and interest, current infrastructure, available resources, and feasibility and likelihood of increasing capacity at the LEA, CMO, private school association, and school levels;

(D) Its proposed plan for collaborating with the State educational agencies (SEAs) to work with and assist LEAs, CMOs, and schools in developing and enhancing sustainable systems, consistent with the *Endrew F.* decision, that include professional development based on adult learning principles and coaching;

(E) Its proposed plan for working with appropriate levels of the education system (*e.g.,* SEAs, LEAs, CMOs, schools, families) to ensure there is communication between each level and there are systems in place to support the use of EBPs; and

(F) Its proposed plan for disseminating lessons learned from LEAs, CMOs, and schools receiving the intensive TA for universal TA recipients;

(iii) Its proposed approach to universal, general TA,[8] which must identify the intended recipients, including the educators, administrators, parents, and service providers, and how they will access and utilize:

(A) The knowledge developed through the research methods described in paragraph (b)(4)(i) of these application and administrative requirements;

(B) The tools and products developed through the activities described in paragraph (b)(5)(i) of these application and administrative requirements; and

(C) The lessons learned from the delivery of intensive TA on IEP development and implementation.

(6) Develop products and implement services that are impartial and maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will ensure that its products and services are not designed to influence the enrollment or placement decisions of parents of children with disabilities and are designed to support services for children with disabilities equally, regardless of placement;

(ii) How the proposed project will use technology to achieve the intended project outcomes;

(iii) How the proposed project will collaborate with other organizations and Department-funded TA centers, including parent centers, and the intended outcomes of this collaboration; and

[6] Logic model (34 CFR 77.1) (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

[7] ''Intensive, sustained TA'' means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. ''TA services'' are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

[8] ''Universal, general TA'' means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

(iv) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under ''Quality of the project evaluation,'' include an evaluation plan for the project as described in the following paragraphs. The evaluation plan must describe: Measures of progress in implementation, including the criteria for determining the extent to which the project's products and services have met the goals for reaching its target population; measures of intended outcomes or results of the project's activities in order to evaluate those activities; and how well the goals or objectives of the proposed project, as described in its logic model, have been met. Applicants must also include a proposed plan for collecting baseline, targeted, and outcome data for each intensive TA site.

The applicant must provide an assurance that, in designing the evaluation plan, it will—

(1) Designate, with the approval of the Office of Special Education Programs (OSEP) project officer, a project liaison staff person with sufficient dedicated time, experience in evaluation, and knowledge of the project to work in collaboration with the Center to Improve Program and Project Performance (CIP3),[9] the project director, and the OSEP project officer on the following tasks:

(i) Revise, as needed, the logic model submitted in the application to provide for a more comprehensive measurement of implementation and outcomes and to reflect any changes or clarifications to the model discussed at the kick-off meeting;

(ii) Refine the evaluation design and instrumentation proposed in the application consistent with the logic model (*e.g.,* prepare evaluation questions about significant program processes and outcomes; develop quantitative or qualitative data collections that permit both the collection of progress data, including fidelity of implementation, as appropriate, and the assessment of project outcomes; and identify analytic strategies); and

(iii) Revise, as needed, the evaluation plan submitted in the application such that it clearly—

(A) Specifies the measures and associated instruments or sources for data appropriate to the evaluation questions, suggests analytic strategies for those data, provides a timeline for conducting the evaluation, and includes staff assignments for completing the plan;

(B) Delineates the data expected to be available by the end of the second project year for use during the project's evaluation (3+2 review) for continued funding described under the heading *Fourth and Fifth Years of the Project;* and

(C) Can be used to assist the project director and the OSEP project officer, with the assistance of CIP3, as needed, to specify the performance measures to be addressed in the project's annual performance report;

(2) Cooperate with CIP3 staff in order to accomplish the tasks described in paragraph (c)(1) of this section; and

(3) Dedicate sufficient funds in each budget year to cover the costs of carrying out the tasks described in paragraphs (c)(1) and (2) of this section and implementing the evaluation plan.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of resources and quality of project personnel,'' how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience, to carry out the proposed activities and achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under ''Quality of the management plan,'' how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) How key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes;

(3) How the proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) How the proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A two-day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two-and-one-half day project directors' conference in Washington, DC, during each year of the project period;

(iii) Three annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) A two-day intensive 3+2 review meeting during the second year of the project period;

(3) Include, in the budget, a line item for an annual set-aside of 10 percent of the grant amount to support emerging needs and future Department policy initiatives that are consistent with the proposed project's intended outcomes, as those needs and initiatives are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period; and

(4) Maintain a high-quality website, with an easy-to-navigate design, that

[9] The major tasks of CIP3 are to guide, coordinate, and oversee the design of formative evaluations for every large discretionary investment (*i.e.,* those awarded $500,000 or more per year and required to participate in the 3+2 process) in OSEP's Technical Assistance and Dissemination; Personnel Development; Parent Training and Information Centers; and Educational Technology, Media, and Materials programs. The efforts of CIP3 are expected to enhance individual project evaluation plans by providing expert and unbiased TA in designing the evaluations with due consideration of the project's budget. CIP3 does not function as a third-party evaluator.

meets government or industry-recognized standards for accessibility;

(5) Ensure that annual project progress toward meeting project goals is posted on the project website; and

(6) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to States during the transition to a new award at the end of this award period, as appropriate.

Fourth and Fifth Years of the Project: In deciding whether to continue funding the project for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), as well as—

(a) The recommendation of a 3+2 review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting that will be held during the last half of the second year of the project period;

(b) The timeliness with which, and how well, the requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The quality, relevance, and usefulness of the project's products and services and the extent to which the project's products and services are aligned with the project's objectives and likely to result in the project achieving its intended outcomes.

Under 34 CFR 75.253, the Secretary may reduce continuation awards or discontinue awards in any year of the project period for excessive carryover balances or a failure to make substantial progress. The Department intends to closely monitor unobligated balances and substantial progress under this program and may reduce or discontinue funding accordingly.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1463 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: $2,000,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2020 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding $2,000,000 for a single budget period of 12 months.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; State lead agencies under Part C of the IDEA; LEAs, including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application. Under 34 CFR 75.708(e), a grantee may contract for supplies, equipment, and other services in accordance with 2 CFR part 200.

4. *Other General Requirements:*

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2019.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1Prime; margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- *Use one of the following fonts:* Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed below:

(a) *Significance (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) *Quality of project services (35 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the TA services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(c) *Quality of the project evaluation (20 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) *Adequacy of resources and quality of project personnel (15 points).*

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan (20 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives is brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the

Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under the Government Performance and Results Act of 1993, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities program. These measures are:

- *Program Performance Measure #1:* The percentage of Technical Assistance and Dissemination products and services deemed to be of high quality by an independent review panel of experts qualified to review the substantive content of the products and services.
- *Program Performance Measure #2:* The percentage of Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be of high relevance to educational and early intervention policy or practice.
- *Program Performance Measure #3:* The percentage of all Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be useful in improving educational or early intervention policy or practice.
- *Program Performance Measure #4:* The cost efficiency of the Technical Assistance and Dissemination Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.
- *Long-term Program Performance Measure:* The percentage of States receiving Special Education Technical Assistance and Dissemination services regarding scientifically or evidence-based practices for infants, toddlers, children, and youth with disabilities that successfully promote the implementation of those practices in school districts and service agencies.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

The Department will also closely monitor the extent to which the products and services provided by the Center meet needs identified by stakeholders and may require the Center

to report on such alignment in their annual and final performance reports.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5081A, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2019–16809 Filed 8–6–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0095]

Agency Information Collection Activities; Comment Request; Application for the Rural Education Achievement Program (REAP)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 7, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2019–ICCD–0095. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Eric Schulz, 202–260–7349.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for the Rural Education Achievement Program (REAP).

OMB Control Number: 1810–0646.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 6,049.

Total Estimated Number of Annual Burden Hours: 20,683.

Abstract: The U.S. Department of Education (the Department) administers the Small, Rural School Achievement (SRSA) program (authorized under sections 5211–5212 of the Elementary and Secondary Education Act of 1965 (ESEA)) and the Rural and Low-Income School (RLIS) program (authorized under ESEA section 5221). In order to make grant awards to eligible SRSA and RLIS entities, the Department must collect information from State and local educational agencies. The information collected is used to determine the eligibility of individual LEAs and calculate the allocation each eligible LEA should receive according to formulas prescribed in the ESEA.

Dated: August 2, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–16900 Filed 8–6–19; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Meeting: Technical Guidelines Development Committee; ''Voluntary Voting Systems Guidelines and Usability Requirements''

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of conference call meeting.

DATES: Friday, August 16, 2019, 11:00 a.m.–1:00 p.m. (EDT).

ADDRESSES: EAC Technical Guidelines Development Committee Conference Call.

To listen and monitor the event as an attendee:

1. Go to: *https://eac-meetings.webex.com/webappng/sites/eac-meetings/meeting/info/13406624056818820 5?MTID=m4eb811c95cc6ce768217e4926ec60a36.*

2. Click ''Join Now''.

To join the audio conference only:

1. Call the number below and enter the access code.

US TOLL FREE: +1–855–892–3345, US TOLL: +1–415–527–5035, Access code: 908 183 138.

(See toll-free dialing restrictions at *https://www.webex.com/pdf/tollfree_restrictions.pdf.*)

For assistance, contact the host, Jerome Lovato at *https://www.eac.gov/contact/.*

FOR FURTHER INFORMATION CONTACT: Jerome Lovato, Telephone: (301) 563–3929.

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. Appendix 2), the U.S. Election Assistance Commission (EAC) Technical Guidelines Development Committee will conduct a conference call to discuss Voluntary Voting System Guidelines and Usability Requirements.

Agenda: The Technical Guidelines Development Committee (TGDC) will discuss the Voluntary Voting System Guidelines 2.0 (VVSG 2.0) High Quality Design, High Quality Implementation, Transparency, and Interoperability Requirements. TGDC will discuss the next TGDC meeting dates and the continuing steps to develop the Requirements. There may be votes conducted on this call.

The TGDC will discuss the Usability and Accessibility Requirements of the VVSG 2.0. Draft VVSG Requirements can be found at the TWiki page link: *https://collaborate.nist.gov/voting/bin/view/Voting/VVSG20DraftRequirements.* The most current version of the draft VVSG 2.0 Requirements is clearly marked at the top of the page to ensure the latest version is the topic of discussion at the time of the meetings. As stated in the disclaimer (and in each document), the Requirements are in a draft state and are not yet ready for final posting in their current form. These are provided ''as is'' for facilitating our on-going discussions, but do not yet represent an official or final version. Members of the public may submit relevant written statements to about the meeting's content the TGDC with no later than 3:00 p.m. EDT on Friday, August 2, 2019.

Statements may be sent electronically via *https://www.eac.gov/contact/,* via standard mail addressed to the U.S. Election Assistance Commission, TGDC, 1335 East West Highway, Suite 4300, Silver Spring, MD 20910, or by fax at 301–734–3108. Notice of this meeting is being published less than 15 days prior to the meeting date and time because the TGDC was unable to establish a quorum prior to the 15 day publication requirement.

This conference call will be open to the public.

Dated: August 1, 2019.

Clifford D. Tatum,

General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2019–16823 Filed 8–6–19; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a combined meeting of the Environmental Monitoring and Remediation Committee and Waste Management Committee of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico (known locally as the Northern New Mexico Citizens' Advisory Board [NNMCAB]). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, August 28, 2019, 1 p.m.–4 p.m.

ADDRESSES: NNMCAB Office, 94 Cities of Gold Road, Pojoaque, NM 87506.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board, 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *menice.santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Purpose of the Environmental Monitoring and Remediation Committee (EM&R): The EM&R Committee provides a citizens' perspective to NNMCAB on current and future environmental remediation activities resulting from historical Los Alamos National Laboratory (LANL) operations and, in particular, issues pertaining to groundwater, surface water and work required under the New Mexico Environment Department Order on Consent. The EM&R Committee will keep abreast of DOE–EM and site programs and plans. The committee will work with the NNMCAB to provide assistance in determining priorities and the best use of limited funds and time. Formal recommendations will be proposed when needed and, after consideration and approval by the full NNMCAB, may be sent to DOE–EM for action.

Purpose of the Waste Management (WM) Committee: The WM Committee reviews policies, practices and procedures, existing and proposed, so as to provide recommendations, advice, suggestions and opinions to the NNMCAB regarding waste management operations at the Los Alamos site.

Tentative Agenda:

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of June 19, 2019
- Old Business
  - Report from Chair
  - Consideration and Action on Reorganization of Standing Committees
  - Other Items
- New Business
- Break
- Discussion on EM Los Alamos and N3B Public Outreach Strategy and the NNMCAB
- Items from EM Los Alamos and Deputy Designated Federal Officer
- Public Comment Period
- Adjourn

Public Participation: The meeting is open to the public. The NNMCAB's Committees welcome the attendance of the public at their combined committee meeting and will make every effort to

accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Committees either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the internet at: *http://energy.gov/em/nnmcab/meeting-materials.*

Signed in Washington, DC, on August 1, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–16909 Filed 8–6–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 12–101–LNG]

Gulf LNG Liquefaction Company, LLC; Opinion and Order Granting Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Record of decision.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of a Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. As discussed, this ROD supports DOE/FE's decision in DOE/FE Order No. 4410, an opinion and order authorizing Gulf LNG Liquefaction Company, LLC to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2627, *Amy.Sweeney@hq.doe.gov*

Kari Twaite, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–6978, *Kari.Twaite@hq.doe.gov*

SUPPLEMENTARY INFORMATION: On July 31, 2019, DOE/FE issued Order No. 4410 to Gulf LNG Liquefaction Company, LLC (Gulf LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order authorizes Gulf LNG to export domestically produced LNG to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). Gulf LNG is authorized to export LNG in a volume equivalent to 558.9 billion cubic feet (Bcf) per year of natural gas (1.53 Bcf/day) from the proposed Gulf LNG Liquefaction Project (Project), to be located in Jackson County, Mississippi.

DOE/FE participated as a cooperating agency with the Federal Energy Regulatory Commission (FERC) in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project that would be used to support the export authorization sought from DOE/FE. DOE adopted the EIS and prepared the ROD, which is attached as an appendix to the Order. The ROD can be found here: *https://www.energy.gov/sites/prod/files/2019/07/f65/ord4410.pdf.*

Signed in Washington, DC, on August 2, 2019.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Fossil Energy.

[FR Doc. 2019–16911 Filed 8–6–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ19–15–000]

Orlando Utilities Commission; Notice of Filing

Take notice that on July 15, 2019, the Orlando Utilities Commission submitted its tariff filing: Revised Non-Jurisdictional Rate Sheets Open Access Transmission Tariff to be effective October 1, 2019.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 5, 2019.

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16849 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–2264–001.

Applicants: Northern Indiana Public Service Company.

Description: Tariff Amendment: Errata to Filing of an Amended CIAC Agreement to be effective 6/27/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5138.

Comments Due: 5 p.m. ET 8/22/19.

Docket Numbers: ER19–2324–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3125R6 Basin Electric Power Cooperative NITSA and NOA Amended Filing to be effective 6/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5073.

Comments Due: 5 p.m. ET 8/22/19.

Docket Numbers: ER19–2511–000.

Applicants: Midcontinent Independent System Operator, Inc., Wolverine Power Supply Cooperative, Inc.

Description: § 205(d) Rate Filing: 2019–07–31_SA 3337 Wolverine-Zeeland Interconnection Facilities Agrmt (Fairview) to be effective 7/19/2019.

Filed Date: 7/31/19.

Accession Number: 20190731–5157.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19–2512–000.

Applicants: North Carolina Electric Membership Corporation, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: PJM and NCEMC submit Revised Service Agreement No. 3347 to be effective 7/1/2019.

Filed Date: 7/31/19.

Accession Number: 20190731–5159.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19–2513–000.

Applicants: Wilton Wind Energy II, LLC.

Description: Baseline eTariff Filing: Wilton Wind Energy II, LLC Application for MBR Authority to be effective 9/30/2019.

Filed Date: 7/31/19.

Accession Number: 20190731–5181.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19–2514–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: 2nd Quarter 2019 Revisions to OA, Schedule 12 and RAA, Schedule 17 to be effective 6/30/2019.

Filed Date: 7/31/19.

Accession Number: 20190731–5197.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19–2515–000.

Applicants: UNS Electric, Inc.

Description: § 205(d) Rate Filing: Hilltop Interconnection Agreement to be effective 7/2/2019.

Filed Date: 7/31/19.

Accession Number: 20190731–5201.

Comments Due: 5 p.m. ET 8/21/19.

Docket Numbers: ER19–2516–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2019–08–01_Revisions to Schedules 7, 8, and 9 to add City of Breckenridge, MN to be effective 10/1/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5042.

Comments Due: 5 p.m. ET 8/22/19.

Docket Numbers: ER19–2517–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Clean-up to OATT, Schedule 12-Appendix A (JCPL) and (MetEd) to be effective 1/1/2018.

Filed Date: 8/1/19.

Accession Number: 20190801–5052.

Comments Due: 5 p.m. ET 8/22/19.

Docket Numbers: ER19–2518–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Claxton Solar LGIA Filing to be effective 7/22/2019.

Filed Date: 8/1/19.

Accession Number: 20190801–5082.

Comments Due: 5 p.m. ET 8/22/19.

Docket Numbers: ER19–2519–000.

Applicants: Avista Corporation.

Description: Tariff Cancellation: Avista Corp Cancellation of RS 532 Dyn Cap and Energy to be effective 8/2/2018.

Filed Date: 8/1/19.

Accession Number: 20190801–5086.

Comments Due: 5 p.m. ET 8/22/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16848 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 77–285]

Mendocino County Inland Water Agency and Power Commission; Sonoma County Water Agency; California Trout, Inc.; County of Humboldt, California

Notice of Continuation of Relicensing Proceeding

On June 28, 2019, Mendocino County Inland Water Agency and Power Commission; Sonoma County Water Agency; California Trout, Inc.; and the County of Humboldt, California (NOI Parties) filed a Notice of Intent (NOI) to File an Application for a New License for the Potter Valley Project.

The 9.4-megawatt project is located on the Eel River and the East Branch Russian River in Mendocino and Lake Counties, California, about 15 miles northeast of the city of Ukiah. Project features include Lake Pillsbury, a 2,300-acre storage reservoir impounded by Scott Dam; 106-acre Van Arsdale Reservoir, impounded by the Cape Horn Diversion Dam; and a tunnel and penstock across a natural divide to the project's powerhouse located in the headwaters of the Russian River Basin.

The Potter Valley Project is currently licensed to the Pacific Gas and Electric Company (PG&E) and the license expires on April 14, 2022. On April 6, 2017, PG&E filed a NOI to relicense the project and a pre-application document (PAD) and initiated the pre-filing steps of the Integrated Licensing Process (ILP). On January 25, 2019, PG&E filed a notice of withdrawal of its NOI and PAD, indicating it was discontinuing its efforts to relicense the project. The withdrawal became effective on February 11, 2019. On March 1, 2019, the Commission issued a Notice Soliciting Applications, establishing a deadline of 120 days from the date of the notice (*i.e.,* July 1, 2019) for interested applicants, other than PG&E, to file NOIs, PADs, and requests to complete the pre-filing stages of the licensing process.

The NOI Parties propose to continue the ILP initiated by PG&E. According to the proposed pre-filing process plan and schedule, the NOI Parties propose to complete a feasibility study in April 2020, consult on the need for additional studies, and file [1] a final license application by April 14, 2022.

[1] The NOI Parties are proxies for a new Regional Entity that ultimately would be the license applicant for the project. The Regional Entity has

With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and (b) the State Historic Preservation Officer, as required by section 106 of the National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR part 800.

With this notice, we are designating the NOI Parties as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

Questions concerning this notice should be directed to Alan Mitchnick at (202) 502–6074 or *alan.mitchnick@ferc.gov.*

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16852 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD19–10–000]

Wallowa Resources Community Solutions, Inc.; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On July 25, 2019, Wallowa Resources Community Solutions, Inc., filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Cook Springs Hydro Station Project would have an installed capacity of 49 kilowatts (kW), and would be located at the end of a newly constructed 8-inch pipeline on private ranchland near the town of Lostine, Wallowa County, Oregon.

Applicant Contact: Kyle Petrocine, Wallowa Resources Community Solutions, Inc., 401 NE 1st St., Enterprise, OR 97828, Phone No. (541) 398–0018, Email: *kyle@wallowaresources.org.*

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) A 13-foot by 14-foot powerhouse containing one 49-kW Pelton turbine-generator unit; (2) a 12-inch pipeline discharging water to an irrigation ditch; and (3) appurtenant facilities. The proposed project would have an estimated annual generation of 400 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Cook Springs Hydro Station Project will not interfere with the primary purpose of the conduit, which is to transport water for irrigation. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY or MOTION TO INTERVENE, as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

not yet been formed under California law, but once formed the Regional Entity would supplant the NOI Parties in this ILP proceeding.

[1] 18 CFR 385.2001–2005 (2018).

A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE, Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the eLibrary link. Enter the docket number (*i.e.,* CD19–10) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16846 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2600–087]

Bangor-Pacific Hydro Associates; Notice of Intent To File License Application, Filing of Pre-Application Document (PAD), Commencement of Pre-Filing Process, and Scoping; Request for Comments on the PAD and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Process.

b. *Project No.:* 2600–087.

c. *Dated Filed:* May 31, 2019.

d. *Submitted By:* Bangor-Pacific Hydro Associates (BPHA).

e. *Name of Project:* West Enfield Project.

f. *Location:* On the Penobscot River in Penobscot County, Maine. The project does not occupy any federal land.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's Regulations.

h. *Potential Applicant Contact:* Randy Dorman, Brookfield Renewable, 150 Main Street, Lewiston, ME 04240; phone at (207) 755–5605, or email at *Randy.Dorman@brookfieldrenewable.com.*

i. *FERC Contact:* Erin Kimsey at (202) 502–8621 or email at *erin.kimsey@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and (b) the Maine State Historic Preservation Officer (SHPO) and Penobscot Nation Tribal Historic Preservation Officer (THPO), as required by section 106 of the National Historic Preservation Act and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Bangor-Pacific Hydro Associates as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act, section 106 of the National Historic Preservation Act, and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act.

m. Bangor-Pacific Hydro Associates filed with the Commission a Pre-Application Document (PAD; including a proposed process plan and schedule), pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website (*http://www.ferc.gov*), using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). Copies are also available by request from Mr. Randy Dorman of Brookfield Renewable at (207) 755–5605 or via email at *Randy.Dorman@brookfieldrenewable.com.*

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, please contact FERC Online Support.

o. With this notice, we are soliciting comments on the PAD and Commission staff's Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission.

The Commission strongly encourages electronic filing. Please file all documents using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov.* In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2600–087.

All filings with the Commission must bear the appropriate heading: Comments on Pre-Application Document, Study Requests, Comments on Scoping Document 1, Request for Cooperating Agency Status, or Communications to and from Commission Staff. Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so within 60 days of the date of this notice.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. The scoping process will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

Scoping Meetings

Commission staff will hold two scoping meetings in the vicinity of the project at the time and place noted below. The daytime meeting will focus on resource agency, Indian tribe, and non-governmental organization concerns, while the evening meeting is primarily for receiving input from the public. We invite all interested individuals, organizations, and agencies to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be

addressed in the environmental document. The times and locations of these meetings are as follows:

Daytime Scoping Meeting

Date: Wednesday, August 28, 2019.
Time: 10:00 a.m.
Location: Enfield Town Office, 789 Hammett Road, Enfield, ME 04493.
Phone: (207) 732–4270.

Evening Scoping Meeting

Date: Wednesday, August 28, 2019.
Time: 6:00 p.m.
Location: Enfield Town Office, 789 Hammett Road, Enfield, ME 04493.
Phone: (207) 732–4270.

SD1, which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 will be available at the scoping meetings, or may be viewed on the web at *http://www.ferc.gov,* using the eLibrary link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

Environmental Site Review

The licensee and Commission staff will conduct an environmental site review of the project on Tuesday, August 27, 2019, starting at 1:00 p.m. All participants should meet at the project, located at 94 Dam Road, West Enfield, ME 04493.

If you plan to attend the environmental site review, please contact Randy Dorman of Brookfield Renewable at (207) 755–5605, or via email at *Randy.Dorman@BrookfieldRenewable.com* on or before August 19, 2019, and indicate how many participants will be attending with you.

Meeting Objectives

At the scoping meetings, staff will: (1) Initiate scoping of the issues; (2) review and discuss existing conditions and resource management objectives; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in Part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of federal, state, and tribal permitting and certification processes; and (5) discuss the appropriateness of any federal or state agency or Indian tribe acting as a cooperating agency for development of an environmental document.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and SD1 are included in item n of this document.

Meeting Procedures

The meetings will be recorded by a stenographer and will be placed in the public records of the project.

Dated: July 30, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16847 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–2513–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization: Wilton Wind Energy II, LLC

This is a supplemental notice in the above-referenced Wilton Wind Energy II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 21, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16845 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–1056–001.
Applicants: Boardwalk Storage Company, LLC.
Description: Compliance filing Compliance Filing in Docket No. RP19–1056–000 to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5031.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1057–001.
Applicants: Texas Gas Transmission, LLC.
Description: Compliance filing Compliance Filing in Docket No. RP19–1057–000 to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5033.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1062–001.
Applicants: Gulf South Pipeline Company, LP.
Description: Compliance filing Compliance Filing in Docket No. RP19–1062–000 to be effective 8/1/2019.

Filed Date: 7/31/19.
Accession Number: 20190731–5029.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1072–001.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Compliance filing Compliance Filing in Docket No. RP19–1072–000 to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5030.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1411–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Columbia Gas 860005 Aug 1 releases to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5002.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1412–000.
Applicants: Great Lakes Gas Transmission Limited Partnership.
Description: Compliance filing Semi-Annual Transporter's Use Report July 2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5004.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1413–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiable Provisions to be effective 8/31/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5024.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1414–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate & Exhibit B Update (FPL Sanford) to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5025.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1415–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various shippers eff 8–1–2019) to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5026.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1416–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Aethon 37657, 50488 to Scona 51400, 51393) to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5027.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1417–000.
Applicants: Ruby Pipeline, L.L.C.
Description: § 4(d) Rate Filing: FLU and EPC Recomputation Filing to be effective 9/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5042.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1418–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Amendment to Negotiated Rate Agreement-Macquarie Energy to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5045.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1419–000.
Applicants: Dauphin Island Gathering Partners.
Description: § 4(d) Rate Filing: Negotiated Rate Filing Chevron 7–31–2019 to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5046.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1420–000.
Applicants: Florida Southeast Connection, LLC.
Description: Compliance filing Order No. 587–Y Compliance Filing to be effective 7/31/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5058.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1421–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Compliance filing Flow Through of Dominion Penalty Sharing 2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5059.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1422–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—NStar release to BP 799653 eff 8–1–19 to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5060.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1423–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (#215882–FTWIC Castleton Commodities) to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5061.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1424–000.
Applicants: Kern River Gas Transmission Company.
Description: § 4(d) Rate Filing: 2019 Concord Amendment to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5063.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1425–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Fuel and L&U Reimbursement Percentage Update to be effective 9/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5064.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1426–000.
Applicants: National Fuel Gas Supply Corporation.
Description: § 4(d) Rate Filing: National Fuel Rate Case (eFiled 07/31/19) to be effective 9/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5067.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1427–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Remove Expired and Terminated Agreements from Tariff to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5076.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1428–000.
Applicants: Dominion Energy Transmission, Inc.
Description: § 4(d) Rate Filing: DETI—July 31, 2019 Gas Processing Provisions to be effective 9/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5103.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1429–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2019–07–31 Six One Commodities to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5165.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1430–000.
Applicants: ETC Tiger Pipeline, LLC.
Description: § 4(d) Rate Filing: Assignment of Petrohawk Agreement to BP Energy to be effective 8/1/2019.
Filed Date: 7/31/19.
Accession Number: 20190731–5184.
Comments Due: 5 p.m. ET 8/12/19.

Docket Numbers: RP19–1431–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: Neg Rate 2019–07–31–19 5 sharing Ks to be effective 8/1/2019.
Filed Date: 7/31/19.

Accession Number: 20190731–5200.
Comments Due: 5 p.m. ET 8/12/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 1, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16851 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF19–4–000]

Venture Global Delta LNG, LLC and Venture Global Delta Express, LLC; Notice of Intent To Prepare an Environmental Impact Statement for the Planned Delta LNG and Delta Express Pipeline Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Session

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that will discuss the environmental impacts of the Delta LNG and Delta Express Pipeline Project (Project) involving construction and operation of facilities by Venture Global Delta LNG, LLC and Venture Global Delta Express, LLC (collectively referred to as Delta LNG) in Plaquemines, Richland, Franklin, Catahoula, Concordia, Avoyelles, St. Landry, Pointe Coupee, West Baton Rouge, Iberville, Ascension, Assumption, Lafourche, and Jefferson Parishes, Louisiana. The Commission will use this EIS in its decision-making process to determine whether the Project is in the public interest and public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies about issues regarding the Project. The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from its action whenever it considers the issuance of an authorization. NEPA also requires the Commission to discover concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of issues to address in the EIS. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on August 29, 2019.

You can make a difference by submitting your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EIS. Commission staff will consider all comments received during the preparation of the EIS.

If you sent comments on this Project to the Commission before the opening of this docket on April 30, 2019 you will need to file those comments in Docket No. PF19–4–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this planned Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable pipeline easement agreement. You are not required to enter into an agreement. However, if the Commission approves the pipeline, that approval conveys with it the right of eminent domain. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law.

A document prepared by the FERC entitled An Interstate Natural Gas Facility On My Land? What Do I Need To Know? is available for viewing on the FERC website (*www.ferc.gov*) at *https://www.ferc.gov/resources/guides/gas/gas.pdf.* This document addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

The Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. To sign up go to *www.ferc.gov/docs-filing/esubscription.asp.*

For your convenience, there are four methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on *eRegister.* You will be asked to select the type of filing you are making; a comment on a particular project is considered a Comment on a Filing; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the Project docket number (PF19–4–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

(4) In lieu of sending written comments, the Commission invites you to attend one of the public scoping

sessions its staff will conduct in the Project area, scheduled as follows:

Date and time	Location
Monday, August 12, 2019, 4:30–7:30 p.m	Belle Chasse High School, 8346 Highway 23, Belle Chasse, LA.
Tuesday, August 13, 2019, 4:30–7:30 p.m	Donaldsonville High School, 100 Tiger Drive, Donaldsonville, LA.
Wednesday, August 14, 2019, 4:30–7:30 p.m	Pointe Coupee Historical Society, Poydras Center, 500 West Main Street, New Roads, LA.
Thursday, August 15, 2019, 4:30–7:30 p.m	Jack Hammons Community Center, 810 Adams Street, Winnsboro, LA.

The primary goal of these scoping sessions is to have you identify the specific environmental issues and concerns that should be considered in the EIS. Individual verbal comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of verbal comments in a convenient way during the timeframe allotted.

Each scoping session is scheduled from 4:30 p.m. to 7:30 p.m. Central Time. You may arrive at any time after 4:30 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 7:30 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 7:00 p.m. Please see appendix 1 for additional information on the session format and conduct.[1]

Your scoping comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see the last page of this notice for instructions on using eLibrary). If a significant number of people are interested in providing verbal comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor.

It is important to note that written comments mailed to the Commission and those submitted electronically are reviewed by staff with the same scrutiny and consideration as the verbal comments given at the public comment session. Therefore, you do not need to attend a meeting in order for your comments to be considered.

Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. Representatives from Delta LNG will also be present to answer Project-specific questions.

Please note this is not your only public input opportunity; please refer to the review process flow chart in appendix 2.

Summary of the Planned Project

The Project would involve the construction of a liquefied natural gas (LNG) export terminal in Plaquemines Parish, Louisiana and two parallel, 42-inch-diameter pipelines in a single approximately 283-mile-long right-of-way in 14 parishes in Louisiana. Domestically sourced natural gas would be transported by the Delta Express Pipeline to the Delta LNG terminal which would produce, store, and deliver up to 24 million tons per annum of LNG to LNG carriers for export overseas. More specifically, the Project would include the following facilities:

- The Delta LNG export terminal, consisting of:
  - Pretreatment facilities;
  - a liquefaction plant with 18 integrated single-mixed refrigerant blocks and supporting facilities;
  - four 200,000-cubic-meter aboveground full-containment LNG storage tanks;
  - three LNG carrier loading docks within a common LNG carrier berthing area; and
  - two 720-megawatt air-cooled electric power generation facilities;
- the Delta Express Pipeline, consisting of:
  - Two approximately 283-mile-long, 42-inch-diameter pipelines beginning in Richland Parish and ending at the Delta LNG export terminal;
  - 4 natural gas-fired compressor stations in Richland, Concordia, Pointe Coupee, and Lafourche Parishes;
  - 16 mainline block valves;
  - 4 pig launchers and receiver facilities;[2]
  - 2 metering and regulation stations; and
  - other pipeline-related facilities (*e.g.,* access roads, contractor and pipe yards).

Delta LNG plans to construct the Project in two phases. Phase 1 at the LNG export terminal site would generally include one-half of the LNG processing and storage facilities, one-half of the electric power generation facilities, and two LNG carrier loading docks. Phase 1 of the Delta Express Pipeline would generally include one of the two planned natural gas transmission pipelines and all four planned compressor stations. Phase 2 of the Project would be based on market conditions and would include construction of the remaining facilities at the LNG export terminal, the second of the two planned natural gas transmission pipelines, and modifications to the four planned compressor stations. The EIS will disclose the environmental impacts of each phase of the Project as well as the total impacts of the Project at completion.

The general location of the Project facilities is shown in appendix 3.

Land Requirements for Construction

Construction and operation of the planned LNG terminal facilities would disturb about 500 acres. Construction of the planned pipeline facilities, including aboveground facilities, would disturb about 6,000 acres. Following construction of the pipeline facilities, Delta LNG would maintain about 2,744 acres for permanent operation of the pipeline Project; the remaining acreage would be restored and revert to former uses.

The EIS Process

The EIS will discuss impacts that could occur as a result of the construction and operation of the planned Project under these general headings:

- Geology and soils;
- water resources and wetlands;
- vegetation, fisheries, and wildlife;

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called eLibrary or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] A pig is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise;
- public safety; and
- cumulative impacts.

Commission staff will also evaluate possible alternatives to the planned Project or portions of the Project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the EIS.

The EIS will present Commission staffs' independent analysis of the issues. The draft EIS will be available in electronic format in the public record through eLibrary [3] and the Commission's website (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). If eSubscribed, you will receive instant email notification when the draft EIS is issued. The draft EIS will be issued for an allotted public comment period. After the comment period on the draft EIS, Commission staff will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure Commission staff have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this Project to formally cooperate in the preparation of the EIS.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

[3] For instructions on connecting to eLibrary, refer to the last page of this notice.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.[5] The EIS for this Project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

Commission staff have already identified several issues that deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Delta LNG. This preliminary list of issues may change based on your comments and our analysis.

- impacts on wetlands including coastal marsh and forested wetlands;
- cumulative impacts on air quality, noise, wetlands, socioeconomic systems and other resources associated with construction and operation of the planned Delta LNG export terminal and the nearby proposed Plaquemines LNG export terminal and other large projects at various stages of planning in the region;
- LNG terminal site alternatives;
- Delta Express Pipeline route alternatives; and
- alternative construction methods and workspace configurations that would avoid or reduce impacts.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned Project.

A *Notice of Availability* of the draft EIS will be sent to the environmental mailing list and will provide instructions to access the electronic document on the FERC's website (*www.ferc.gov*). If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please return the attached Mailing List Update Form (appendix 4).

Becoming an Intervenor

Once Delta LNG files its application with the Commission, you may want to become an intervenor which is an official party to the Commission's proceeding. Only intervenors have the right to seek rehearing of the Commission's decision and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp*. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the Project, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on General Search and enter the docket number in the Docket Number field, excluding the last three digits (*i.e.,* PF19–4). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

[5] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

Public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: July 30, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–16861 Filed 8–6–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0367; FRL–9996–71]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of application 73049–EUP–RE from Valent BioSciences LLC, requesting an experimental use permit (EUP) for 1-Aminocyclopropane-1-carboxylic acid. EPA has determined that the permit may be of regional or national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before September 6, 2019.

ADDRESSES: Submit your comments, identified by Docket Identification (ID) Number EPA–HQ–OPP–2019–0367, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on more than 10 acres of land or more than one surface acre of water.

Pursuant to 40 CFR 172.11(a), EPA has determined that the following EUP application may be of regional or national significance, and therefore is seeking public comment on the EUP application:

Submitter: Valent BioSciences LLC, 870 Technology Way, Libertyville, IL 60048 (73049–EUP–RE).

Pesticide Chemical: 1-Aminocyclopropane-1-carboxylic acid (ACC).

Summary of Request: The biochemical plant regulator ACC is intended to be applied to apples and stone fruits at flowering for the purpose of fruit thinning. The objective of the testing is to verify the efficacy of and crop tolerance to the test pesticide product under commercial production methods. The testing is intended to last 3 years. The testing will take place on 1,800 acres and 325 pounds of formulated pesticide product (30 pounds of active ingredient) will be applied in total each year. The testing on apples will occur in the following states: California, Connecticut, Maine, Maryland, Massachusetts, Michigan, Minnesota, New York, North Carolina, Ohio, Oregon, Pennsylvania, Vermont, Virginia, Washington, West Virginia, and Wisconsin. The apple applications will be applied at 46 fluid ounces of pesticide per acre on a total of 1,150 acres each year. The testing on stone fruits will occur in the following states: California, Georgia, Michigan, New Jersey, New York, North Carolina, Ohio, Pennsylvania, and South Carolina. The stone fruit applications will be applied at 103 fluid ounces of pesticide per acre on a total of 650 acres each year. (Note: The formulated pesticide product contains 10% active ingredient and is diluted for spraying.)

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 15, 2019.

Delores Barber,

Director, Information Technology and Re

[FR Doc. 2019–16810 Filed 8–6–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9997–76–OA]

Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office requests public nominations for a pool of scientific consultants to support the chartered CASAC by providing subject matter expertise, as requested, on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) and ozone.

DATES: Nominations should be submitted by (August 21, 2019) per instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Mr. Aaron Yeow, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–2050 or via email at *yeow.aaron@epa.gov.* General information concerning the CASAC can be found at the CASAC website at *http://www.epa.gov/casac.*

SUPPLEMENTARY INFORMATION:

Background: The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. The CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and NAAQS under sections 108 and 109 of the Act. The CASAC shall also: Advise the EPA Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; describe the research efforts necessary to provide the required information; advise the EPA Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS.

As amended, Section 109(d)(1) of the Clean Air Act (CAA) requires that EPA reviews the NAAQS at five-year intervals and revise, as appropriate, the air quality criteria and the NAAQS for the six ''criteria'' air pollutants, including PM and ozone.

This **Federal Register** notice solicitation is seeking nominations for consultants to support the Chartered CASAC for the PM and ozone reviews. These consultants will review science and policy assessments, and related documents, and will make themselves available, as requested, to provide feedback to the Chartered CASAC as part of EPA's review of the PM and Ozone NAAQS. The Chartered CASAC will provide advice to the EPA Administrator in a manner consistent with the Clean Air Act, Federal Advisory Committee Act, and CASAC's charter. These consultants should be available for consultation, through CASAC's Chair and Designated Federal Official. Chartered CASAC members will have the opportunity to seek input from consultants through written requests provided to CASAC's Chair and facilitated by the Designated Federal Official.

The Chartered CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA). As a Federal Advisory Committee, the chartered CASAC conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The Chartered CASAC will comply with the provisions of FACA.

Request for Nominations: The SAB Staff Office is seeking nominations of scientists with demonstrated expertise and research in the field of air pollution related to PM and ozone, including:

- Air quality, atmospheric science and chemistry (including ambient measurements and satellite remote sensing aerosol optical depth analysis);
- exposure assessment (including dispersion modeling, photochemical grid modeling, and errors-in-variables methods and effects of exposure/covariate estimation errors on epidemiologic study results);
- dosimetry;
- toxicology;
- comparative toxicology (including extrapolation of findings in animals to humans);
- controlled clinical exposure;
- epidemiology (including low-dose causal concentration-response functions);
- biostatistics;
- human exposure modeling;
- causal inference;
- biological mechanisms of causation;
- risk assessment/modeling;
- multi-stressor interactions;
- ecology and effects on welfare and the environment;
- and effects on visibility impairment, climate, and materials.

Any interested person or organization may nominate qualified individuals in the areas of expertise described above. Individuals may self-nominate. Nominations should be submitted via email to the DFO, Mr. Aaron Yeow, as identified above. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability or ethnicity. Nominations should be submitted by August 21, 2019.

The following information should be provided to the DFO: Contact information for the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's *curriculum vitae;* and a biographical sketch of the nominee indicating current position, educational background; research activities; sources of research funding for the last two years; and recent service on other national advisory committees or national professional organizations. Persons having questions about the nomination process should contact the DFO, as identified above. The DFO will acknowledge receipt of nominations. The Administrator shall select the expert consultants.

In selecting these consultants, the Administrator will consider information provided by the candidates themselves, and additional background information. Selection criteria to be used for selecting consultants include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors) necessary to address anticipated questions from the CASAC; (b) availability and willingness to provide feedback to the Chartered CASAC as requested; (c) skills providing subject matter expertise to committees, subcommittees and advisory panels; and, (d) diversity of expertise.

Dated: July 29, 2019.

Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2019–16913 Filed 8–6–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0214, 3060–0316, 3060–0750, 3060–1065]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 7, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0214.

Title: Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 73.1212, 76.1701 and 73.1943, Political Files.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for profit entities; Not for profit institutions; State, Local or Tribal government; Individuals or households.

Number of Respondents and Responses: 23,984 respondents; 62,839 responses.

Estimated Time per Response: 1–52 hours.

Frequency of Response: On occasion reporting requirement, Recordkeeping requirement, Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections is contained in Sections 151, 152, 154(i), 303, 307 and 308 of the Communications Act of 1934, as amended.

Total Annual Burden: 2,043,805 hours.

Total Annual Cost: None.

Privacy Impact Assessment: The Commission prepared a system of records notice (SORN), FCC/MB–2, ''Broadcast Station Public Inspection Files,'' that covers the PII contained in the broadcast station public inspection files located on the Commission's website. The Commission will revise appropriate privacy requirements as necessary to include any entities and information added to the online public file in this proceeding.

Nature and Extent of Confidentiality: Most of the documents comprising the public file consist of materials that are not of a confidential nature. Respondents complying with the information collection requirements may request that the information they submit be withheld from disclosure. If confidentiality is requested, such requests will be processed in accordance with the Commission's rules, 47 CFR 0.459.

In addition, the Commission has adopted provisions that permit respondents subject to the information collection requirement for Shared Service Agreements to redact confidential or proprietary information from their disclosures.

Needs and Uses: On July 10, 2019, the Commission adopted a *Report and Order* in MB Docket Nos. 18–202 and 17–105, FCC 19–67, *In the Matter of Children's Television Programming Rules; Modernization of Media Regulation Initiative,* which modernizes the children's television programming rules in light of changes to the media landscape that have occurred since the rules were first adopted. The *Report and Order* revises the following information collection requirements:

Pursuant to 47 CFR 73.3526(e)(11)(ii), commercial TV and Class A TV broadcast stations must maintain records sufficient to permit substantiation of the station's certification, in its license renewal application, of compliance with the commercial limits on children's programming established in 47 U.S.C. Section 303a and 47 CFR 73.670. In the *Report and Order,* the Commission revises this rule to permit these stations to place such records in their public files annually rather than quarterly and to permit the filing of these records within 30 days after the end of the calendar year. The Commission also revises 47 CFR 73.3526(e)(11)(iii) to require commercial television stations to place in their public files the Children's Television Programming Report (Report) (FCC Form 2100 Schedule H) on an annual rather than quarterly basis, within 30 days after the end of the calendar year and to eliminate the requirement to publicize the existence and location of the Report.

All other information collection requirements contained under 47 CFR 73.1212, 73.3526, 73.3527, 73.1943, and 76.1701 are still a part of the information collection and remain unchanged since last approved by OMB.

OMB Control Number: 3060–0316.

Title: 47 CFR 76.5, Definitions, 76.1700, Records to Be Maintained Locally by Cable System Operators; 76.1702, Equal Employment Opportunity; 76.1703, Commercial

Records on Children's Programs; 76.1707, Leased Access; 76.1711, Emergency Alert System (EAS) Tests and Activation.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 3,000 respondents; 3,000 responses.

Estimated Time per Response: 14 hours.

Frequency of Response: Recordkeeping requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in sections 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573 of the Communications Act of 1934, as amended.

Total Annual Burden: 42,000 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On July 10, 2019, the Commission adopted a *Report and Order* in MB Docket Nos. 18–202 and 17–105, FCC 19–67, *In the Matter of Children's Television Programming Rules; Modernization of Media Regulation Initiative,* which modernizes the children's television programming rules in light of changes to the media landscape that have occurred since the rules were first adopted. The *Report and Order* revises the following information collection requirements:

Pursuant to 47 CFR 76.1703, cable operators that air children's programming must maintain records sufficient to verify compliance with 47 CFR 76.225 and make such records available to the public. Such records must be maintained for a period sufficient to cover the limitations period specified in 47 U.S.C. Section 503(b)(6)(B). In the *Report and Order,* the Commission revises the rules to permit cable television operators to file their certifications of compliance with the commercial limits in children's programming annually rather than quarterly and to permit the filing of these certifications within 30 days after the end of the calendar year.

All other information collection requirements contained under 47 CFR 76.5, 76.1700, 76.1702, 76.1703, 76.1707, and 76.1711 are still a part of the information collection and remain unchanged since last approved by OMB.

OMB Control Number: 3060–0750.

Title: 47 CFR 73.671, Educational and Informational Programming for Children; 47 CFR 73.673, Public Information Initiatives Regarding Educational and informational Programming for Children.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 1,770 respondents; 1,125,720 responses.

Estimated Time per Response: 0.017–0.084 hours.

Frequency of Response: Third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i), 303, and 336 of the Communications Act of 1934, as amended.

Total Annual Burden: 57,560 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On July 10, 2019, the Commission adopted a *Report and Order* in MB Docket Nos. 18–202 and 17–105, FCC 19–67, *In the Matter of Children's Television Programming Rules; Modernization of Media Regulation Initiative,* which modernizes the children's television programming rules in light of changes to the media landscape that have occurred since the rules were first adopted. The *Report and Order* revises the following information collection requirements:

Pursuant to 47 CFR 73.671(c)(5), each commercial television broadcast station must identify programming as specifically designed to educate and inform children by the display on the television screen throughout the program of the symbol E/I. This requirement is intended to assist parents in identifying educational and informational programming for their children. Noncommercial television broadcast stations are no longer be required to identify Core Programming by displaying the E/I symbol throughout the program.

Pursuant to 47 CFR 73.671(e), each television broadcast station that preempts an episode of a regularly scheduled weekly Core Program on its primary stream will be permitted to count the episode toward the Core Programming processing guidelines if it reschedules the episode on its primary stream in accordance with the requirements of 47 CFR 73.671(e). Similarly, each television broadcast station that preempts an episode of a regularly scheduled weekly Core Program on a multicast stream will be permitted to count the episode toward the Core Programming processing guidelines if it reschedules the episode on the multicast stream in accordance with the requirements of 47 CFR 73.671(e). Among other requirements, the station must make an on-air notification of the schedule change during the same time slot as the preempted episode. The on-air notification must include the alternate date and time when the program will air. This requirement will help to ensure that parents and children are able to locate the rescheduled program.

Pursuant to 47 CFR 73.673, each commercial television broadcast station licensee must provide information identifying programming specifically designed to educate and inform children to publishers of program guides. This requirement is intended to improve the information available to parents regarding programming specifically designed for children's educational and informational needs. Commercial television broadcast station licensees are no longer be required to provide program guide publishers an indication of the age group for which the programming is intended. The *Report and Order* finds that very few program guides include this information.

OMB Control Number: 3060–1065.

Title: Section 25.701 of the Commission's Rules, Direct Broadcast Satellite Public Interest Obligations.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2 respondents; 2 responses.

Estimated Time per Response: 1–10 hours.

Frequency of Response: Recordkeeping requirement; on occasion reporting requirement; one time reporting requirement; annual reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority which covers this information collection is contained in Section 335 of the Communications Act of 1934, as amended.

Total Annual Burden: 48 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impacts.

Nature and Extent of Confidentiality: Although the Commission does not believe that any confidential information will need to be disclosed in order to comply with the information collection requirements, applicants are free to request that materials or information submitted to the Commission be withheld from public inspection. (See 47 CFR 0.459).

Needs and Uses: On July 10, 2019, the Commission adopted a *Report and Order* in MB Docket Nos. 18–202 and 17–105, FCC 19–67, *In the Matter of Children's Television Programming Rules; Modernization of Media Regulation Initiative,* which modernizes the children's television programming rules in light of changes to the media landscape that have occurred since the rules were first adopted. The *Report and Order* revises the following information collection requirements:

Pursuant to 47 CFR 25.701(e)(3), DBS providers that air children's programming must maintain records sufficient to verify compliance with this rule and make such records available to the public. Such records must be maintained for a period sufficient to cover the limitations period specified in 47 U.S.C. Section 503(b)(6)(B). In the *Report and Order,* the Commission revises the rules to permit DBS operators to file their certifications of compliance with the commercial limits in children's programming annually rather than quarterly and to permit the filing of these certifications within 30 days after the end of the calendar year.

All other information collection requirements contained under 47 CFR 25.701 are still a part of the information collection and remain unchanged since last approved by OMB.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–16893 Filed 8–6–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0626]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 7, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control No.: 3060–0626.

Title: Section 90.483, Permissible Methods and Requirements of Interconnecting Private and Public Systems of Communications.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business of other for-profit entities.

Number of Respondents and Responses: 100 respondents; 100 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirements; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

T*otal Annual Burden:* 100 hours.

Annual Cost Burden: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection.

Needs and Uses: When a frequency is shared by more than one system, automatic monitoring equipment must be installed at the base station to prevent activation of the transmitter when signals of co-channel stations are present and activation would interfere with communications in progress. Licensees may operate without the monitoring equipment if they have obtained the consent of all co-channel licensees located within a 120 kilometer (75 mile) radius of the interconnected base station transmitter. A statement must be submitted to the Commission indicating that all co-channel licensees have consented to operate without the monitoring equipment. This information is necessary to ensure that licensees comply with the Commission's technical and operational rules, and to prevent activation of the transmitter when signals of co-channel stations are present and could possibly interfere with communications in process.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–16894 Filed 8–6–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX]

Information Collection Being Submitted to the Office of Management and Budget for Emergency Review and Approval

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before September 6, 2019.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.ongele@fcc.gov.* Include in the comments the Title as shown in the ''Supplementary Information'' section below.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The Commission is requesting emergency OMB processing of the information collection requirement(s) contained in this notice and has requested OMB approval no later than 35 days after the collection is received at OMB. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of Commission ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

OMB Control Number: 3060–XXXX.

Title: Application to Participate in a Toll Free Number Auction, FCC Form 833.

Form Number: FCC Form 833.

Type of Review: New information collection.

Respondents: Business or other for-profit entities, Individuals or households, Not-for-profit institutions, Federal Government, State, Local or Tribal Governments.

Number of Respondents and Responses: 200 respondents; 200 responses.

Estimated Time per Response: 1.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection is contained in sections 1, 4(i), 201(b) and 251(e)(1) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201(b), 251(e)(1).

Total Annual Burden: 300 hours.

Total Annual Cost: $0.

Privacy Impact Assessment: The Commission is preparing to conduct a Privacy Impact Assessment.

Nature and Extent of Confidentiality: Information collected on FCC Form 833 is made available for public inspection, and the Commission is not requesting that respondents submit confidential information as part of the pre-auction application process. For individuals, the Privacy Act, 5 U.S.C. 552(a), is the statutory authority for confidentiality and applies to this information collection. To the extent the information submitted pursuant to this information collection is determined to be confidential, it will be protected by the Commission. If a respondent seeks to have certain information collected on FCC Form 833 withheld from public inspection, the respondent may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules. *See* 47 CFR 0.459.

Needs and Uses: The Commission's rules and related requirements are designed to ensure that the competitive bidding process for assigning toll free numbers is limited to qualified applicants, deter possible abuse of the bidding process, and enhance the use of competitive bidding to assign toll free numbers in furtherance of the public interest. Applicants will use FCC Form 833 to submit the required disclosures and certifications, and the information collected on FCC Form 833 will then be reviewed to determine if an applicant is qualified to bid in the 833 code toll free number auction (833 Auction). The 833 Auction will not be able to occur without the collection of information on FCC Form 833. Without the information collected on FCC Form 833, a determination of whether the applicant is qualified to bid in the 833 Auction cannot be made.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–16895 Filed 8–6–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections.

Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before October 7, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Toll Free Number Auctions.

Form Number: FCC–5633.

Type of Review: New information collection.

Respondents: Individuals or Households, Business or other for-profit, Not-for-profit Institutions, Farms and/or Federal, State, Local and/or Tribal government agencies.

Number of Respondents and Responses: 1,220 respondents; 1,220 responses.

Estimated Time per Response: 0.084 hours (5 minutes)–0.166 hours (10 minutes).

Frequency of Response: On occasion and one-time reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 251(e)(1).

Total Annual Burden: 105 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: The Commission is preparing to conduct a Privacy Act Impact Assessment (PIA).

Nature and Extent of Confidentiality: The Commission is not requesting that respondents for this information collection (LOA and Secondary Market) submit confidential information to the FCC. For individuals, the Privacy Act, 5 U.S.C. 552a, is the statutory authority for confidentiality and it applies to this information collection. Respondents may, however, request confidential treatment for information they believe to be confidential under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: On September 27, 2018, the Commission released a *Report and Order* in WC Docket No. 17–192, FCC 18–137 (*Report and Order*). In the *Report and Order,* the Commission established competitive bidding as a toll free number assignment method, and called for an auction for select numbers in the toll free code 833 as an experiment to test this method. To verify the relationship between the responsible organization (RespOrg) and the potential subscriber, a Letter of Authorization (LOA) is required during the bidding process. Additionally, a key component to the effectiveness of the auction is the adoption of a post-auction secondary market (Secondary Market) for the sale of the rights to use 833 code toll free numbers. Collecting data on Secondary Market transactions will allow the Commission to evaluate the entire experimental auction process and determine the potential use of competitive bidding in future toll free number assignments.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–16896 Filed 8–6–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10175	Charter Bank	Santa Fe	NM	8/1/2019
10322	First Southern Bank	Batesville	AR	8/1/2019
10365	Atlantic Southern Bank	Macon	GA	8/1/2019
10529	The F & M State Bank of Argonia	Argonia	KS	8/1/2019

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

Dated at Washington, DC, on August 1, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–16804 Filed 8–6–19; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS19–06]

Appraisal Subcommittee; Final Order Granting in Part Temporary Waiver Relief

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Final order granting in part, with specified terms and conditions,

and with the Federal Financial Institutions Examination Council (FFIEC) concurrence, temporary waiver relief.

SUMMARY: The Appraisal Subcommittee (ASC) of the FFIEC is issuing a final order pursuant to section 1119(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (Title XI) and the rules promulgated thereunder. This order grants in part, with specified terms and conditions, and with the FFIEC concurrence, a request for temporary waiver relief received from Governor Doug Burgum, State of North Dakota, the North Dakota Department of Financial Institutions, and the North Dakota Bankers Association, notice of which was published in the **Federal Register** on May 30, 2019.

DATES: Applicable August 7, 2019.

FOR FURTHER INFORMATION CONTACT: James R. Park, Executive Director, at (202) 595–7575, or Alice M. Ritter, General Counsel, at (202) 595–7577, ASC, 1325 G Street NW, Suite 500, Washington, DC 20005.

SUPPLEMENTARY INFORMATION:

I. Background

A. Relevant Statutory Provisions and Regulations

The ASC was established by Title XI.[1] The purpose of Title XI is ''to provide that Federal financial and public policy interests in real estate related transactions will be protected by requiring that real estate appraisals utilized in connection with federally related transactions are performed in writing, in accordance with uniform standards, by individuals whose competency has been demonstrated and whose professional conduct will be subject to effective supervision.'' [2] Section 1119(b) of Title XI authorizes the ASC to waive, on a temporary basis and with concurrence of the FFIEC, ''any requirement relating to certification or licensing of a person to perform appraisals under [Title XI] upon a written determination that there is a scarcity of certified or licensed appraisers to perform appraisals in connection with federally related transactions [3] in a State, or in any geographical political subdivision of a State, leading to significant delays in the performance of such appraisals.'' [4] Congress intended that the ASC exercise this waiver authority ''cautiously.'' [5]

The ASC has promulgated regulations that set forth procedures [6] governing the processing of temporary waiver requests. After receiving a waiver request, the ASC is required to issue a public notice in the **Federal Register** requesting comment on the request for a proposed temporary waiver. Within 15 days of the close of the 30-day comment period, the ASC, by order, must grant or deny a waiver, in whole or in part, and with specified terms or conditions, including provisions for waiver termination. The ASC's order shall respond to comments received, provide reasons for its finding, and be published promptly in the **Federal Register**. Any ASC approval order shall be effective only upon FFIEC concurrence.

B. Procedural Status

On August 1, 2018, a letter requesting a temporary waiver was submitted to the ASC by Governor Doug Burgum, State of North Dakota, the North Dakota Department of Financial Institutions, and the North Dakota Bankers Association (collectively, the Requester). On September 7, 2018, ASC staff replied to the Requester by letter, in which ASC staff described the information required to file a completed waiver request pursuant to 12 CFR 1102.2 and 1102.3. The Requester submitted additional information in a letter dated April 10, 2019, in response to the ASC's September 7, 2018 letter. On April 15, 2019, the ASC convened a Special Meeting and determined to publish a notice for comment on the request for temporary waiver in the **Federal Register**. The request seeks a waiver of appraiser credentialing requirements for appraisals for FRTs under $500,000 for 1-to-4 family residential real estate transactions and under $1,000,000 for agricultural and commercial real estate transactions throughout the State of North Dakota for a period of not less than five years.

On May 30, 2019, the ASC published a Notice of Received Request for a Temporary Waiver giving interested persons 30 days to submit comments, including submission of written data, views and arguments.[7] The comment period closed on July 1, 2019. A discussion of the public comments received by the ASC concerning the request for temporary waiver relief follows in Section III below.

The ASC called a Special Meeting to consider this matter on July 9, 2019, and voted to approve the issuance of this final order granting in part, upon specified terms and conditions, and subject to FFIEC concurrence, temporary waiver relief. The FFIEC met via teleconference on July 12, 2019, and a quorum of the Council being present, took the following action: Pursuant to § 1119(b) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, the Council approved the temporary waiver granted by the ASC on July 9, 2019.

II. Request for a Temporary Waiver

The Requester sought a temporary waiver of the appraiser credentialing requirements for appraisals for FRTs under $500,000 for 1-to-4 family residential real estate transactions and under $1,000,000 for agricultural and commercial real estate transactions throughout the State of North Dakota for a period of not less than five years. The Requester stated that a scarcity of appraisers exists, particularly in the rural areas of the western part of the State, indicating that of the 53 counties in North Dakota, 29 counties do not have a single appraiser residing in the county, and that while the most severe impact of the appraiser scarcity has been experienced in western and the most rural districts in North Dakota, the population centers are also impacted.

The Requester conducted a survey to assess what lenders deem are appropriate turnaround times for residential and commercial appraisals. The Requester summarized the results of the survey as follows:

- 81 percent reported that up to 30 days is appropriate for residential appraisals.
- 80 percent reported that up to 60 days is appropriate for commercial appraisals.
- 65 percent reported a delay in receiving a residential real estate appraisal, and 71 percent reported a delay in receiving a commercial appraisal.
- 57 percent reported unreasonable delays in receiving residential real

[1] The ASC Board consists of seven members. Five members are designated by the heads of the FFIEC agencies (Board of Governors of the Federal Reserve System [Board], Bureau of Consumer Financial Protection [Bureau], Federal Deposit Insurance Corporation [FDIC], Office of the Comptroller of the Currency [OCC], and National Credit Union Administration [NCUA]). The other two members are designated by the heads of the Department of Housing and Urban Development (HUD) and the Federal Housing Finance Agency (FHFA).

[2] Title XI § 1101, 12 U.S.C. 3331.

[3] ''Federally related transaction'' (FRT) refers to any real estate related financial transaction which: (a) A federal financial institutions regulatory agency engages in, contracts for, or regulates; and (b) requires the services of an appraiser. (Title XI § 1121 (4), 12 U.S.C. 3350.)

[4] 12 U.S.C. 3348(b).

[5] House Comm. on Banking, Finance and Urban Affairs, Report Together with Additional, Supplemental, Minority, Individual, and Dissenting Views, Financial Institutions Reform, Recovery, and Enforcement Act of 1989, H.R. Rep. No. 101–54 Part 1, 101st Cong., 1st Sess., at 482–83.

[6] 12 CFR part 1102, subpart A.

[7] 84 FR 25052 (May 30, 2019).

estate appraisals in the prior 12 months. 72 percent reported unreasonable delays in receiving commercial appraisals in the prior 12 months.

The Requester acknowledged that federal banking agencies and NCUA have proposed increases to the appraisal thresholds,[8] stating that ''[if adopted, it] will have a positive effect that is similar to that which can be achieved by the granting of this waiver since both approaches will provide much needed relief.''

III. Summary of Comments

The ASC received 109 [9] comment letters in response to the published Notice of Received Request for a Temporary Waiver and request for comment. These comment letters were received from State appraiser certifying and licensing agencies, appraiser and mortgage lending associations, professional associations, appraisal firms, appraisers, and several banks and financial institution associations in the State of North Dakota.

While a few commenters supported the granting of a temporary waiver, the majority of comments received were from appraisers opposing the granting of a temporary waiver. Associations representing insured depository institutions in North Dakota (banks and credit unions) meanwhile argued that the waiver would provide some measure of relief in local communities without increasing any safety and soundness risks. Several other commenters disputed that there was a shortage of appraisers in North Dakota and that there are significant delays. Specifically, commenters offered data showing that the number of appraisers in North Dakota is consistent with other similarly populated States. Commenters also stated that the turn time of appraisals in North Dakota average within the Requester's range of appropriate turn times. Commenters also noted decreased economic activity in North Dakota and that turn times have improved in recent years. Several commenters also expressed varying concerns about the long term impact a waiver would have on appraisers and the appraisal profession, consumers and the safety and soundness of the North Dakota banking system. Several commenters reported making attempts to be added to lender lists of approved appraisers without success. Several commenters asked if a waiver were granted, who would be qualified to perform a *Uniform Standards of Professional Appraisal Practice* (USPAP)-compliant appraisal without the training and education a credentialed appraiser is required to have, and with whom consumers and other parties would file a complaint. Commenters also expressed concern over the loss of protection to the public if a waiver is granted. The ASC acknowledges these concerns and emphasizes that this is a temporary waiver while more long-term solutions are researched and implemented by the Requester and interested stakeholders in the State of North Dakota. In the interim, lenders are still required to obtain USPAP-compliant appraisals for FRTs and should review appraisals for compliance with USPAP. Several commenters challenged the ASC's authority to exercise temporary waiver discretion at this point in time, commenting that the statutory provision was meant to be applied when States were first setting up appraiser regulatory programs and were perhaps not going to be able to meet the statutory deadline to establish a program. The ASC notes that the statute includes no expiration of the waiver provisions in the statute.

The North Dakota Real Estate Appraiser Qualifications and Ethics Board (Appraiser Board) provided a letter in which they recommend denying the request. The Appraiser Board reported a 44 percent increase in appraisers since 2009 and submitted data in support of their position. The letter from the Appraiser Board also addressed recent regulatory changes that have been made or are being considered that address many of the concerns in the request.

IV. ASC Discussion

In order to grant a temporary waiver, the ASC must make a determination that a scarcity of credentialed appraisers is leading to significant delays in obtaining appraisals for FRTs in the geographic area [10] specified in the request. In considering this request, the ASC examined both evidence of a scarcity of appraisers in North Dakota, and evidence of scarcity leading to significant delay. The ASC noted that North Dakota's appraisal turnaround time is one of the slowest in the country. In this case, while data provided to the ASC by the Requester and the Appraiser Board and included in public comments, was not consistent and sometimes conflicted, the majority of the ASC members concluded that a scarcity of appraisers does exist in North Dakota and that the scarcity is leading to a significant delay in appraisal services for FRTs. Therefore, by majority vote, the ASC determined to grant in part, subject to specified terms and conditions, and subject to FFIEC concurrence, temporary waiver relief as follows:

- A temporary waiver of appraiser credentialing requirements for appraisals of FRTs under $500,000 for 1-to-4 family residential real estate transactions throughout the State of North Dakota for a period of one year, unless the federal banking agencies issue a rule increasing appraisal exemption threshold limits for residential real estate transactions,[11] in which case the residential waiver will terminate 60 days after the effective date of that threshold increase.
- A temporary waiver of appraiser credentialing requirements for appraisals of FRTs under $1,000,000 for commercial real estate transactions [12] throughout the State of North Dakota for a period of one year.
- During the one-year period, the Requester is expected to develop a plan through continued dialogue with North Dakota stakeholders, including the Appraiser Board, to identify potential solutions to address appraiser scarcity and appraisal delay.
- At least 30 days prior to the expiration of the one-year period, the Requester should provide (1) a status report to the ASC on the plan that was developed in collaboration with stakeholders and any implementation progress made on that plan toward identifying meaningful solutions to resolve appraiser scarcity and delay issues faced in North Dakota; and (2) supporting data showing that appraiser scarcity leading to significant delays continues to exist, which may include information to identify specific localities affected by appraiser scarcity. The ASC will consider the information as presented by the Requester, and by vote in open session, may extend the temporary waiver for an additional one-year period.
- The ASC at any time may terminate a waiver order on a finding that significant delay in the receipt of appraisals for FRTs no longer exists, or

[8] *See* 83 FR 63110 (December 7, 2018) (OCC, Board, and FDIC proposing to increase the residential real estate appraisal threshold level from $250,000 to $400,000); 83 FR 49857 (October 3, 2018) (NCUA proposing to increase the appraisal threshold for non-residential real estate transactions from $250,000 to $1,000,000).

[9] *Regulations.gov* shows 109 comments received in total with 105 viewable comments due to duplicates and 2 withdrawals.

[10] The ASC's section 1119(b) temporary waiver authority is with respect to a State or any geographical political subdivision of a State.

[11] 83 FR 63110 (December 7, 2018).

[12] The request was for commercial and agricultural, but agricultural loans are already included in either commercial or business loans.

that the terms and conditions of the order are not being satisfied.

V. Order

For the reasons stated above, and pursuant to section 1119(b) of Title XI and 12 CFR part 1102, subpart A, the ASC grants temporary waiver relief to the Requester, subject to the following specified terms and conditions:

- A temporary waiver of appraiser credentialing requirements for appraisals of FRTs under $500,000 for 1-to-4 family residential real estate transactions throughout the State of North Dakota for a period of one year, unless the federal banking agencies issue a rule increasing appraisal exemption threshold limits for residential real estate transactions,[13] in which case the residential waiver will terminate 60 days after the effective date of that threshold increase.
- A temporary waiver of appraiser credentialing requirements for appraisals of FRTs under $1,000,000 for commercial real estate transactions throughout the State of North Dakota for a period of one year.
- During the one-year period, the Requester is expected to develop a plan through continued dialogue with North Dakota stakeholders, including the Appraiser Board, to identify potential solutions to address appraiser scarcity and appraisal delay.
- At least 30 days prior to the expiration of the one-year period, the Requester should provide (1) a status report to the ASC on the plan that was developed in collaboration with stakeholders and any implementation progress made on that plan toward identifying meaningful solutions to resolve appraiser scarcity and delay issues faced in North Dakota; and (2) supporting data showing that appraiser scarcity leading to significant delays continues to exist, which may include information to identify specific localities affected by appraiser scarcity. The ASC will consider the information as presented by the Requester, and by vote in open session, may extend the temporary waiver for an additional one-year period.
- The ASC at any time may terminate a waiver order on a finding that significant delay in the receipt of appraisals for FRTs no longer exists, or that the terms and conditions of the order are not being satisfied.

* * * * *

By the Appraisal Subcommittee.

Dated: August 2, 2019.

Arthur Lindo,

Chairman.

[FR Doc. 2019–16908 Filed 8–6–19; 8:45 am]

BILLING CODE 6700–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–4131, FDA–2018–N–0821, FDA–2013–N–0032, FDA–2014–N–0801, FDA–2007–D–0429, FDA–2013–N–0013, and FDA–2008–D–0530]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
FDA Adverse Event and Products Experience Reports; Electronic Submissions	0910–0645	6/30/2022
Investigation of Consumer Perceptions of Expressed Modified Risk Claims	0910–0873	6/30/2022
Food Labeling: Notification Procedures for Statements on Dietary Supplements	0910–0331	7/31/2022
Export Notification and Recordkeeping Requirements	0910–0482	7/31/2022
Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act	0910–0641	7/31/2022
Sanitary Transportation of Human and Animal Food	0910–0773	7/31/2022
Guidance for Industry on Tropical Disease Priority Review Vouchers	0910–0822	7/31/2022

[13] 83 FR 63110 (December 7, 2018).

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16889 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2832]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nomination for Nonvoting Industry Representatives on the Vaccines and Related Biological Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the VRBPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by *September 6, 2019,* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 6, 2019.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002, 240–402–5771, Fax: 301–595–1307, Serina.Hunter-Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. CBER Advisory Committee

Vaccines and Related Biological Products Advisory Committee

The committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA has regulatory responsibility. The committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs (Commissioner).

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, as well as a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate, and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16877 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3369]

Evaluating the Clinical Pharmacology of Oligonucleotide Therapeutics; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments on evaluating the clinical pharmacology of oligonucleotide therapeutics. There are many unique clinical pharmacology considerations concerning the development of oligonucleotide therapeutics; however, for the purposes of this request, the Agency is specifically interested in

comments regarding the characterization of the effects of hepatic and renal impairment, drug-drug interactions, and immunogenicity on the pharmacokinetics of oligonucleotide therapeutics as well as the effects of oligonucleotide therapeutics on cardiac electrophysiology. Public comments will help the Agency develop recommendations for the design and conduct of studies important to the safe and effective use of oligonucleotide therapeutics and facilitate the regulatory assessment of such studies.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment in our development of recommendations, submit either electronic or written information and comments by October 7, 2019.

ADDRESSES: You may submit comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3369 for ''Evaluating the Clinical Pharmacology of Oligonucleotide Therapeutics; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hobart Rogers, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2213, *Hobart.Rogers@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Oligonucleotide therapeutics typically are synthetically modified single- or double-stranded ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) that exert pharmacologic effects through a variety of mechanisms (*e.g.,* altered splicing, RNA interference, immunomodulation, microRNA modulation). Compared to small molecule or biological products, oligonucleotide therapeutics have unique characteristics regarding their chemistry, pharmacology, sites of action, pharmacokinetic disposition, and pharmacodynamics. As a result, there may be special considerations for the design and conduct of clinical pharmacology studies to assess oligonucleotide therapeutics, such as those designed to evaluate the effects of organ impairment or drug interactions. Currently, none of FDA's currently published guidance documents on clinical pharmacology assessments contain specific recommendations for oligonucleotide therapeutics.

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on certain aspects of evaluating the clinical pharmacology of oligonucleotide therapeutics. This request focuses on oligonucleotide therapeutics designed to hybridize to a cognate RNA to elicit a pharmacologic effect. For all questions, organize any discussion by the type of oligonucleotide therapeutics (*e.g.,* by chemistry or modification type). Please provide the rationale for your suggestions and include supporting data if available. FDA is particularly interested in responses to the following overarching questions:

(1) Evaluating Drug-Drug Interactions (DDIs)

(a) Under what circumstances should clinical DDI assessment be warranted or not warranted for oligonucleotide therapeutics?

(b) In circumstances where DDI assessments are warranted:

(i) What types of DDI assessments are suitable and why (*e.g.,* in vitro studies, dedicated clinical studies, cocktail studies, population pharmacokinetic analyses)? Please discuss the advantages, challenges, and limitations with each type of assessment.

(ii) What are the study design considerations (*e.g.,* in vitro test

systems, population, analytes) for the types of assessments discussed in item (1)(b)(i) above? Please describe the rationale for any design considerations proposed.

(2) Evaluating the Pharmacokinetics in Organ Impairment

(a) Under what circumstances are organ impairment assessments for oligonucleotide therapeutics warranted or not warranted for:

(i) Renal function

(ii) hepatic function

(b) In circumstances where organ impairment assessments are warranted:

(i) What types of assessments are suitable for renal and/or hepatic impairment and why (*e.g.,* dedicated clinical studies, population pharmacokinetic analyses)? Please discuss the advantages, challenges, and limitations with each type of assessment.

(ii) What are the study design considerations (*e.g.,* study population) for the types of assessments discussed in item (2)(b)(i) above for renal and/or hepatic impairment? Please describe the rationale for any design considerations proposed.

(3) Evaluating Immunogenicity

(a) Under what circumstances are immunogenicity assessments of oligonucleotide therapeutics warranted or not warranted?

(b) In circumstances where immunogenicity assessments are warranted:

What types of assessments are suitable and why (*e.g.,* antibodies against other components of the formulation, antibodies against a newly created ''splice-altered'' protein, neutralizing titers, cytokine measurements)? Please discuss the advantages, challenges, and limitations with each type of assessment.

(4) Evaluating QT Prolongation

(a) Under what circumstances are cardiac electrophysiology assessments warranted or not warranted in the evaluation of oligonucleotide therapeutics?

(b) In circumstances where cardiac electrophysiology assessments are warranted:

What types of assessments are suitable and why (*e.g.,* hERG inhibition assay, thorough QT assessment) in nonclinical or clinical studies? Please discuss the advantages, challenges, and limitations with each type of assessment.

(5) With regard to the four questions above, when a sponsor seeks to rely on previously generated data and information that it owns or to which it has a right of reference, what scientific findings may be applied across the sponsor's oligonucleotide therapeutics with shared characteristics (*e.g.,* similar backbone modifications)?

FDA will consider all information and comments submitted.

III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: August 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16880 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to InBios International, Inc. (InBios), for the ZIKV Detect 2.0 IgM Capture ELISA. FDA revoked this Authorization on May 23, 2019, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in consideration of the De Novo classification request granted to the InBios ZIKV Detect 2.0 IgM Capture ELISA as a Class II device under the generic name Zika virus serological reagents on May 23, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of May 23, 2019.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 17, 2016, FDA issued an EUA to InBios for the ZIKV Detect 2.0 IgM Capture ELISA, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on October 28, 2016 (81 FR 75092), as required by section 564(h)(1) of the FD&C Act. In response to requests from InBios, the EUA was amended on March 27, 2017, and May 18, 2018. Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services (HHS) may revoke an EUA if, among other things, the criteria for issuance are no longer met.

II. EUA Criteria for Issuance No Longer Met

On March 23, 2019, FDA revoked the EUA for the InBios ZIKV Detect 2.0 IgM Capture ELISA because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. The InBios ZIKV Detect 2.0 IgM Capture ELISA had a De Novo classification request granted as a Class II device under the generic name Zika virus serological reagents on May 23, 2019 (*https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf*). FDA has concluded that this is an adequate, approved, and available alternative for diagnosing Zika virus infection.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for the InBios ZIKV Detect 2.0 IgM Capture ELISA. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

May 23, 2019

Estela Raychaudhuri
President
InBios International, Inc.
562 1st Avenue S., Suite 600
Seattle, WA 98104

Dear Ms. Raychaudhuri:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA160013) for emergency use of InBios International, Inc.'s ("InBios") ZIKV Detect 2.0 IgM Capture ELISA, issued on August 17, 2016, and amended on March 27, 2017, and May 18, 2018.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. The InBios ZIKV Detect 2.0 IgM Capture ELISA had a De Novo classification request granted as a Class II device under the generic name Zika virus serological reagents in 21 CFR 866.3935 on May 23, 2019 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf). FDA has concluded that this is an adequate, approved, and available alternative for diagnosing Zika virus infection.

Accordingly, FDA revokes EUA160013 for emergency use of ZIKV Detect 2.0 IgM Capture ELISA, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the ZIKV Detect 2.0 IgM Capture ELISA test that was authorized by FDA for emergency use under EUA 160013 is no longer authorized by FDA.

FDA does not have concerns with the use of any remaining inventory of the ZIKV Detect 2.0 IgM Capture ELISA that was distributed prior to revocation of the EUA, when such product is used in conjunction with the ZIKV Detect 2.0 IgM Capture ELISA package insert/manufacturer instructions for use associated with the De Novo request granted May 23, 2019. FDA encourages the relabeling of any product already manufactured but not distributed prior to the revocation of the EUA with the ZIKV Detect 2.0 IgM Capture ELISA package

Page 2 – Ms. Raychaudhuri, InBios International, Inc.

insert/manufacturer instructions for use associated with the De Novo request granted May 23, 2019. Importantly, the ZIKV Detect 2.0 IgM Capture ELISA product for which FDA had issued an EUA and the product for which FDA has granted De Novo classification are manufactured under the same quality system with the same lot release criteria. InBios should instruct customers who have remaining ZIKV Detect 2.0 IgM Capture ELISA EUA product inventory to use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the De Novo request granted May 23, 2019. FDA encourages InBios to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the package insert/manufacturer instructions for use labeling associated with the De Novo request granted May 23, 2019.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16881 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products.

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants have committed to, or are required to conduct, and for which annual status reports have been submitted.

Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drugs and licensed biologics are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial otherwise undertaken to investigate a safety issue.

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

The report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct is on the FDA's ''Postmarketing Requirements and Commitments: Reports'' web page at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/ucm064436.htm.*

II. Fiscal Year 2018 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year (FY) 2018 (*i.e.,* as of September 30, 2018). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) The number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment [2] (FY2012 to FY2018) for PMRs and PMCs open at the end of FY2018, or those closed within FY2018. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.*

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16878 Filed 8–6–19; 8:45 am]

BILLING CODE 4164–01–P

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 6, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

A 60-day notice was published in the **Federal Register** on May 9, 2019, vol. 84, No. 90; pp. 20373–75. There were four public comments received. Some comments addressed policy issues that are outside of the scope of this information collection request. HRSA responded to technical comments that pertain to the ICR and revised the draft instruments based on technical comments received.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must

comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Need and Proposed Use of the Information: To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency, and integrity, HRSA developed a process of registration for covered entities to address specific statutory mandates. Section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except that HRSA has transitioned completely to online versus hardcopy instruments. In doing so, some of the instruments have been revised to increase program efficiency and integrity. Below are descriptions of each of the instruments and any resulting revisions captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).

Enrollment/Registration

To enroll and certify the eligible federally funded grantees and other safety net health care providers, HRSA requires entities to submit administrative information (*e.g.,* shipping and billing arrangements, Medicaid participation), certifying information (*e.g.,* Medicare Cost Report information, documentation supporting the hospital's selected classification) and attestation from appropriate grantee level or entity level authorizing officials and primary contacts. The purpose of this registration information is to determine eligibility for the 340B Program. To maintain accurate records, HRSA requests entities to submit modifications to any administrative information that they submitted when initially enrolling into the Program. 340B covered entities have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. No less than on an annual basis, entities must certify the accuracy of the information provided and continued maintenance of their eligibility and comply with statutory mandates of the Program.

Registration and annual recertification information is entered into the 340B OPAIS by entities and verified by HRSA staff according to 340B Program requirements. In response to the comments received, HRSA has made technical revisions to the draft instruments and explains the revisions below.

1. 340B Program Registrations & Certifications for Hospitals (applies to all hospital types): With the launch of 340B OPAIS in September 2017, HRSA removed the requirement for a Government Official to attest to the hospital classification of a parent hospital. HRSA would like to require parent hospitals to attach documents supporting the hospital classification that they select during registration. This is a more accurate and efficient way to determine the eligibility of parent hospital registrations, without increasing the burden, since the Government Official attestation has been removed. In response to comments, HRSA notes that the 340B Program Hospital Registration Instructions lists examples of the types of documentation that supports the hospital's classification. The instructions are located at *https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf.*

2. 340B Program Registrations for STD/TB Clinics: HRSA is requesting that any STD and TB entity provide its Notice of Funding Opportunity (NOFO) number at the time of registration. HRSA is also requesting that an entity describe the type of in-kind funding it receives, as well as the period of the funding. This will assist HRSA in accurately determining the eligibility of the covered entity registration. This requirement would impose minimal burden on the public, as the NOFO number correlates to the Federal Grant Number, which is already required during registration.

In response to comments submitted during the first public review of this ICR, HRSA continues to believe there will be no additional burden associated with providing what type of in-kind funding they receive as it is expected to be provided as part of an audit of a covered entity. The draft instruments explain that in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

3. 340B Registrations for Ryan White Entities: HRSA is requesting that any Ryan White entity provide its NOFO number at the time of registration. HRSA is also requesting that an entity provide the period of assistance. This will assist HRSA in accurately determining the eligibility of the registration. This requirement would impose minimal burden on the public, as the NOFO number correlates to the Federal Grant Number, which is already required during registration.

4. Medicaid Billing: HRSA is making a minor change to clarify the question about Medicaid billing. In response to comments received, HRSA has made general technical and editorial revisions to this instrument.

Accurate records are critical to the prevention of drug diversion to non-eligible individuals as well as duplicate discounts in the 340B Program. To maintain accurate records, HRSA also requires that covered entities recertify eligibility annually, and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. HRSA expects that the burden imposed these processes is low for recertification and minimal for submitting change requests.

Contract Pharmacy Self-Certification

To ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are required to submit general information about the arrangements and certify that signed agreements are in place with those contract pharmacies. In response to comments, HRSA has made several technical corrections to this instrument.

Pharmaceutical Pricing Agreement and Addendum

In accordance with the 340B Program guidance issued in the May 7, 1993, **Federal Register**, section 340B(a)(1) of the PHS Act provides that a manufacturer who sells covered

outpatient drugs to eligible entities must sign a PPA with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price (''AMP'') decreased by a rebate percentage. In addition, section 340B(a)(1) of the PHS Act includes specific required components of the PPA with manufacturers of covered outpatient drugs. In particular, section 340B(a)(1) includes the following requirements:

I. ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price'') and

II. ''. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

The burden imposed on manufacturers by submission of the PPA and PPA Addendum is low as the information is readily available.

Pricing Data Submission, Validation and Dissemination

To implement section 340B(d)(1)(B)(i)(II) of the PHS Act, HRSA developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as a third party commercial database. However, to conduct the comparison required under the statute, manufacturers must submit the quarterly pricing data as required by section 340B(d)(1)(B)(i)(II). The 340B OPAIS securely collects the following data from manufacturers on a quarterly basis: Average manufacturer price, unit rebate amount, package size, case pack size, unit type, national drug code, labeler code, product code, period of sale (year and quarter), FDA product name, labeler name, wholesale acquisition cost, and the manufacturer determined ceiling price for each covered outpatient drug produced by a manufacturer subject to a PPA. One commenter suggested that HRSA list FDA ''ingredient names'' in the 340B OPAIS to simplify the search process for covered entities. HRSA will consider this for future collections due to system changes that would need to occur to operationalize this suggestion.

The burden imposed on manufacturers is low because the information requested is readily available and utilized by manufacturers in other areas.

Likely Respondents: Drug manufacturers and covered entities.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per respondent	Total burden hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals *	248	1	248	2.00	496
Certifications to Enroll Hospital Outpatient Facilities	665	8	5,320	0.50	2,660
Hospital Annual Recertifications	2,481	10	24,810	0.25	6,202
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers *	360	3	1,080	1.00	1,080
340B Registrations for STD/TB Clinics *	535	1	535	1.00	535
340B Registrations for Various Other Eligible Entity Types *	392	1	392	1.00	392
Community Health Center Annual Recertifications	1,277	7	8,939	0.25	1,008
STD & TB Annual Recertifications	4,033	1	4,033	0.25	1,008
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics	4,472	1	4,472	0.25	1,118
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	2,048	11	22,528	1.00	22,528
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	19,322	1	19,322	** 0.25	4,831
Submission of Administrative Changes for any Manufacturer	350	1	350	0.50	175
Pharmaceutical Pricing Agreement and PPA Addendum	200	1	200	1	200
Manufacturer Data Required to Verify the 340B Ceiling Price	600	4	2,400	0.50	1,200
Total	36,983		94,629		43,433

* Revised since last OMB submission, but burden was not affected.
** Burden changed from .50 to .25 due to the 340B OPAIS improvement.

During the first public review of the ICR, HRSA inadvertently omitted the burden estimate for the instrument pertaining to manufacturer data required to verify the 340B ceiling price. The estimate for that instrument has been included here and HRSA invites comments to be submitted to OMB for consideration during the review and approval period.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–16872 Filed 8–6–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Advisory Council: Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Center for Scientific Review Advisory Council was renewed for an additional two-year period on March 31, 2019.

It is determined that the Center for Scientific Review Advisory Council is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *harriscl@mail.nih.gov.*

Dated: August 1, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–16825 Filed 8–6–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Advisory Committee for Women's Services (ACWS); Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Advisory Committee for Women's Services (ACWS) on August 20, 2019.

The meeting will include discussions on assessing SAMHSA's current strategies, including the mental health and substance use needs of the women and girls population. Additionally, the ACWS will be speaking with the Assistant Secretary of Mental Health and Substance Use regarding priorities and directions around behavioral health services and access for women and children.

The meeting is open to the public and will be held at SAMHSA, 5600 Fishers Lane, Rockville, MD 20857. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be forwarded to the contact person by August 13, 2019. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact person on or before August 13, 2019. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone or web meeting. To obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at *http://snacregister.samhsa.gov/MeetingList.aspx,* or communicate with SAMHSA's Designated Federal Officer, Ms. Valerie Kolick.

Substantive meeting information and a roster of ACWS members may be obtained either by accessing the SAMHSA Committees' Web *https://www.samhsa.gov/about-us/advisory-councils/meetings,* or by contacting Ms. Kolick.

Committee Name: Substance Abuse and Mental Health Services Administration, Advisory Committee for Women's Services (ACWS).

Date/Time/Type: Tuesday, August 20, 2019, from: 9:00 a.m. to 3:00 p.m. EDT (OPEN).

Place: SAMHSA, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Valerie Kolick, Designated Federal Officer, SAMHSA's Advisory Committee for Women's Services, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (240) 276–1738, Email: *Valerie.kolick@samhsa.hhs.gov.*

Dated: August 1, 2019.

Carlos Castillo,

CAPT, USPHS, Committee Management Officer, Substance Abuse and Mental Health, Services Administration.

[FR Doc. 2019–16831 Filed 8–6–19; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORW00000.10200000. DF0000.LXSSH1080000.19X.HAG 19–0096]

Notice of Public Meetings for the San Juan Islands National Monument Advisory Committee

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM), San Juan Islands National Monument Advisory Committee (MAC) will meet as indicated below:

DATES: The MAC will hold a public meeting on Tuesday, Sept. 24, 2019. This meeting will run from 10 a.m. to 3:30 p.m. The public comment period is scheduled for 2 p.m.

ADDRESSES: The meeting will be held at the Lopez Community Center for the Arts, 204 Village Rd, Lopez Island, WA 98261. The public may send written comments to the MAC at BLM Spokane District, Attn. MAC, 1103 N Fancher, Spokane Valley, WA 99212.

FOR FURTHER INFORMATION CONTACT: Jeff Clark, Spokane District Public Affairs Officer, 1103 N Fancher, Spokane Valley, WA 99212, (509) 536–1297, or *jeffclark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1(800) 877–8339 to contact the above individual during normal business hours. This service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The San Juan Islands MAC is comprised of 12 members representing a wide array of interests, including recreation, tribal interests, education, environmental organizations, and landowners. The MAC advises the Secretary of the Interior with respect to the preparation and implementation of the San Juan

Islands National Monument Resource Management Plan.

The meeting will begin at 10:00 a.m. with a welcome to the new MAC members. After introductions, the members will spend time reviewing the Proposed Resource Management Plan and Environmental Impact Statement and clarifying items from the BLM. The next agenda topic will be a discussion regarding opportunities for the MAC to support implementation of the management plan once the record of decision is signed. A roundtable discussion on local landscape status over the last two years will follow. The public comment period will be held at 2 p.m. The MAC will adjourn no later than 3:30 p.m. All advisory council meetings are open to the public.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Persons wishing to make comments during the public comment period should register in person with the BLM by 1 p.m. on the meeting day, at the meeting location. Depending on the number of persons wishing to comment, the length of comments may be limited.

The public may send written comments to the MAC as described in the **ADDRESSES** section of this notice. The BLM appreciates all comments.

Authority: 43 CFR 1784.4–1.

Linda Clark,

Spokane District Manager.

[FR Doc. 2019–16910 Filed 8–6–19; 8:45 am]

BILLING CODE 4310–33–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–747 (Final)]

Fresh Tomatoes From Mexico; Scheduling of the Final Phase of an Antidumping Duty Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation No. 731–TA–747 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of fresh tomatoes from Mexico, provided for in heading 0702 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be sold at less than fair value.

DATES: May 7, 2019.

FOR FURTHER INFORMATION CONTACT: Christopher W. Robinson ((202) 205–2542), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of this investigation, Commerce has defined the subject merchandise as ''all fresh or chilled tomatoes (fresh tomatoes) which have Mexico as their origin, except for those tomatoes which are for processing. Processing is defined to include preserving by any commercial process, such as canning, dehydrating, drying, or the addition of chemical substances, or converting the tomato product into juices, sauces, or purees. Fresh tomatoes that are imported for cutting up, not further processing (*e.g.,* tomatoes used in the preparation of fresh salsa or salad bars), are covered by the investigation.

Commercially grown tomatoes, both for the fresh market and for processing, are classified as Lycopersicon esculentum. Important commercial varieties of fresh tomatoes include common round, cherry, grape, plum, greenhouse, and pear tomatoes, all of which are covered by this investigation.

Tomatoes imported from Mexico covered by this investigation are classified under the following subheading of the Harmonized Tariff Schedule of the United States (HTSUS), according to the season of importation: 0702. Although the HTSUS numbers are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.''

Background.—The final phase of this investigation is being scheduled, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)), as a result of an affirmative preliminary determination by Commerce that imports of fresh tomatoes from Mexico are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The final phase of this investigation was resumed on May 7, 2019 (84 FR 27805, June 14, 2019).

For further information concerning the conduct of this phase of the investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigation and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of this investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigation. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of this investigation will be placed in the nonpublic record on September 3, 2019, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final

phase of this investigation beginning at 9:30 a.m. on Tuesday, September 19, 2019, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before September 12, 2019. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on September 13, 2019, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is September 10, 2019. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is September 26, 2019. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation, including statements of support or opposition to the petition, on or before September 26, 2019. On October 17, 2019, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before October 21, 2019, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: August 2, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–16918 Filed 8–6–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number: 1110–New]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection

AGENCY: Federal Bureau of Investigation, Office of Private Sector, Department of Justice.

ACTION: 30-Day notice (Supplemental).

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Office of Private Sector, is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. Upon further review, the FBI's Office of Private Sector has modified its original request for a 20 question ''Sector and Industry'' survey to a five question ''Needs Assessment/Request for Information'' splash page hosted on the InfraGard and DSAC portals. This 30 day notice is a supplement to the original notices posted on 07/09/2018 (60 day notice) and on 09/10/2018 (30 day notice).

DATES: The Department of Justice encourages public comment and will accept input until September 6, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Johnny Starrunner, Unit Chief, Federal Bureau of Investigation, Office of Private Sector, 935 Pennsylvania Ave., Washington, DC, *jrstarrunner@fbi.gov,* 202–436–8136. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the [Component or Office name], including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. Type of Information Collection: New Collection.
2. The Title of the Form/Collection: Sector and Industry Survey.
3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: ''There is no agency form number for this collection.'' The applicable component within the Department of Justice is the Federal Bureau of Investigation, Office of Private Sector.

4. Affected public who will be asked or required to respond, as well as a brief abstract: Primary respondents will be individuals. Information will be collected from FBI InfraGard and Domestic Security Alliance Council (DSAC) members to assist in determining the private sector partner's perspective in regards to the status of critical infrastructure sector/sub-sector/industry's risks and concerns.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: There is an expectation of approximately 500 respondents per RFI. It is estimated that each survey will take approximately 5 minutes to complete.

6. An estimate of the total public burden (in hours) associated with the collection: (Approximation) 20 surveys of 500 respondents each at 5 minute survey completion rate = 1,200 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: August 1, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–16807 Filed 8–6–19; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0085]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension, Without Change, of a Currently Approved Collection

AGENCY: United States Trustee Program, Department of Justice.

ACTION: Notice.

SUMMARY: The Department of Justice, United States Trustee Program, is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until October 7, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Juliet Drake, Deputy Assistant Director, Executive Office for United States Trustees, 441 G Street NW, Suite 6150, Washington DC 20530, *Juliet.Drake@usdoj.gov,* (202) 307–3698.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the United States Trustee Program, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Approval as a Provider of a Personal Financial Management Instructional Course (Application).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the United States Trustee Program.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Individuals and businesses that wish to offer instructional courses to debtors concerning personal financial management pursuant to the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 (''BAPCPA''), Public Law 109–8, 119 Stat. 23, 37, 38 (April 20, 2005), and codified at 11 U.S.C. 109(h) and 111, and Application Procedures and Criteria for Approval of Providers of a Personal Financial Management Instructional Course by United States Trustees, 78 FR 16,159 (March 14, 2013) (Rule).

The BAPCPA requires individual debtors in bankruptcy cases to complete a personal financial management instructional course given by a provider that has been approved by the United States Trustee as a condition of receiving a discharge. The Application collects information from such providers in order to ensure compliance with the law and the Rule.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 147 respondents will complete the Application; initial applicants will complete the Application in approximately ten (10) hours, while renewal applicants will complete the Application in approximately four (4) hours. In addition, it is estimated that approximately 996,970 debtors will complete a survey evaluating the effectiveness of an instructional course in approximately one (1) minute.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 17,228 hours: the applicants' burden is 612 hours and the debtors' burden is 16,616 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: August 2, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–16874 Filed 8–6–19; 8:45 am]

BILLING CODE 4410–40–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0084]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension, Without Change, of a Currently Approved Collection

AGENCY: United States Trustee Program, Department of Justice.

ACTION: Notice.

SUMMARY: The Department of Justice, United States Trustee Program, is submitting the following information collection request to the Office of

Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until October 7, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Juliet Drake, Deputy Assistant Director, Executive Office for United States Trustees, 441 G Street NW, Suite 6150, Washington DC 20530, *Juliet.Drake@usdoj.gov,* (202) 307–3698.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the United States Trustee Program, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Approval as a Nonprofit Budget and Credit Counseling Agency (Application).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the United States Trustee Program.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Nonprofit agencies that wish to offer credit counseling services pursuant to the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 (''BAPCPA''), Public Law 109–8, 119 Stat. 23, 37, 38 (April 20, 2005), and codified at 11 U.S.C. 109(h) and 111, and Application Procedures and Criteria for Approval of Nonprofit Budget and Credit Counseling Agencies by United States Trustees, 78 FR 16,138 (March 14, 2013) (Rule).

The BAPCPA requires any individual who wishes to file for bankruptcy to obtain credit counseling, within 180 days before filing for bankruptcy relief, from a nonprofit budget and credit counseling agency that has been approved by the United States Trustee. The Application collects information from such agencies in order to ensure compliance with the law and the Rule.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 86 respondents will complete the Application; initial applicants will complete the Application in approximately ten (10) hours, while renewal applicants will complete the Application in approximately four (4) hours.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 362 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: August 2, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–16873 Filed 8–6–19; 8:45 am]

BILLING CODE 4410–40–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before September 6, 2019.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Email: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect a copy of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Roslyn Fontaine, Deputy Director, Office of Standards, Regulations, and Variances at 202–693–9475 (voice), *Fontaine.Roslyn@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor (Secretary) determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a

diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2019–002–M.

Petitioner: Graymont (PA) Inc., 375 Graymont Road, Bellefonte, Pennsylvania 16823.

Mine: Graymont (PA) Inc. Pleasant Gap, MSHA I.D. 36–06468, located in Centre County, Pennsylvania.

Regulation Affected: 30 CFR 57.14105 (Procedures during repairs or maintenance).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance during its automated and robotic bagging operations. The petitioner proposes a Category Three PLC Interlock energy-control method (PLC Interlock) as a means of compliance with existing energy-control and lockout/tagout methods.

The petitioner states that:

(1) The petitioner uses automated and robotic bagging systems at the mine. The bagging systems are equipped with area guarding that includes a PLC Interlock.

(2) With the automated and robotic bagging systems, miners need to perform routine operational tasks such as: Removing broken bags from the hydrate spout, emptying bag falls on the discharge conveyor, fixing pallet alignment on the pallet infeed, adjusting slip sheets on the pallet, replacing empty or torn bags on the robot, removing film from the stretch hood machine, removing overweight bags from the open mouth packer, removing bags at the flattener if reset is tripped, and cleaning sensors in order to ensure good operating function of the equipment. These tasks are routine, low risk, very limited in duration, and performed by miners trained on the equipment.

(3) To perform such tasks, miners are required to open the door and enter the area beyond the physical guarding (Operating Area), necessitating energy control procedures.

(4) Isolating power from the control computers upwards of 15–20 times per shift to perform routine non-maintenance tasks will cause computer and mechanical failures that would result in increased non-routine maintenance tasks that pose greater risk to miners. Only control power shutdowns will uphold the level of safety inherent in complete source power shutdown and will further maintain the lifespan and integrity of the equipment. This would have the effect of reducing required maintenance and making the equipment safer, which enhances miner safety.

(5) The PLC Interlock method does not cut full source power to the area and equipment surrounding the Operating Area. The equipment adjacent to the Operating Area does have electricity flow, with power cables still carrying power to the system as a whole, even though control power to the Operating Area where the miners work is cut off.

The petitioner proposes the following terms and conditions:

(a) To control energy related to this system, once a worker enters the Operating Area, the PLC Interlock system would engage and the electronic Category Three interlocks within the door completely cut control power to the area in order to ensure there would not be any unexpected reenergization or movement of the equipment being accessed.

(b) The PLC Interlock method also includes lockable mechanisms on all applicable doors whereby a miner can lock the interlock with a traditional lockout/tagout padlock, such that the lock(s) can only be removed by the miner who installed them or by other authorized personnel.

(c) Suitable notices are posted at the power switch and signed by the miner assigned the tasks.

(d) Only upon completion of the tasks, the miner would remove the lock, unlock the gate, close the gate, leave the Operating Area, walk to the control panel, reset the system, and restart operation by reenergizing the control system while ensuring no miners are exposed to an unexpected release of energy or any associated potential hazards. PLC Interlock devices are designed so that the safety-related parts of the control system do not have a single fault that could lead to loss of safety function. The PLC Interlock devices are designed with redundancy to ensure that a failure within the device will not allow operation of the machine. Additionally, miners are not exposed to any live electrical conductors when they work beyond the guarding.

(e) Component failures are protected via redundant and fail-safe design, and the computer program is not controlling the system when the interlocks are not met. Program errors, power surges, or magnetic field interference could not cause the equipment to operate because every time an operator stops the system, the computer program must be reset and re-started.

The petitioner asserts that the proposed alternative method will provide no less than the same measure of protection afforded the miners under the existing standard.

Docket Number: M–2019–003–M.

Petitioner: Graymont (PA) Inc., 375 Graymont Road, Bellefonte, Pennsylvania 16823.

Mine: Graymont (PA) Inc. Pleasant Gap, MSHA I.D. 36–06468, located in Centre County, Pennsylvania.

Regulation Affected: 30 CFR 57.12016 (Work on electrically-powered equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance during its automated and robotic bagging operations. The petitioner proposes a Category Three PLC Interlock energy-control method (PLC Interlock) as a means of compliance with existing energy-control and lockout/tagout methods.

The petitioner states that:

(1) The petitioner uses automated and robotic bagging systems at the mine. The bagging systems are equipped with area guarding that includes a PLC Interlock.

(2) With the automated and robotic bagging systems, miners need to perform routine operational tasks such as: Removing broken bags from the hydrate spout, emptying bag falls on the discharge conveyor, fixing pallet alignment on the pallet infeed, adjusting slip sheets on the pallet, replacing empty or torn bags on the robot, removing film from the stretch hood machine, removing overweight bags from the open mouth packer, removing bags at the flattener if reset is tripped, and cleaning sensors in order to ensure good operating function of the equipment. These tasks are routine, low risk, very limited in duration, and performed by miners trained on the equipment.

(3) To perform such tasks, miners are required to open the door and enter the area beyond the physical guarding (Operating Area), necessitating energy control procedures.

(4) Isolating power from the control computers upwards of 15–20 times per shift to perform routine non-maintenance tasks will cause computer and mechanical failures that would result in increased non-routine maintenance tasks that pose greater risk to miners. Only control power shutdowns will uphold the level of safety inherent in complete source power shutdown and will further maintain the lifespan and integrity of the equipment. This would have the effect of reducing required maintenance and making the equipment safer, which enhances miner safety.

(5) The PLC Interlock method does not cut full source power to the area and equipment surrounding the Operating Area. The equipment adjacent to the Operating Area does have electricity flow, with power cables still carrying power to the system as a whole, even though control power to the Operating Area where the miners work is cut off.

The petitioner proposes the following terms and conditions:

(a) To control energy related to this system, once a worker enters the Operating Area, the PLC Interlock system would engage and the electronic Category Three interlocks within the door completely cut control power to the area in order to ensure there would not be any unexpected reenergization or movement of the equipment being accessed.

(b) The PLC Interlock method also includes lockable mechanisms on all applicable doors whereby a miner can lock the interlock with a traditional lockout/tagout padlock, such that the lock(s) can only be removed by the miner who installed them or by other authorized personnel.

(c) Suitable notices are posted at the power switch and signed by the miner assigned the tasks.

(d) Only upon completion of the tasks, the miner would remove the lock, unlock the gate, close the gate, leave the Operating Area, walk to the control panel, reset the system, and restart operation by reenergizing the control system while ensuring no miners are exposed to an unexpected release of energy or any associated potential hazards. PLC Interlock devices are designed so that the safety-related parts of the control system do not have a single fault that could lead to loss of safety function. The PLC Interlock devices are designed with redundancy to ensure that a failure within the device will not allow operation of the machine. Additionally, miners are not exposed to any live electrical conductors when they work beyond the guarding.

(e) Component failures are protected via redundant and fail-safe design, and the computer program is not controlling the system when the interlocks are not met. Program errors, power surges, or magnetic field interference could not cause the equipment to operate because every time an operator stops the system, the computer program must be reset and re-started.

The petitioner asserts that the proposed alternative method will provide no less than the same measure of protection afforded the miners under the existing standard.

Docket Number: M–2019–004–M.

Petitioner: Solvay Chemicals, Inc., P.O. Box 1167, 400 County Road 85, Green River, WY 82935.

Mine: Solvay Chemicals, Inc. Mine, MSHA I.D. 48–01295, located in Sweetwater County, WY.

Regulation Affected: 30 CFR 57.22305 (Approved equipment (III mines)).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance for the respiratory protection of miners. The petitioner proposes to use non-MSHA approved, intrinsically safe battery-powered air purifying respirators (PAPR) to protect miners from potential exposure to respirable dust and ammonia gas during normal mining conditions in or in by the last open crosscut and where methane may be present.

The petitioner states that:

(1) The operator may use the following battery-powered PAPR units to provide respiratory protection for personnel, subject to the conditions of this petition:

—Sundström SR 500 EX

—Drager X-plore 8000

—3M TR–800 Versaflo

The petitioner proposes the following terms and conditions:

(a) The batteries for the PAPRs will be charged outby the last open crosscut when not in operation.

(b) Affected miners will be trained in the proper use and care of the PAPR units in accordance with manufacturers' instructions.

(c) If methane is detected in concentrations of 1.0 percent or more, procedures in accordance with 30 CFR 57.22234 will be followed.

The petitioner asserts that the proposed alternative method will provide no less than the same measure of protection afforded the miners under the existing standard.

Docket Number: M–2019–05–M.

Petitioner: Nevada Gold Mines, LLC, 1655 Mountain City Highway, Elko, Nevada 89801.

Mine: Genesis Mine, MSHA I.D. 26–00062, 26 Miles on SR766, North of Carlin, Carlin, Nevada 89822, located in Eureka County, Nevada.

South Area Mine, MSHA I.D. 26–00500, 6 Miles on SR766, North of Carlin, Carlin, Nevada, located in Eureka County, Nevada.

Regulation Affected: 30 CFR 56.6309(b) (Fuel oil requirements for ANFO).

Modification Request: The petitioner requests a modification of the existing standard to allow the use of recycled used waste oil blended with diesel fuel (blended oil) to prepare ammonium nitrate fuel oil (ANFO).

The petitioner states that:

(1) On July 1, 2019, petitioner assumed the operation of multiple gold mines in Nevada, including Goldstrike Mine, Genesis Mine and South Area Mine.

(2) Blended oil has been approved for use to prepare ANFO at petitioner's Goldstrike Mine, pursuant to MSHA's Amended Decision and Order of December 1, 1998, reinstated by Decision and Order of November 4, 2011, granting modification of the application of 30 CFR 56.6309(b) at Goldstrike Mine (Goldstrike Modification Order). The petitioner states that it seeks only to use the blended oil that has already been recycled and tested at Goldstrike Mine according to the conditions set out in the Goldstrike Modification Order in its ANFO blasting agents, and use the blended oil prepared and approved for use at Goldstrike Mine in ANFO mixtures at petitioner's Genesis Mine and South Area Mine.

(3) The Genesis Mine and South Area Mine are open-pit gold mines that consist of series of sediment hosted Carlin-style gold deposits. The Genesis Mine is adjacent to the Goldstrike Mine. The principle blasting method to be applied at both mines involves the use of ANFO loaded in pre-drilled blast holes, similar to the blasting methods at Goldstrike Mine. The petitioner states that it intends to ignite approximately 1,000 blast holes per month at each mine.

The petitioner proposes the following terms and conditions:

(a) The ANFO blasting agents the petitioner seeks to load in its blast holes at Genesis Mine and South Area Mine will consist of blended oil prepared at Goldstrike Mine according to the conditions set forth in the Goldstrike Modification Order, combined with ammonium nitrate.

(b) The ammonium nitrate to be combined with the blended oil to create ANFO will be stored separate and apart from the blended oil in three 100-ton silos in a locked and secured compound in the same vicinity at Goldstrike Mine. Only authorized blasting personnel will have access to the blended oil and ammonium nitrate storage facilities.

(c) The blended oil and ammonium nitrate will be transported from Goldstrike Mine to the respective blast sties at Genesis Mine and South Area Mine in separate containers and will be combined at each mine only as part of the actual process of loading the blast holes. The same certified blasting personnel operating at Goldstrike Mine

will perform blasting operations at Genesis Mine and South Area Mine.

(d) The ANFO will not be used in confined spaces or underground blasting operations. The ANFO will be used only at Genesis Mine and South Area Mine, and not be sold or transported to other mine properties.

(e) The petitioner will maintain a daily ''load'' and ''shot'' report detailing all holes loaded and shots fired which contain the ANFO.

(f) Emulsions (heavy ANFO) will not be used with the recycled oil unless the emulsion manufacturer certifies compatibility of the product with the oil.

(g) Misfires/hangfires which are reasonably suspected to have been caused by the blended oil will be reported to the MSHA District Manager in a timely manner.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2019–16840 Filed 8–6–19; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by MSHA's Office of Standards, Regulations, and Variances on or before September 6, 2019.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Office of Standards, Regulations, and Variances at 202–693–9440 (Voice), *mcconnell.sheila.a@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2019–025–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 88 Mine, MSHA I.D. No. 15–19400, located in Knott County, Kentucky.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, within 150 feet of pillar workings and longwall faces.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372, 75.1002(a), and 75.1200, use of the most practical and accurate surveying equipment is necessary. It is necessary to determine the exact location and extent of mine workings to ensure the safety of miners in active mines and to protect miners in future mines which may mine in close proximity to the active mines.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater within 150 feet of pillar workings or longwall faces subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used within 150 feet of pillar workings or longwall faces will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating

condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn further than 150 feet from pillar workings and longwall faces. All requirements of 30 CFR 75.323 will be complied with prior to entering within 150 feet of pillar workings or longwall faces.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment within 150 of pillar workings and longwall faces, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used within 150 feet of pillar workings or longwall faces when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment within 150 feet of pillar workings and longwall faces. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air more than 150 feet from pillar workings or longwall faces. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, within 150 feet of pillar workings or longwall faces is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces, regardless of whether the equipment is

used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.
—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.
—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.
—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.
—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.
—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.
—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–026–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 88 Mine, MSHA I.D. No. 15–19400, located in Knott County, Kentucky.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in or inby the last open crosscut.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) The operator utilizes the continuous mining method. Accurate surveying is critical to the safety of the miners at the mine.

(3) Mechanical surveying equipment has been obsolete for a number of years. Such equipment of acceptable quality is not commercially available. Further, it is difficult, if not impossible, to have such equipment serviced or repaired.

(4) Electronic surveying equipment is, at a minimum, 8 to 10 times more accurate than mechanical equipment.

(5) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in or inby the last open crosscut will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying

equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in or inby the last open crosscut will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn outby the last open crosscut. All requirements of 30 CFR 75.323 will be complied with prior to entering in or inby the last open crosscut.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within in or inby the last open crosscut, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in or inby the last open crosscut when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in or inby the last open crosscut. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air outby the last open crosscut. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in or inby the last open crosscut is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in or inby the last open crosscut. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in or inby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–027–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 88 Mine, MSHA I.D. No. 15–19400, located in Knott County, Kentucky.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in return airways.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200(a), use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in return airways, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in return airways will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in return airways will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn out of return airways. All requirements of 30 CFR 75.323 will be complied with prior to entering in return airways.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment in return airways, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a

continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in return airways, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in return airways when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in return airways. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air out of return airways. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in return airways, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in return airways is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in return airways. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in return airways, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by

surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–028–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 77 Mine, MSHA I.D. No. 15–09636, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, within 150 feet of pillar workings and longwall faces.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372, 75.1002(a), and 75.1200, use of the most practical and accurate surveying equipment is necessary. It is necessary to determine the exact location and extent of mine workings to ensure the safety of miners in active mines and to protect miners in future mines which may mine in close proximity to the active mines.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater within 150 feet of pillar workings or longwall faces subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used within 150 feet of pillar workings or longwall faces will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn further than 150 feet from pillar workings and longwall faces. All requirements of 30 CFR 75.323 will be complied with prior to entering within 150 feet of pillar workings or longwall faces.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment within 150 of pillar workings and longwall faces, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used within 150 feet of pillar workings or longwall faces when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment within 150 feet of pillar workings and longwall faces. If there are two people in the surveying crew, both persons will

continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air more than 150 feet from pillar workings or longwall faces. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, within 150 feet of pillar workings or longwall faces is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.
—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.
—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.
—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.
—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.
—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.
—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–029–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 77 Mine, MSHA I.D. No. 15–09636, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in or inby the last open crosscut.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) The operator utilizes the continuous mining method. Accurate surveying is critical to the safety of the miners at the mine.

(3) Mechanical surveying equipment has been obsolete for a number of years. Such equipment of acceptable quality is not commercially available. Further, it is difficult, if not impossible, to have such equipment serviced or repaired.

(4) Electronic surveying equipment is, at a minimum, 8 to 10 times more accurate than mechanical equipment.

(5) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in or inby the last open crosscut will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in or inby the last open crosscut will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn outby the last open crosscut. All requirements of 30 CFR 75.323 will be complied with prior to entering in or inby the last open crosscut.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within in or inby the last open crosscut, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in or inby the last open crosscut when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in or inby the last open crosscut. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air outby the last open crosscut. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently

so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in or inby the last open crosscut is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in or inby the last open crosscut. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in or inby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–030–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: No. 77 Mine, MSHA I.D. No. 15–09636, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in return airways.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200(a), use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in return airways, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in return airways will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in return airways will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn out of return airways. All requirements of 30 CFR 75.323 will be complied with prior to entering in return airways.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment in return airways, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in return airways, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in return airways when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in return airways. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air out of return airways. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in return airways, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in return airways is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in return airways. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes

final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in return airways, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–031–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Calvary No. 81 Mine, MSHA I.D. No. 15–12753, located in Leslie County, Kentucky.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, within 150 feet of pillar workings and longwall faces.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372, 75.1002(a), and 75.1200, use of the most practical and accurate surveying equipment is necessary. It is necessary to determine the exact location and extent of mine workings to ensure the safety of miners in active mines and to protect miners in future mines which may mine in close proximity to the active mines.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater within 150 feet of pillar workings or longwall faces subject to this petition:

—TopCon GTS 233 W

—TopCon GPT 3003 LW

—TopCon GTS 223

—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used within 150 feet of pillar workings or longwall faces will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these

examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn further than 150 feet from pillar workings and longwall faces. All requirements of 30 CFR 75.323 will be complied with prior to entering within 150 feet of pillar workings or longwall faces.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment within 150 of pillar workings and longwall faces, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used within 150 feet of pillar workings or longwall faces when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment within 150 feet of pillar workings and longwall faces. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air more than 150 feet from pillar workings or longwall faces. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, within 150 feet of pillar workings or longwall faces is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces, regardless of whether the equipment is

used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–032–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Calvary No. 81 Mine, MSHA I.D. No. 15–12753, located in Leslie County, Kentucky.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in or inby the last open crosscut.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) The operator utilizes the continuous mining method. Accurate surveying is critical to the safety of the miners at the mine.

(3) Mechanical surveying equipment has been obsolete for a number of years. Such equipment of acceptable quality is not commercially available. Further, it is difficult, if not impossible, to have such equipment serviced or repaired.

(4) Electronic surveying equipment is, at a minimum, 8 to 10 times more accurate than mechanical equipment.

(5) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, subject to this petition:

—TopCon GTS 233 W

—TopCon GPT 3003 LW

—TopCon GTS 223

—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in or inby the last open crosscut will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying

equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in or inby the last open crosscut will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn outby the last open crosscut. All requirements of 30 CFR 75.323 will be complied with prior to entering in or inby the last open crosscut.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within in or inby the last open crosscut, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in or inby the last open crosscut when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in or inby the last open crosscut. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air outby the last open crosscut. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in or inby the last open crosscut is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in or inby the last open crosscut. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in or inby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–033–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Calvary No. 81 Mine, MSHA I.D. No. 15–12753, located in Leslie County, Kentucky.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in return airways.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200(a), use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in return airways, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in return airways will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in return airways will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn out of return airways. All requirements of 30 CFR 75.323 will be complied with prior to entering in return airways.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment in return airways, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a

continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in return airways, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in return airways when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in return airways. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air out of return airways. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in return airways, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in return airways is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in return airways. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in return airways, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in

accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–034–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Orchard Branch Mine No. 89, MSHA I.D. No. 15–19405, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, within 150 feet of pillar workings and longwall faces.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372, 75.1002(a), and 75.1200, use of the most practical and accurate surveying equipment is necessary. It is necessary to determine the exact location and extent of mine workings to ensure the safety of miners in active mines and to protect miners in future mines which may mine in close proximity to the active mines.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater within 150 feet of pillar workings or longwall faces subject to this petition:

—TopCon GTS 233 W

—TopCon GPT 3003 LW

—TopCon GTS 223

—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used within 150 feet of pillar workings or longwall faces will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn further than 150 feet from pillar workings and longwall faces. All requirements of 30 CFR 75.323 will be complied with prior to entering within 150 feet of pillar workings or longwall faces.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment within 150 of pillar workings and longwall faces, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used within 150 feet of pillar workings or longwall faces when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment within 150 feet of pillar workings and longwall faces. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be

a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air more than 150 feet from pillar workings or longwall faces. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, within 150 feet of pillar workings or longwall faces is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment within 150 feet of pillar workings or longwall faces. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used within 150 feet of pillar workings or longwall faces, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.
—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.
—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.
—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.
—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.
—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.
—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–035–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Orchard Branch Mine No. 89, MSHA I.D. No. 15–19405, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible

surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in or inby the last open crosscut.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200, use of the most practical and accurate surveying equipment is necessary.

(2) The operator utilizes the continuous mining method. Accurate surveying is critical to the safety of the miners at the mine.

(3) Mechanical surveying equipment has been obsolete for a number of years. Such equipment of acceptable quality is not commercially available. Further, it is difficult, if not impossible, to have such equipment serviced or repaired.

(4) Electronic surveying equipment is, at a minimum, 8 to 10 times more accurate than mechanical equipment.

(5) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they have an ingress protection (IP) rating of 66 or greater in or inby the last open crosscut, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in or inby the last open crosscut will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in or inby the last open crosscut will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn outby the last open crosscut. All requirements of 30 CFR 75.323 will be complied with prior to entering in or inby the last open crosscut.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment within in or inby the last open crosscut, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in or inby the last open crosscut when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in or inby the last open crosscut. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air outby the last open crosscut. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor

will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in or inby the last open crosscut is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in or inby the last open crosscut. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in or inby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Docket Number: M–2019–036–C.

Petitioner: Blue Diamond Coal Company, One Oxford Centre, 301 Grant Street, Suite 4300, Pittsburgh, Pennsylvania 15219.

Mines: Orchard Branch Mine No. 89, MSHA I.D. No. 15–19405, located in Perry County, Kentucky.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance to allow the use of battery-powered nonpermissible surveying equipment including, but not limited to, portable battery-operated mine transits, total station surveying equipment, distance meters, and data loggers, in return airways.

The petitioner states that:

(1) To comply with requirements for mine ventilation maps and mine maps in 30 CFR 75.372 and 75.1200(a), use of the most practical and accurate surveying equipment is necessary.

(2) Application of the existing standard would result in a diminution of safety to miners. Underground mining by its nature, size, and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner.

As an alternative to the existing standard, the petitioner proposes the following:

(a) The operator may use the following total stations and theodolites and similar low-voltage battery-operated total stations and theodolites if they

have an ingress protection (IP) rating of 66 or greater in return airways, subject to this petition:

—TopCon GTS 233 W
—TopCon GPT 3003 LW
—TopCon GTS 223
—TopCon GTS 243 NW

(b) The nonpermissible electronic surveying equipment is low-voltage or battery-powered nonpermissible total stations and theodolites. All nonpermissible electronic total stations and theodolites will have an IP 66 or greater rating.

(c) The operator will maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook will contain the date of manufacture and/or purchase of each particular piece of electronic surveying equipment. The logbook will be made available to MSHA on request.

(d) All nonpermissible electronic surveying equipment to be used in return airways will be examined by the person who operates the equipment prior to taking the equipment underground to ensure the equipment is being maintained in a safe operating condition. The result of these examinations will be recorded in the logbook and will include:

(i) Checking the instrument for any physical damage and the integrity of the case;

(ii) Removing the battery and inspecting for corrosion;

(iii) Inspecting the contact points to ensure a secure connection to the battery;

(iv) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(v) Checking the battery compartment cover or battery attachment to ensure that it is securely fastened.

(e) The equipment will be examined at least weekly by a qualified person, as defined in 30 CFR 75.153. The examination results will be recorded weekly in the equipment logbook and will be maintained for at least 1 year.

(f) The operator will ensure that all nonpermissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Dates of service will be recorded in the equipment's logbook and will include a description of the work performed.

(g) The nonpermissible electronic surveying equipment used in return airways will not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of this petition.

(h) Nonpermissible electronic surveying equipment will not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more methane is detected while such equipment is being used, the equipment will be de-energized immediately and withdrawn out of return airways. All requirements of 30 CFR 75.323 will be complied with prior to entering in return airways.

(i) Prior to setting up and energizing nonpermissible electronic surveying equipment in return airways, the surveyor(s) will conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the equipment will not be energized until sufficient rock-dust has been applied and/or the accumulations of float coal dust have been cleaned up. If nonpermissible electronic surveying equipment is to be used in an area not rock-dusted within 40 feet of a working face where a continuous mining machine is used, the area will be rocked-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors will be MSHA-approved and maintained in permissible and proper operating condition, as defined in 30 CFR 75.320. All methane detectors will provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing nonpermissible electronic surveying equipment in return airways, methane tests will be made in accordance with 30 CFR 75.323(a). Nonpermissible electronic surveying equipment will not be used in return airways when production is occurring.

(l) Prior to surveying, the area will be examined according to 30 CFR 75.360. If the area has not been examined, a supplemental examination according to 30 CFR 75.361 will be performed before any non-certified person enters the area.

(m) A qualified person, as defined in 30 CFR 75.151, will continuously monitor for methane immediately before and during the use of nonpermissible electronic surveying equipment in return airways. If there are two people in the surveying crew, both persons will continuously monitor for methane. The other person will either be a qualified person, as defined in 30 CFR 75.151, or be in the process of being trained to be a qualified person but has yet to make such tests for a period of 6 months, as required in 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew must become qualified, as defined in 30 CFR 75.151, in order to continue on the surveying crew. If the surveying crew consists of one person, that person will monitor for methane with two separate devices.

(n) Batteries contained in the nonpermissible electronic surveying equipment will be changed out or charged in fresh air out of return airways. Replacement batteries will be carried only in the compartment provided for a spare battery in the nonpermissible electronic surveying equipment carrying case. Before each shift of surveying, all batteries for the nonpermissible electronic surveying equipment will be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using nonpermissible electronic surveying equipment in return airways, the surveyor will confirm by measurement or by inquiry of the person in charge of the section, that the air quantity on the section, on that shift, in return airways is at least the minimum quantity that is required by the mine's ventilation plan.

(p) Personnel engaged in the use of nonpermissible electronic surveying equipment will be properly trained to recognize the hazards and limitations associated with the use of such equipment in areas where methane could be present.

(q) All members of the surveying crew will receive specific training on the terms and conditions of the petition before using nonpermissible electronic surveying equipment in return airways. A record of the training will be kept with the other training records.

(r) If the petition is granted, the operator will submit within 60 days after the petition is final, proposed revisions for its approved 30 CFR part 48 training plans to the District Manager. These revisions will specify initial and refresher training regarding the terms and conditions of the petition. When training is conducted on the terms and conditions in the petition, an MSHA Certificate of Training (Form 5000–23) will be completed and will indicate that it was surveyor training.

(s) The operator will replace or retire from service any electronic surveying instrument that was acquired prior to December 31, 2004 within 1 year of the petition becoming final. Within 3 years of the date that the petition becomes final, the operator will replace or retire from service any theodolite that was acquired more than 5 years prior to the date that the petition becomes final or any total station or other electronic

surveying equipment identified in this petition and acquired more than 10 years prior to the date that the petition becomes final. After 5 years, the operator will maintain a cycle of purchasing new electronic surveying equipment whereby theodolites will be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment will be no older than 10 years from the date of manufacture.

(t) The operator will ensure that all surveying contractors hired by the operator are using nonpermissible electronic surveying equipment in accordance with the terms and conditions of this petition. The conditions of use in the petition will apply to all nonpermissible electronic surveying equipment used in return airways, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) The petitioner states that it may use nonpermissible electronic surveying equipment when production is occurring, subject to the following conditions:

—On a mechanized mining unit (MMU) where production is occurring, nonpermissible electronic surveying equipment will not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

—Production may continue while nonpermissible electronic surveying equipment is used, if such equipment is used in a separate split of air from where production is occurring.

—Nonpermissible electronic surveying equipment will not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

—If, while surveying, a surveyor must disrupt ventilation, the surveyor will cease surveying and communicate to the section foreman that ventilation must be disrupted. Production will stop while ventilation is disrupted. Ventilation controls will be reestablished immediately after the disruption is no longer necessary. Production will only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans, and other applicable laws, standards, or regulations.

—Any disruption in ventilation will be recorded in the logbook required by the petition. The logbook will include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption and the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

—All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations will receive training in accordance with 30 CFR 48.7 on the requirements of the petition within 60 days of the date the petition becomes final. The training will be completed before any nonpermissible electronic surveying equipment can be used while production is occurring. The operator will keep a record of the training and provide the record to MSHA on request.

—The operator will provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator will train new miners on the requirements of the petition in accordance with 30 CFR 48.5, and will train experienced miners, as defined in 30 CFR 48.6, on the requirements of the petition in accordance with 30 CFR 48.6. The operator will keep a record of the training and provide the record to MSHA on request.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2019–16839 Filed 8–6–19; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Collection; Comment Request

AGENCY: Division of Federal Employees' Compensation, Office of Workers' Compensation Programs, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Peace Corps Volunteer Authorization for Examination and/or Treatment (CA–15). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before October 7, 2019.

ADDRESSES: You may submit comments by mail, delivery service, or by hand to Mr. Vincent Alvarez, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3201, Washington, DC 20210; by fax,(202) 354–9643, or email to *alvarez.vincent@dol.gov* Please use only one method of transmission for comments (mail/delivery, fax, or email). Please note that comments submitted after comment period will not be considered.

SUPPLEMENTARY INFORMATION:

I. Background: The Department of Labor (DOL) is requesting an approval of a new information collection as a result of the recent passage of the Sam Farr and Nick Castle Peace Corps Reform Act of 2018 (Farr-Castle), which modified various aspects of the Peace Corps, including changes to the provision of health care to volunteers.

Peace Corps Volunteers are considered to be in the performance of duty while abroad during the period of Peace Corps service for purposes of FECA coverage. An injury sustained outside the United States during service is deemed proximately caused by such service, unless the injury or illness was proximately caused by willful misconduct, intention to bring about injury or death, or intoxication.

Under the provisions of the FECA, 5 U.S.C. 8142 of the FECA defines Peace Corps volunteer as

(1) A volunteer enrolled in the Peace Corps under section 2504 of title 22;

(2) A volunteer leader enrolled in the Peace Corps under section 2505 of title 22; and

(3) An applicant for enrollment as a volunteer or volunteer leader during a period of training under section 2507(a) of title 22 before enrollment.

Entitlement to disability compensation payments does not commence until the day after the date of termination of service as a volunteer. 5 U.S.C. 8142(b).

Farr-Castle directs the Secretary of the Department of Labor to authorize the Director of the Peace Corps to furnish medical benefits to a volunteer, who is injured during the volunteer's period of service, for a period of 120 days following the termination of such service if the Director certifies that the volunteer's injury probably meets the requirements set forth in 5 U.S.C. 8142(c)(3).

To this end, the Office of Workers' Compensation Programs (OWCP) and the Peace Corps have collaborated to initiate a new form, the CA–15, Peace Corps Volunteer Authorization for Examination and/or Treatment, that will authorize medical treatment for recently terminated Peace Corps volunteers who require medical treatment for injuries/exposure sustained in the performance of their volunteer service. Issuance of this form will solely be at the discretion of the Peace Corps, and will bridge a gap between the occurrence of an initial injury and/or disease exposure and the actual adjudication of a claim by OWCP by helping ensure that recently terminated volunteers receive prompt medical care, without delay, for a period of 120 days following separation from service.

II. Review Focus: The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks approval of this new information in order to carry out its responsibility to meet the statutory requirements of the Federal Employees' Compensation Act as amended by the Sam Farr and Nick Castle Peace Corps Reform Act of 2018 (Farr-Castle).

Type of Review: New Collection.

Agency: Office of Workers' Compensation Programs.

Title: Peace Corps Volunteer Authorization for Examination and/or Treatment.

OMB Number: 1240–0NEW.

Agency Number: CA–15Affected Public: Individuals or Households.

Total Respondents: 252.

Total Annual Responses: 252.

Average Time per Response: 15 minutes.

Estimated Total Burden Hours: 63.

Frequency: Once.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $146.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Vincent Alvarez

Agency Clearance Officer, Office of Workers' Compensation Programs US Department of Labor.

[FR Doc. 2019–16069 Filed 8–6–19; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Collection; Comment Request

AGENCY: Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Attorney Fee Approval Request (LS–4), Application for Special Fund Relief (LS–5), Commutation Application (LS–6), Request for Intervention (LS–7), Settlement Approval Request 8(i) (LS–8) and Stipulation Approval Request (LS–9). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before October 7, 2019.

ADDRESSES: You may submit comments by mail, delivery service, or by hand to Ms. Anjanette Suggs, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax,(202) 354–9660 or email to *suggs.anjanette@dol.gov.* Please use only one method of transmission for comments (mail/delivery, fax, or email). Please note that comments submitted after comment period will not be considered.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor (DOL) is requesting an approval of a new information collection. This information collection is essential to the mission of DOL and the Office of Workers' Compensation Programs (OWCP) Longshore and Harbor Workers' Compensation Act (LHWCA or Act). The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the LHWCA's coverage to certain other employee groups. LHWCA section 39(a) generally authorizes the Secretary of Labor to prescribe rules and regulations to implement the Act. See 33 U.S.C. 939(a).

Title 20 CFR 702.132 empowers the District Directors to award or deny attorney fees for services rendered on behalf of a claimant. In addition, 20 CFR 702.134 establishes certain guidelines for determining an attorney fee when the employer or carrier declines to pay compensation. The attorney representing a claimant must file an

itemized fee petition for services performed at the Office of Workers' Compensation (OWCP). Form (LS–4) has been designated for this purpose.

The implementing regulations at 20 CFR 702.321 require that pursuant to section 8(f) of the Act, 33 U.S.C. 908(f), if the work injury resulted in additional disability or impairment when combined with a pre-existing condition, the employer is liable for the first 104 weeks of compensation and the Special Fund is liable thereafter. Hearing loss claims are different in that the Special Fund pays for the pre-existing hearing loss and the employer for the added hearing loss. Request for relief must be submitted by the employer/carrier to OWCP and relief may be granted by the District Director or an Administrative Law Judge. To identify and timely respond to the requests from the employers and carriers, OWCP is requiring Form LS–5 Application for Special Fund Relief be submitted. The regulatory provisions are codified at 20 CFR 702.321. Because the Form LS–5 is of a statutory and regulatory nature, it should be formalized in a uniform manner and in a clear writing.

The implementing regulations at 20 CFR 702.142 require that pursuant to section 9(g) of the Act, 33 U.S.C. 909(g), compensation paid to aliens not residents, or about to become nonresidents, of the United States or Canada shall be in the same amount as provided for residents except that dependents in any foreign country shall be limited to surviving spouse and child or children, or if there be no surviving spouse or child or children, to surviving father or mother whom the employee has supported, either wholly or in part, for the period of 1 year prior to the date of injury. The Director, OWCP, may, at his or her option, or upon the application of the employer or insurance carrier, shall commute all future installments of compensation to be paid to such aliens by paying or causing to be paid to them one-half of the commuted amount of such future installments of compensation as determined by the Director. [See LHWCA 33 U.S.C. 909(g)].

In response to its stakeholders and to facilitate the commutation of payments to injured workers, and the beneficiaries of deceased workers, OWCP is requiring Form LS–6 Commutation Request with the Public Burden Statement and Privacy Act Statement. The regulatory provisions are codified at CFR 702.142. Because the Form LS–6 is of a statutory and regulatory nature, it should be formalized in a uniform manner and in a clear writing.

Title 20 CFR 702.311 empowers the District Directors to resolve disputes with respect to claims in a manner designed to protect the rights of the parties and to resolve such disputes at the earliest practicable date. In some cases, the best resolution method is an informal conference. See also 33 U.S.C. 923(a) (same); 20 CFR 702.301 (''[B]y § 702.311 *et seq.,* the district directors are empowered to amicably and promptly resolve such problems by informal procedures.'') In addition, 20 CFR 702.312–702.316 establish certain guidelines for conducting informal conferences. Usually one of the parties requests an intervention or informal conference to assist with dispute resolution. Prior to scheduling an informal conference, the issues in dispute must be established and the District Director, or designee, will determine if the type of intervention requested is the most effective means for resolving the disputed issues. The Form LS–7, Request for Intervention, will be used for that purpose.

Title 20, CFR 702.242 pursuant to 33 U.S.C. 908(i) allow the parties to settle claims for compensation and/or medical benefits. A Settlement Approval Request is a time sensitive request because once the parties submit a settlement, the District Director within thirty days must determine if the settlement is adequate, whether it was procured under duress and issue a Compensation Order in response. To facilitate prompt processing of settlement approval requests, OWCP is requiring the parties to use Form LS–8 as a cover page. The parties must also attach a signed settlement document that outlines the terms of the settlement.

Title 20 CFR 702.315(a)requires the District Directors to issue formal compensation orders, ''Following an informal conference at which agreement is reached on all issues, the deputy commissioner shall (within 10 days after conclusion of the conference), embody the agreement in a memorandum or within 30 days issue a formal compensation order. The District Director may also issue an Order Approving Stipulations signed by all parties. Form LS–9 Stipulation Approval Request will be submitted together with the parties' stipulated agreement.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The Department of Labor seeks the extension of approval of this information collection in order to carry out its responsibility to meet the statutory requirements to provide compensation or death benefits under the Act to workers covered by the Act.

Type of Review: New Collection (Request for New OMB control Number).

Agency: Office of Workers' Compensation Programs.

Title: Request for Intervention, Longshore and Harbor Workers' Compensation Act.

OMB Number: 1240–0NEW.

Agency Number: LS–007.

Affected Public: Business or other for-profit.

Form No.	Estimated response time in minutes	Estimated number of responses	Burden in hours	Annualized burden cost
LS–4	15	486	122	$2,303.36
LS–5	20	577	192	3,624.96
LS–6	10	40	7	132.16
LS–7	10	5,390	898	16,954.24
LS–8	20	5,400	1,800	33,984.00

Form No.	Estimated response time in minutes	Estimated number of responses	Burden in hours	Annualized burden cost
LS–9	20	521	174	3,285.12
Total	95	12,414	3,193	60,283.84

Total Respondents: 12,414.

Total Annual Responses: 12,414.

Estimated Total Burden Hours: 3,193 hours.

Estimated Time per Response: 15 minutes.

Frequency: On occasion.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: August 1, 2019.

Anjanette C. Suggs,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2019–16838 Filed 8–6–19; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–19–0010; NARA–2019–033]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA)

ACTION: Notice of availability of proposed records schedules; request for comments

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by September 23, 2019.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule. We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. You may request additional information about the disposition process through the contact information listed above.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Agriculture, Forest Service, Management Improvement Administration (DAA–0095–2018–0071).
2. Department of Agriculture, Forest Service, Knowledge Sharing and Conservation (DAA–0095–2018–0072).
3. Department of Agriculture, Forest Service, Performance Accountability (DAA–0095–2018–0076).
4. Department of Agriculture, Forest Service, Public Service Programs (DAA–0095–2018–0077).
5. Department of the Army, Agency-wide, Logistics Readiness Center (LRC) Automatic Return Item List (DAA–AU–2016–0078).
6. Department of Homeland Security, Transportation Security Administration, Human Resources (DAA–0560–2018–0012).
7. Department of Homeland Security, U.S. Citizenship and Immigration Services, Employee Communications and Engagement (DAA–0566–2017–0033).
8. Department of Homeland Security, U.S. Citizenship and Immigration Services, I–824 Applications for Action on an Approved Application or Petition (DAA–0566–2018–0006).
9. Department of Homeland Security, U.S. Citizenship and Immigration Services, Situational Advisory Form Evaluation (SAFE) (DAA–0566–2019–0023).
10. Department of Homeland Security, U.S. Secret Service, Protective Operations Records (DAA–0087–2017–0004).
11. Department of Justice, Office of Justice Programs, Public Safety Officer Benefits Claim Files (DAA–0423–2018–0005).
12. Department of Labor, Office of Workers' Compensation Programs, Records of the Division of Federal Employees' Compensation (DAA–0271–2017–0003).
13. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Compliance Progress Records (DAA–0571–2015–0012).
14. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Inspector Training Files (DAA–0571–2015–0013).
15. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Records of Oil Spill Preparedness and Emergency Support (DAA–0571–2019–0003).
16. Administrative Office of the United States Courts, Defender Services Office, Records of the Defender Services Office (DAA–0116–2019–0007).
17. General Services Administration, Agency-wide, Audiovisual Records (DAA–0269–2017–0002).
18. National Archives and Records Administration, Government-wide, GRS 4.1—Records Management Records (DAA–GRS–2019–0003).
19. National Archives and Records Administration, Government-wide, GRS 2.4—Employee Compensation and Benefits Records (DAA–GRS–2019–0004).
20. National Science Foundation, National Science Board, Records of the National Science Board (DAA–0307–2018–0001).
21. Office of Government Ethics, General Counsel and Legal Policy Division, Records of the General Counsel and Legal Policy Division (DAA–0522–2019–0004).
22. Office of Government Ethics, Agency-wide, Publications (DAA–0522–2019–0005).
23. Office of Government Ethics, Agency-wide, Ethics Mission Records (DAA–0522–2019–0007).
24. Office of Personnel Management, Office of the Inspector General, Records of the Office of the Inspector General (DAA–0478–2019–0002).
25. Peace Corps, Agency-wide, Volunteer Recruitment and Selection University Programs (DAA–0490–2019–0002).
26. Peace Corps, Office of Health Services, Medical Inventory (DAA–0490–2019–0003).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2019–16843 Filed 8–6–19; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0155]

Reactor Oversight Process Enhancement Initiative

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for public comment.

SUMMARY: In an effort to revise and improve the Reactor Oversight Process (ROP), the U.S. Nuclear Regulatory Commission (NRC) staff recently proposed targeted, near-term ROP enhancements to the Commission, described in SECY–19–0067, ''Recommendations for Enhancing the Reactor Oversight Process,'' dated June 28, 2019. The NRC staff is currently evaluating possible long-term ROP enhancements in the following areas: the problem identification and resolution inspection program, the cross-cutting issues process, radiation protection inspection procedures, the inspection program for Independent Spent Fuel Storage Installations (ISFSI), and the Significance Determination Process (SDP), particularly for the emergency preparedness cornerstone. The NRC is soliciting comments from the public on potential improvements in these areas, along with other areas of the ROP. Any comments received on SECY–19–0067 will be forwarded to the Commission for its consideration.

DATES: Comments should be filed no later than October 7, 2019. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0155. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Russell Gibbs, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8578, email: *Russell.Gibbs@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to docket ID NRC–2019–0155 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for docket ID NRC–2019–0155.
- *NRC's Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *ROP Enhancement Website:* Go to *https://www.nrc.gov/reactors/operating/oversight/rop-enhancement.html.*

B. Submitting Comments

Please include ROP Enhancement and docket ID NRC–2019–0155 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will enter the comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The ROP is the program that provides oversight and assessment of operating U.S. nuclear power plants. In 2018, the NRC staff solicited input from both NRC staff and external stakeholders on ways to improve the ROP. The NRC held numerous public meetings to discuss the disposition of this stakeholder feedback, resulting in several staff recommendations for Commission approval, described in SECY–19–0067, ''Recommendations for Enhancing the Reactor Oversight Process,'' dated June 28, 2019 ADAMS Package Accession No. ML19070A036. Documents, presentations, and meeting summaries associated with the development of this paper are listed on the ROP Enhancement public web page.

As described in SECY–19–0067, the NRC staff completed a comprehensive review of every core safety inspection procedure to determine if current sample requirements and resource estimates were appropriate. Of the 16 reactor safety inspection procedures, the staff recommended reducing minimum sample sizes in five inspection procedures, increasing the minimum sample size in one inspection procedure, consolidating two different inspection procedures into one procedure, and revising the frequency of one inspection from biennial to triennial. The NRC staff also initially considered an industry recommendation to credit licensee self-assessments in lieu of some safety inspections; however, the NRC is no longer considering this recommendation.

The NRC is currently working on long-term recommendations to enhance the ROP in the following areas: The problem identification and resolution inspection program, the cross-cutting issues process, radiation protection inspection procedures, ISFSI inspections, and the SDP, particularly for the emergency preparedness cornerstone.

The NRC is soliciting public comment on these long-term ROP enhancement efforts, the broad range of ROP topics described in SECY–19–0067, and any other areas of the ROP that the staff should consider under this initiative. Specifically, the NRC staff is seeking public comment on the following questions:

1. What areas of the ROP are working well?

2. What areas of the ROP are not working well?

3. How can the NRC improve the ROP in the following areas: The problem identification and resolution inspection program, the cross-cutting issues process, radiation protection inspections, ISFSI inspections, and the SDP?

The public comment period is scheduled to close on October 7, 2019. Any comments received on SECY–19–0067 will be forwarded to the Commission for its consideration.

Dated at Rockville, Maryland, this 2nd day of August, 2019.

For the Nuclear Regulatory Commission.

Christopher G. Miller,

Director, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–16876 Filed 8–6–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–277 and 50–278; NRC–2018–0130]

Exelon Generation Company, LLC; Peach Bottom Atomic Power Station, Units 2 and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft supplemental environmental impact statement; public meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft plant-specific Supplement 10, Second Renewal, to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants, NUREG–1437, regarding the subsequent renewal of Facility Operating License Nos. DPR–44 and DPR–56 for an additional 20 years of operation for Peach Bottom Atomic Power Station, Units 2 and 3 (Peach Bottom). The Peach Bottom facility is located in York County, Pennsylvania. Possible alternatives to the proposed action (subsequent license renewal) include no action and reasonable replacement power alternatives. The NRC staff will hold a public meeting to present an overview of the draft plant-specific supplement to the GEIS and to accept public comment on the document.

DATES: The public meeting will be held on September 12, 2019, from 6:00 p.m. to 8:00 p.m. at the Peach Bottom Inn, 6085 Delta Road, Delta, PA 17314. Submit either electronic or written comments by September 23, 2019. Comments received after this date will be considered, if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2018–0130. Address questions about NRC docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER**

INFORMATION CONTACT section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, ATTN: Program Management, Announcements and Editing Staff, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Drucker, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6223; email: *David.Drucker@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0130 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2018–0130.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that the document is referenced here. Draft plant-specific Supplement 10, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available in ADAMS under Accession No. ML19210D453.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *Library:* A copy of draft plant-specific Supplement 10, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, is available at the following location: Hartford County Public Library, Whiteford Branch, 2407 Whiteford Road, Whiteford, MD 21160.

B. Submitting Comments

Please include Docket ID NRC–2018–0130 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC will post all comment submissions at *https://www.regulations.gov/* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC is issuing for public comment draft plant-specific Supplement 10, Second Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, regarding the subsequent renewal of Facility Operating License Nos. DPR–44 and DPR–56 for an additional 20 years of operation for Peach Bottom Units 2 and 3. Draft plant-specific Supplement 10, Second Renewal, to the GEIS includes the preliminary analysis that evaluates the environmental impacts of the proposed action and alternatives to the proposed action. The NRC's preliminary recommendation is that the adverse environmental impacts of subsequent license renewal for Peach Bottom are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would be unreasonable.

III. Public Meeting

The NRC staff will hold a public meeting prior to the close of the public comment period to present an overview of the draft plant-specific supplement to the GEIS and to accept public comment on the document. The meeting will be held on September 12, 2019, from 6:00 p.m. to 8:00 p.m. at the Peach Bottom Inn, 6085 Delta Road, Delta, PA 17314. There will be an open house one hour before the meeting for members of the public to meet with NRC staff members and sign in to speak. The meeting will be transcribed and will include: (1) A presentation of the contents of the draft plant-specific supplement to the GEIS and (2) the opportunity for interested government agencies, organizations, and individuals to provide comments on the draft plant-specific supplement to the GEIS. To be considered in the final supplement to the GEIS, comments must be provided either at the transcribed public meeting or submitted in writing by the comment deadline identified above. Persons may pre-register to attend or present oral comments at the meeting by contacting Mr. David Drucker, the NRC Project Manager, at 301–415–6223, or by email at *David.Drucker@nrc.gov* no later than Thursday, August 29, 2019. Members of the public may also register to provide oral comments within 15 minutes before the start of the meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register. If special equipment or accommodations are needed to attend or present information at the public meeting, the need should be brought to Mr. Drucker's attention no later than Thursday, August 29, 2019, to provide the NRC staff adequate notice to determine whether the request can be accommodated.

Dated at Rockville, Maryland, this 1st day of August, 2019.

For the Nuclear Regulatory Commission.

Eric R. Oesterle,

Chief, License Renewal Projects Branch, Division of Materials and License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–16794 Filed 8–6–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–178 and CP2019–200; MC2019–179 and CP2019–201]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 9, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://*

www.prc.gov. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–178 and CP2019–200; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 64 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* August 9, 2019.

2. *Docket No(s).:* MC2019–179 and CP2019–201; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 97 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* August 9, 2019.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–16871 Filed 8–6–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 7, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express & Priority Mail Contract 97 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–179, CP2019–201.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–16827 Filed 8–6–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* August 7, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on August 1, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 64 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–178, CP2019–200.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–16826 Filed 8–6–19; 8:45 am]

BILLING CODE 7710–12–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86542; File No. 4–566]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Among Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., NYSE Chicago, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., Nasdaq BX, Inc., Nasdaq PHLX LLC, The Nasdaq Stock Market LLC, NYSE National, Inc., New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., Investors Exchange LLC, and Long-Term Stock Exchange, Inc. Relating to the Surveillance, Investigation, and Enforcement of Insider Trading Rules

August 1, 2019.

Notice is hereby given that the Securities and Exchange Commission (''Commission'') has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (''Act''),[1] approving and declaring effective an amendment to the plan for allocating regulatory responsibility (''Plan'') filed on July 15, 2019, pursuant to Rule 17d–2 of the Act,[2] by Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), NYSE Chicago, Inc. (''CHX''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE National, Inc. (''National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''American''), NYSE Arca, Inc. (''NYSE Arca''), Investors Exchange LLC (''IEX''), and Long-Term Stock Exchange, Inc. (''LTSE'') (collectively, ''Participating Organizations'' or ''Parties'').

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization (''SRO'') registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d)[4] or Section 19(g)(2)[5] of the Act. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (''common members''). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[6] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[7] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[8] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[9] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[10] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system, and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On September 12, 2008, the Commission declared effective the Participating Organizations' Plan for allocating regulatory responsibilities pursuant to Rule 17d–2.[11] The Plan is designed to eliminate regulatory duplication by allocating regulatory responsibility over Common FINRA Members[12] (collectively ''Common Members'') for the surveillance, investigation, and enforcement of common insider trading rules (''Common Rules'').[13] The Plan assigns regulatory responsibility over Common FINRA Members to FINRA for surveillance, investigation, and enforcement of insider trading by broker-dealers, and their associated persons, with respect to Listed Stocks (as defined in the Plan), irrespective of the marketplace(s) maintained by the Participating Organizations on which the relevant trading may occur.

III. Proposed Amendment to the Plan

On July 15, 2019, the Parties submitted a proposed amendment to the Plan. The proposed amendment was submitted to add LTSE as a Participant

[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

[3] 15 U.S.C. 78s(g)(1).

[4] 15 U.S.C. 78q(d).

[5] 15 U.S.C. 78s(g)(2).

[6] 15 U.S.C. 78q(d)(1).

[7] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[8] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[9] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[10] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

[11] *See* Securities Exchange Act Release No. 58536 (September 12, 2008), 73 FR 54646 (September 22, 2008). *See also* Securities Exchange Act Release Nos. 58806 (October 17, 2008), 73 FR 63216 (October 23, 2008); 61919 (April 15, 2010), 75 FR 21051 (April 22, 2010); 63103 (October 14, 2010), 75 FR 64755 (October 20, 2010); 63750 (January 21, 2011), 76 FR 4948 (January 27, 2011); 65991 (December 16, 2011), 76 FR 79714 (December 22, 2011); 78473 (August 3, 2016), 81 FR 52722 (August 9, 2016); and 84392 (October 10, 2018), 83 FR 52243 (October 16, 2018).

[12] Common FINRA Members include members of FINRA and at least one of the Participating Organizations.

[13] Common rules are defined as: (i) Federal securities laws and rules promulgated by the Commission pertaining to insider trading, and (ii) the rules of the Participating Organizations that are related to insider trading. *See* Exhibit A to the Plan.

to the Plan and to reflect the name change of Chicago Stock Exchange, Inc. to NYSE Chicago, Inc. The text of the proposed amended 17d–2 plan is as follows (additions are *italicized;* deletions are [bracketed]):

* * * * *

Agreement for the Allocation of Regulatory Responsibility of Surveillance, Investigation and Enforcement for Insider Trading pursuant to § 17(d) of the Securities Exchange Act of 1934, 15 U.S.C. § 78q (d), and Rule 17d–2 Thereunder

This agreement (the ''Agreement'') by and among Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), *NYSE* Chicago [Stock Exchange], Inc. (''CHX''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE National, Inc. (''NYSE National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), [and] Investors' Exchange LLC (''IEX'') *and Long-Term Stock Exchange, Inc.* (each a ''Participating Organization'' and together, the ''Participating Organizations''), is made pursuant to § 17(d) of the Securities Exchange Act of 1934 (the ''Act''), 15 U.S.C. 78q(d), and Securities and Exchange Commission (''SEC'') Rule 17d–2, which allow for plans to allocate regulatory responsibility among self-regulatory organizations (''SROs''). Upon approval by the SEC, this Agreement shall amend and restate the agreement among the Participating Organizations approved by the SEC on [August 3, 2016]*October 10, 2018.*

WHEREAS, the Participating Organizations desire to: (a) Foster cooperation and coordination among the SROs; (b) remove impediments to, and foster the development of, a national market system; (c) strive to protect the interest of investors; and (d) eliminate duplication in their regulatory surveillance, investigation and enforcement of insider trading;

WHEREAS, the Participating Organizations are interested in allocating to FINRA regulatory responsibility for Common FINRA Members (as defined below) for surveillance, investigation and enforcement of Insider Trading (as defined below) in NMS Stocks (as defined below) irrespective of the marketplace(s) maintained by the Participating Organizations on which the relevant trading may occur in violation of Common Insider Trading Rules (as defined below);

WHEREAS, the Participating Organizations will request regulatory allocation of these regulatory responsibilities by executing and filing with the SEC a plan for the above stated purposes (this Agreement, also known herein as the ''Plan'') pursuant to the provisions of § 17(d) of the Act, and SEC Rule 17d–2 thereunder, as described below; and

WHEREAS, the Participating Organizations will also enter into a Regulatory Services Agreement (the ''Insider Trading RSA''), of even date herewith, to provide for the investigation and enforcement of suspected Insider Trading against broker-dealers, and their associated persons, that are not Common FINRA Members in the case of Insider Trading in NMS Stocks.

NOW, THEREFORE, in consideration of the mutual covenants contained hereafter, and other valuable consideration to be mutually exchanged, the Participating Organizations hereby agree as follows:

1. *Definitions.* Unless otherwise defined in this Agreement, or the context otherwise requires, the terms used in this Agreement will have the same meaning they have under the Act, and the rules and regulations thereunder. As used in this Agreement, the following terms will have the following meanings:

a. ''Rule'' of an ''exchange'' or an ''association'' shall have the meaning defined in Section 3(a)(27) of the Act.

b. ''Common FINRA Members'' shall mean members of FINRA and at least one of the Participating Organizations.

c. ''Common Insider Trading Rules'' shall mean (i) the federal securities laws and rules thereunder promulgated by the SEC pertaining to insider trading, and (ii) the rules of the Participating Organizations that are related to insider trading, as provided on Exhibit A to this Agreement.

d. ''Effective Date'' shall have the meaning set forth in paragraph 27.–

e. ''Insider Trading'' shall mean any conduct or action taken by a natural person or entity related in any way to the trading of securities by an insider or a related party based on or on the basis of material non-public information obtained during the performance of the insider's duties at the corporation, or otherwise misappropriated, that could be deemed a violation of the Common Insider Trading Rules.

f. ''Intellectual Property'' will mean any: (1) Processes, methodologies, procedures, or technology, whether or not patentable; (2) trademarks, copyrights, literary works or other works of authorship, service marks and trade secrets; or (3) software, systems, machine-readable texts and files and related documentation.

g. ''Plan'' shall mean this Agreement, which is submitted as a Plan for the allocation of regulatory responsibilities of surveillance for insider trading pursuant to § 17(d) of the Act, 15 U.S.C. 78q(d), and SEC Rule 17d–2.

h. ''NMS Stock(s)'' shall have the meaning set forth in Rule 600(b)(47) of SEC Regulation NMS.

i. ''Listing Market'' shall mean an exchange that lists NMS stocks.

2. *Assumption of Regulatory Responsibilities.* On the Effective Date of the Plan, FINRA will assume regulatory responsibilities for surveillance, investigation and enforcement of Insider Trading by broker-dealers, and their associated persons, for Common FINRA Members with respect to NMS Stocks, irrespective of the marketplace(s) maintained by the Participant Organizations on which the relevant trading may occur in violation of the Common Insider Trading Rules (''Regulatory Responsibilities'').

3. *Certification of Insider Trading Rules.*

a. *Initial Certification.* By signing this Agreement, the Participating Organizations, other than FINRA, hereby certify to FINRA that their respective lists of Common Insider Trading Rules contained in Exhibit A hereto are correct, and FINRA hereby confirms that such rules are Common Insider Trading Rules as defined in this Agreement.

b. *Yearly Certification.* Each year following the commencement of operation of this Agreement, or more frequently if required by changes in the rules of the Participating Organizations, each Participating Organization shall submit a certified and updated list of Common Insider Trading Rules to FINRA for review, which shall (i) add Participating Organization rules not included in the then-current list of Common Insider Trading Rules that qualify as Common Insider Trading Rules as defined in this Agreement; (ii) delete Participating Organization rules included in the current list of Common Insider Trading Rules that no longer qualify as Common Insider Trading Rules as defined in this Agreement; and (iii) confirm that the remaining rules on the current list of Common Insider Trading Rules continue to be Participating Organization rules that qualify as Common Insider Trading Rules as defined in this Agreement. FINRA shall review each Participating Organization's annual certification and

confirm whether FINRA agrees with the submitted certified and updated list of Common Insider Trading Rules by each of the Participating Organizations.

4. *No Retention of Regulatory Responsibility.* The Participating Organizations do not contemplate the retention of any responsibilities with respect to the regulatory activities being assumed by FINRA under the terms of this Agreement.

5. *Fees.* FINRA shall charge Participating Organizations for performing the Regulatory Responsibilities, as set forth in the Schedule of Fees, attached as Exhibit B.

6. *Applicability of Certain Laws, Rules, Regulations or Orders.* Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule, or order is inconsistent with one or more provisions of this Agreement, the statute, rule, or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

7. *Exchange Committee; Reports.*

a. *Exchange Committee.* The Participating Organizations shall form a committee (the ''Exchange Committee''), which shall act on behalf of all of Participating Organizations in receiving copies of the reports described below and in reviewing issues that arise under this Agreement. Each Participating Organization shall appoint a representative to the Exchange Committee. The Exchange Committee representatives shall report to their respective executive management bodies regarding status or issues under this Agreement. The Participating Organizations agree that the Exchange Committee will meet regularly up to four (4) times a year, with no more than one meeting per calendar quarter. At these meetings, the Exchange Committee will discuss the conduct of the Regulatory Responsibilities and identify issues or concerns with respect to this Agreement, including matters related to the calculation of the cost formula and accuracy of fees charged and provision of information related to the same. The SEC shall be permitted to attend the meetings as an observer.

b. *Reports.* FINRA shall provide the reports set forth in Exhibit C hereto and any additional reports related to this Agreement reasonably requested by a majority vote of all representatives to the Exchange Committee at each Exchange Committee meeting, or more often as the Participating Organizations deem appropriate, but no more often than once every quarterly billing period.

8. *Customer Complaints.* If a Participating Organization receives a copy of a customer complaint relating to Insider Trading or other activity or conduct that is within FINRA's Regulatory Responsibilities as set forth in this Agreement, the Participating Organization shall promptly forward to FINRA, as applicable, a copy of such customer complaint.

9. *Parties to Make Personnel Available as Witnesses.* Each Participating Organization shall make its personnel available to FINRA to serve as testimonial or non-testimonial witnesses as necessary to assist FINRA in fulfilling the Regulatory Responsibilities allocated under this Agreement. FINRA shall provide reasonable advance notice when practicable and shall work with a Participating Organization to accommodate reasonable scheduling conflicts within the context and demands as the entity with ultimate regulatory responsibility. The Participating Organization shall pay all reasonable travel and other expenses incurred by its employees to the extent that FINRA requires such employees to serve as witnesses, and provide information or other assistance pursuant to this Agreement.

10. *Market Data; Sharing of Work-Papers, Data and Related Information.*

a. *Market Data.* FINRA shall obtain raw market data necessary to the performance of regulation under this Agreement from (a) the Consolidated Tape Association (''CTA'') and (b) the NASDAQ Unlisted Trading Privileges Plan.

b. *Sharing.* A Participating Organization shall make available to FINRA information necessary to assist FINRA in fulfilling the Regulatory Responsibilities assumed under the terms of this Agreement. Such information shall include *any* information collected by a Participating Organization in the course of performing its regulatory obligations under the Act, including information relating to an on-going disciplinary investigation or action against a member, the amount of a fine imposed on a member, financial information, or information regarding proprietary trading systems gained in the course of examining a member (''Regulatory Information''). This Regulatory Information shall be used by FINRA solely for the purposes of fulfilling its Regulatory Responsibilities.

c. *No Waiver of Privilege.* The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

d. *Intellectual Property.*

(i) *Existing Intellectual Property.* FINRA is and will remain the owner of all right, title and interest in and to the proprietary Intellectual Property it employs in the provision of regulation hereunder (including the SONAR system), and any derivative works thereof. To the extent certain elements of FINRA's systems, or portions thereof, may be licensed or leased from third parties, all such third party elements shall remain the property of such third parties, as applicable. Likewise, any other Participating Organization is and will remain the owner of all right, title and interest in and to its own existing proprietary Intellectual Property.

(ii) *Enhancements to Existing Intellectual Property or New Developments.* In the event FINRA (a) makes any changes, modifications or enhancements to its Intellectual Property for any reason, or (b) creates any newly developed Intellectual Property for any reason, including as a result of requested enhancements or new development by the Exchange Committee (collectively, the ''New IP''), the Participating Organizations acknowledge and agree that FINRA shall be deemed the owner of the New IP created by it (and any derivative works thereof), and shall retain all right, title and interest therein and thereto, and each other Participating Organization hereby irrevocably assigns, transfers and conveys to FINRA without further consideration all of its right, title and interest in or to all such New IP (and any derivative works thereof).

(iii) *Fees for New IP.* FINRA will not charge the Participating Organizations any fees for any New IP created and used by FINRA; provided, however, that FINRA will be permitted to charge fees for software maintenance work performed on systems used in the discharge of its duties hereunder.

11. *Special or Cause Examinations.* Nothing in this Agreement shall restrict or in any way encumber the right of a party to conduct special or cause examinations of Common FINRA Members as any party, in its sole discretion, shall deem appropriate or necessary.

12. *Dispute Resolution Under this Agreement.*

a. *Negotiation.* The parties to this Agreement will attempt to resolve any disputes through good faith negotiation and discussion, escalating such discussion up through the appropriate management levels until reaching the executive management level. In the event a dispute cannot be settled

through these means, the parties shall refer the dispute to binding arbitration.

b. *Binding Arbitration.* All claims, disputes, controversies, and other matters in question between the parties to this Agreement arising out of or relating to this Agreement or the breach thereof that cannot be resolved by the parties will be resolved through binding arbitration. Unless otherwise agreed by the parties, a dispute submitted to binding arbitration pursuant to this paragraph shall be resolved using the following procedures:

(i) The arbitration shall be conducted in the city of New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof; and

(ii) There shall be three arbitrators, and the chairperson of the arbitration panel shall be an attorney.

13. *Limitation of Liability.* As between the Participating Organizations, no Participating Organization, including its respective directors, governors, officers, employees and agents, will be liable to any other Participating Organization, or its directors, governors, officers, employees and agents, for any liability, loss or damage resulting from any delays, inaccuracies, errors or omissions with respect to its performing or failing to perform regulatory responsibilities, obligations, or functions, except (a) as otherwise provided for under the Act, (b) in instances of a Participating Organization's gross negligence, willful misconduct or reckless disregard with respect to another Participating Organization, (c) in instances of a breach of confidentiality obligations owed to another Participating Organization, or (d) in the case of any Participating Organization paying fees hereunder, for any payments due. The Participating Organizations understand and agree that the Regulatory Responsibilities are being performed on a good faith and best effort basis and no warranties, express or implied, are made by any Participating Organization to any other Participating Organization with respect to any of the responsibilities to be performed hereunder. This paragraph is not intended to create liability of any Participating Organization to any third party.

14. *SEC Approval.*

a. The parties agree to file promptly this Agreement with the SEC for its review and approval. FINRA shall file this Agreement on behalf, and with the explicit consent, of all Participating Organizations.

b. If approved by the SEC, the Participating Organizations will notify their members of the general terms of this Agreement and of its impact on their members.

15. *Subsequent Parties; Limited Relationship.* This Agreement shall inure to the benefit of and shall be binding upon the Participating Organizations hereto and their respective legal representatives, successors, and assigns. Nothing in this Agreement, expressed or implied, is intended or shall: (a) Confer on any person other than the Participating Organizations hereto, or their respective legal representatives, successors, and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, (b) constitute the Participating Organizations hereto partners or participants in a joint venture, or (c) appoint one Participating Organization the agent of the other.

16. *Assignment.* No Participating Organization may assign this Agreement without the prior written consent of all the other Participating Organizations, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that any Participating Organization may assign this Agreement to a corporation controlling, controlled by or under common control with the Participating Organization without the prior written consent of any other party.

17. *Severability.* Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

18. *Termination.*

a. Any Participating Organization may cancel its participation in this Agreement at any time, provided that it has given 180 days written notice to the other Participating Organizations (or in the case of a change of control in ownership of a Participating Organization, such other notice time period as that Participating Organization may choose), and provided that such termination has been approved by the SEC. The cancellation of its participation in this Agreement by any Participating Organization shall not terminate this Agreement as to the remaining Participating Organizations.

b. The Regulatory Responsibilities assumed under this Agreement by FINRA may be terminated by FINRA against any Participating Organization as follows. The Participating Organization will have thirty (30) days from receipt to satisfy the invoice. If the Participating Organization fails to satisfy the invoice within thirty (30) days of receipt (''Default''), FINRA will notify the Participating Organization of the Default. The Participating Organization will have thirty (30) days from receipt of the Default notice to satisfy the invoice.

c. FINRA will have the right to terminate the Regulatory Responsibilities assumed under this Agreement if a Participating Organization has Defaulted in its obligation to pay the invoice on more than three (3) occasions in any rolling twenty-four (24) month period.

19. *Intermarket Surveillance Group (''ISG'').* In order to participate in this Agreement, all Participating Organizations to this Agreement must be members of the ISG.

20. *General.* The Participating Organizations agree to perform all acts and execute all supplementary instruments or documents that may be reasonably necessary or desirable to carry out the provisions of this Agreement.

21. *Liaison and Notices.* All questions regarding the implementation of this Agreement shall be directed to the persons identified below, as applicable. All notices and other communications required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly given upon (i) actual receipt by the notified party or (ii) constructive receipt (as of the date marked on the return receipt) if sent by certified or registered mail, return receipt requested. To the following addresses:

For Cboe BZX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe BZX Exchange, Inc., 400 S LaSalle Street, Chicago, IL 60605. Telephone: (312) 786–7844. Facsimilie: (312) 786–7982. Email: *hoogasian@cboe.com.*

For Cboe BYX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe BZX Exchange, Inc., 400 S LaSalle Street, Chicago, IL 60605. Telephone: (312) 786–7844. Facsimilie: (312) 786–7982. Email: *hoogasian@cboe.com.*

For *NYSE* Chicago [Stock Exchange], Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE Group, Inc., 11 Wall Street, New York, NY 10005. Telephone: (212) 656–8297. Facsimile: (212) 656–2027. Email: *Anthony.Albanese@theice.com*

For Cboe EDGA Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe BZX Exchange, Inc., 400 S LaSalle Street, Chicago, IL 60605. Telephone: (312) 786–7844. Facsimilie: (312) 786–7982. Email: *hoogasian@cboe.com.*

For Cboe EDGX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe BZX Exchange, Inc., 400 S LaSalle Street, Chicago, IL 60605. Telephone: (312) 786–7844. Facsimilie: (312) 786–7982. Email: *hoogasian@cboe.com.*

For Financial Industry Regulatory Authority, Inc.: Cameron Funkhouser, Executive Vice President, Office of Fraud Detection and Market Intelligence. FINRA, 1735 K Street NW, Washington, DC 20006. Telephone: (240) 386–5021. Facsimile: (301) 407–4635. Email: *Cameron.Funkhouser@finra.org.*

For Nasdaq BX, Inc.: John A. Zecca, Senior Vice President. The Nasdaq Stock Market LLC, 9600 Blackwell Road, Rockville, MD 20850. Telephone: (301) 978–8498. Facsimile: (301) 978–8472. Email: *John.Zecca@nasdaqomx.com.*

For Nasdaq PHLX LLC: Joseph Cusick, Chief Regulatory Officer, Nasdaq PHLX LLC, 1900 Market Street, Philadelphia, PA 19103. Telephone: (215) 496–1576. Facsimile: (215) 496–5104. Email: *joeseph.cusick@nasdaqomx.com.*

For The Nasdaq Stock Market LLC: John A. Zecca, Senior Vice President, The Nasdaq Stock Market LLC, 9600 Blackwell Road, Rockville, MD 20850. Telephone: (301) 978–8498. Facsimile: (301) 978–8472. Email: *John.Zecca@nasdaqomx.com.*

For NYSE National, Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE National, Inc., 11 Wall Street, New York, NY 10005. Telephone: (212) 656–8927. Facsimile: (212) 656–2027. Email: *Anthony.albanese@theice.com.*

For New York Stock Exchange LLC: Anthony Albanese, Chief Regulatory Officer, NYSE, 11 Wall Street, New York, NY 10005. Telephone: (212) 656–8927. Facsimile: (212) 656–2027. Email: *Anthony.albanese@theice.com.*

For NYSE American LLC: Anthony Albanese, Chief Regulatory Officer, NYSE American, 11 Wall Street, New York, NY 10005. Telephone: (212) 656–8927. Facsimile: (212) 656–2027. Email: *Anthony.albanese@theice.com.*

For NYSE Arca, Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE Arca, 11 Wall Street, New York, NY 10005. Telephone: (212) 656–8927. Facsimile: (212) 656–2027. Email: *Anthony.albanese@theice.com.*

For Investors' Exchange LLC.: Claudia Crowley, Chief Regulatory Officer, IEX, 4 World Trade Center, 150 Greenwich Street, 44th Floor, New York, NY 10007. Telephone: (646) 343–2041. Facsimile: (646) 365–6862. Email: *Claudia.crowley@iextrading.com.*

For Long-Term Stock Exchange, Inc.: Howard Steinberg, General Counsel and Chief Regulatory Officer, LTSE, 300 Montgomery St., STE 790, San Francisco, CA 94104. Telephone: (202) 880–4022. Email: howard@longtermstockexchange.com.

22. *Confidentiality.* The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations under this Agreement. No party shall assert regulatory or other privileges as against the other with respect to Regulatory Information that is required to be shared pursuant to this Agreement, as defined by paragraph 10, above.

23. *Regulatory Responsibility.* Pursuant to Section 17(d)(1)(A) of the Act, and Rule 17d–2 thereunder, the Participating Organizations jointly and severally request the SEC, upon its approval of this Agreement, to relieve the Participating Organizations, jointly and severally, of any and all responsibilities with respect to the matters allocated to FINRA pursuant to this Agreement for purposes of §§ 17(d) and 19(g) of the Act.

24. *Governing Law.* This Agreement shall be deemed to have been made in the State of New York, and shall be construed and enforced in accordance with the law of the State of New York, without reference to principles of conflicts of laws thereof. Each of the parties hereby consents to submit to the jurisdiction of the courts of the State of New York in connection with any action or proceeding relating to this Agreement.

25. *Survival of Provisions.* Provisions intended by their terms or context to survive and continue notwithstanding delivery of the regulatory services by FINRA, the payment of the Fees by the Participating Organizations, and any expiration of this Agreement shall survive and continue.

26. *Amendment.*

a. This Agreement may be amended to add a new Participating Organization, provided that such Participating Organization does not assume regulatory responsibility, solely by an amendment executed by FINRA and such new Participating Organization. All other Participating Organizations expressly consent to allow FINRA to add new Participating Organizations to this Agreement as provided above. FINRA will promptly notify all Participating Organizations of any such amendments to add a new Participating Organization.

b. All other amendments must be approved by each Participating Organization. All amendments, including adding a new Participating Organization, must be filed with and approved by the SEC before they become effective.

27. *Effective Date.* The Effective Date of this Agreement will be the date the SEC declares this Agreement to be effective pursuant to authority conferred by § 17(d) of the Act, and SEC Rule 17d–2 thereunder.

28. *Counterparts.* This Agreement may be executed in any number of counterparts, including facsimile, each of which will be deemed an original, but all of which taken together shall constitute one single agreement between the parties.

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IN WITNESS WHEREOF, the parties hereto have each caused this Agreement for the Allocation of Regulatory Responsibility of Surveillance, Investigation and Enforcement for Insider Trading to be signed and delivered by its duly authorized representative.

* * * * *

Exhibit A: Common Insider Trading Rules

1. Securities Exchange Act of 1934 Section 10(b), and rules and regulations promulgated there under in connection with insider trading, including SEC Rule 10b–5 (as it pertains to insider trading), which states that:

Rule 10b–5—Employment of Manipulative and Deceptive Devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

a. To employ any device, scheme, or artifice to defraud,

b. To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

c. To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

2. Securities Exchange Act of 1934 Section 17(a), and rules and regulations promulgated there under in connection with insider trading, including SEC Rule 17a–3 (as it pertains to insider trading).

3. The following SRO Rules as they pertain to violations of insider trading:

FINRA Rule 2010 (Standards of Commercial Honor and Principles of Trade)

FINRA Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
FINRA Rule 3110 (Supervision)
FINRA Rule 4511 (General Requirements)
FINRA Rule 4512 (Customer Account Information)
NYSE Rule 440 (Books and Records)
NYSE Rule 476(a) (Disciplinary Proceedings Involving Charges Against Members, Member Organizations, Principal Executives, Approved Persons, Employees, or Others)
NYSE Rule 2010 (Standards of Commercial Honor and Principles of Trade)
NYSE Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE Rule 3110 (Supervision)
NYSE American General and Floor Rule 3(j) (General Prohibitions and Duty to Report)
NYSE American Rule 2.24–E (ETP Books and Records)
NYSE American Rule 476(a) (Disciplinary Proceedings Involving Charges Against Members, Member Organizations, Principal Executives, Approved Persons, Employees, or Others)
NYSE American Rule 2010 (Equities. Standards of Commercial Honor and Principles of Trade)
NYSE American Rule 2020 (Equities. Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE American Rule 3110 (Equities. Supervision)
Nasdaq Rule 2010A (Standards of Commercial Honor and Principles of Trade)
Nasdaq Rule 2120 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
Nasdaq Rule 3010 (Supervision)
Nasdaq Rule 4511A (General Requirements
Nasdaq Rule 4512A (Customer Account Information)
CHX Article 8, Rule 3 (Fraudulent Acts)
CHX Article 9, Rule 2 (Just & Equitable Trade Principles)
CHX Article 11, Rule 2 (Maintenance of Books and Records)
CHX Article 6, Rule 5 (Supervision of Registered Persons and Branch and Resident Offices)
PHLX Rule 707 (Conduct Inconsistent with Just and Equitable Principles of Trade)
PHLX Rule 748 (Supervision)
PHLX Rule 760 (Maintenance, Retention and Furnishing of Books, Records and Other Information)
PHLX Rule 761 (Supervisory Procedures Relating to ITSFEA and to Prevention of Misuse or Material Nonpublic Information)
PHLX Rule 782 (Manipulative Operations)
NYSE Arca Rule 2.28 (Books and Records)
NYSE Arca Rule 5.1–E(a)(2)(v)(D) (General Provisions and Unlisted Trading Privileges)
NYSE Arca Rule 11.1 (Adherence to Law)
NYSE Arca Rule 11.2(b) (Prohibited Acts (J&E))
NYSE Arca Rule 11.3 (Prevention of the Misuse of Material, Nonpublic Information)
NYSE Arca Rule 11.18 (Supervision)
NYSE Arca Rule 9.1–E(c) (Office Supervision)
NYSE Arca Rule 9.2–E(b) (Account Supervision)
NYSE Arca Rule 9.2–E(c) (Customer Records)
NYSE Arca Rule 9.2010–E (Standards of Commercial Honor and Principles of Trade)
NYSE Arca Rule 9.2020–E (Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE National Rule 5.1(a)(2)(D)(iv) (Unlisted Trading Privileges)
NYSE National Rule 11.3.1 (Business Conduct of ETP Holders)
NYSE National Rule 11.3.2 (Violations Prohibited)
NYSE National Rule 11.3.3 (Use of Fraudulent Devices)
NYSE National Rule 11.4.1 (Requirements)
NYSE National Rule 11.5.1 (Written Procedures)
NYSE National Rule 11.5.3 (Records)
NYSE National Rule 11.5.5 (Prevention of the Misuse of Material, Nonpublic Information)
NYSE National Rule 11.12.4 (Manipulative Transactions)
BX Rule 2110 (Standards of Commercial Honor and Principles of Trade)
BX Rule 2120 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
BX Rule 3010 (Supervision)
BX Rule 3110 (a) and (c) (Books and Records; Financial Condition)
BZX Rule 3.1 (Business Conduct of Members)
BZX Rule 3.2 (Violations Prohibited)
BZX Rule 3.3 (Use of Fraudulent Devices)
BZX Rule 4.1 (Requirements)
BZX Rule 5.1 (Written Procedures)
BZX Rule 5.3 (Records)
BZX Rule 5.5 (Prevention of the Misuse of Material, Non-Public Information)
BZX Rule 12.4 (Manipulative Transactions)
BYX Rule 3.1 (Business Conduct of ETP Holders)
BYX Rule 3.2 (Violations Prohibited)
BYX Rule 3.3 (Use of Fraudulent Devices)
BYX Rule 4.1 (Requirements)
BYX Rule 5.1 (Written Procedures)
BYX Rule 5.3 (Records)
BYX Rule 5.5 (Prevention of the Misuse of Material, Non-Public Information)
BYX Rule 12.4 (Manipulative Transactions)
EDGA Rule 3.1 (Business Conduct of Members)
EDGA Rule 3.2 (Violations Prohibited)
EDGA Rule 3.3 (Use of Fraudulent Devices)
EDGA Rule 4.1 (Requirements)
EDGA Rule 5.1 (Written Procedures)
EDGA Rule 5.3 (Records)
EDGA Rule 5.5 (Prevention of Misuse of Material, Nonpublic Information)
EDGA Rule 12.4 (Manipulative Transactions)
EDGX Rule 3.1 (Business Conduct of Members)
EDGX Rule 3.2 (Violations Prohibited)
EDGX Rule 3.3 (Use of Fraudulent Devices)
EDGX Rule 4.1 (Requirements)
EDGX Rule 5.1 (Written Procedures)
EDGX Rule 5.3 (Records)
EDGX Rule 5.5 (Prevention of Misuse of Material, Nonpublic Information)
EDGX Rule 12.4 (Manipulative Transactions)
IEX Rule 3.110 (Business Conduct of Members)
IEX Rule 3.120 (Violations Prohibited)
IEX Rule 3.130 (Use of Fraudulent Devices)
IEX Rule 4.511 (General Requirements)
IEX Rule 4.512 (Customer Account Information)
IEX Rule 5.110 (Supervision)
IEX Rule 5.150 (Prevention of Misuse of Material, Non-Public Information)
IEX Rule 10.140 (Manipulative Transactions)
LTSE Rule 3.110 (Business Conduct of Members)
LTSE Rule 3.120 (Violations Prohibited)
LTSE Rule 3.130 (Use of Fraudulent Devices)
LTSE Rule 4.511 (General Requirements)
LTSE Rule 4.512 (Customer Account Information)
LTSE Rule 5.110 (Supervision)
LTSE Rule 5.150 (Prevention of Misuse of Material, Non-Public Information)
LTSE Rule 10.140 (Manipulative Transactions)

Exhibit B: Fee Schedule

1. *Fees.* FINRA shall charge each Participating Organization a Quarterly Fee in arrears for the performance of FINRA's Regulatory Responsibilities under the Plan (each, a ''Quarterly Fee,'' and together, the ''Fees'').

a. *Quarterly Fees.*

(1) Quarterly Fees for each Participating Organization will be charged by FINRA according to the Participating Organization's ''Percentage of Publicly Reported Trades'' occurring over three-month billing periods. The ''Percentage of Publicly Reported Trades'' shall equal a Participating Organization's total number of reported NMS Stock trades during the relevant period as specified in paragraph 1b. (the ''Numerator''), divided by the total number of all NMS Stock trades for the same period as specified in paragraph 1b. (the ''Denominator''). For purposes of clarification, ADF and Trade Reporting Facility (''TRF'') activity will be included in the Denominator. Additionally, with regard to TRFs, TRF trade volume will be charged to FINRA. Consequently, for purposes of calculating the Quarterly Fees, the volume for each Participant Organization's TRF will be calculated separately (that is, TRF volume will be broken out from the Participating Organization's overall Percentage of Publicly Reported Trades) and the fees for such will be billed to FINRA in accordance with paragraph 1a.(2), rather than to the applicable Participating Organization.

(2) The Quarterly Fees shall be determined by FINRA in the following manner for each Participating Organization:

(a) Less than 1.0%: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is less than 1.0%, the Quarterly Fee shall be $6,250, per quarter (''Static Fee'');

(b) Less than 2.0% but No Less than 1.0%: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is less than 2.0% but no less than 1.0%, the Quarterly Fee shall be $18,750, per quarter (''Static Fee'');

(c) 2.0% or Greater: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is 2.0% or greater, the Quarterly Fee shall be the amount equal to the Participating Organization's Percentage of Publicly Reported Trades multiplied by FINRA's total charge (''Total Charge'') for its performance of Regulatory Responsibilities for the relevant three-month billing period.

(3) Increases in Static Fees. FINRA will re-evaluate the Quarterly Fees on an annual basis during the annual budget process outlined in paragraph 1.c. below. During each annual re-evaluation, FINRA will have the discretion to increase the Static Fees by a percentage no greater than the percentage increase in the Final Budget over the preceding year's Final Budget. Any changes to the Static Fees shall not require an amendment to this Agreement, but rather shall be memorialized through the budget process.

(4) Increases in Total Charges. Any change in the Total Charges (whether a Final Budget increase or any mid year change) shall not require an amendment to this Agreement, but rather shall be memorialized through the budget process.

b. *Source of Data.* For purposes of calculation of the Percentage of Publicly Reported Trades for each Participating Organization, FINRA will use trades reported to the two SIPs (a) the Consolidated Tape Association (''CTA''), and (b) the Unlisted Trading Privileges Plan. In each case, FINRA will use the total trades as may be adjusted by the Participating Organization. Adjustments will include any separation or breakup of the number of trades as a result of reporting of bunched or bundled trades by a Participating Organization but will not include any adjustments resulting from single-priced opening, reopening or closing auction trades. Each Participating Organization that reports bunched or bundled trades will report to FINRA any adjustments to its total number of NMS Stock trades on the 15th of the month following the end of the quarter.

c. *Annual Budget Forecast.* FINRA will notify the Participating Organizations of the forecasted costs of its insider trading program for the following calendar year by close of business on October 15 of the then-current year (the ''Forecasted Budget''). FINRA shall use best efforts to provide as accurate a forecast as possible. FINRA shall then provide a final submission of the costs following approval of such costs by its Board of Governors (the ''Final Budget''). Subject to paragraph 1d. below, in the event of a difference between the Forecasted Budget and the Final Budget, the Final Budget will govern.

d. *Increases in Fees over Five Percent.*

(1) In the event that any proposed increase to Fees by FINRA for a given calendar year (which increase may arise either during the annual budgetary forecasting process or through any mid-year increase) will result in a cumulative increase in such calendar year's Fees of more than five percent (5%) above the preceding calendar year's Final Budget (a ''Major Increase''), then senior management of any Participating Organization (a) that is a Listing Market or (b) for which the Percentage of Publicly Reported Trades is then currently twenty percent (20%) or greater, shall have the right to call a meeting with the senior management of FINRA in order to discuss any disagreement over such proposed Major Increase. By way of example, if FINRA provides a Final Budget for 2011 that represents an 4% increase above the Final Budget for 2010, the terms of this paragraph 1.d.(1) shall not apply; if, however, in April of 2011, FINRA notifies the Exchange Committee of an increase in Fees that represents an additional 3% increase above the Final Budget for 2010, then the increase shall be deemed a Major Increase, and the terms of this paragraph 1.d.(1) shall become applicable (*i.e.,* 4% and 3% represents a cumulative increase of 7% above the 2010 Final Budget).

(2) In the event that senior management members of the involved parties are unable to reach an agreement regarding the proposed Major Increase, then the matter shall be referred back to the Exchange Committee for final resolution. Prior to the matter being referred back to the Exchange Committee, nothing shall prohibit the parties from conferring with the SEC. Resolution shall be reached through a vote of no fewer than all Participating Organizations seated on the Exchange Committee, and a simple majority shall be required in order to reject the proposed Major Increase.

e. *Time Tracking.* FINRA shall track the time spent by staff on insider trading responsibilities under this Agreement; however, time tracking will not be used to allocate costs.

2. *Invoicing and Payment.* FINRA shall invoice each Participating Organization for the Quarterly Fee associated with the regulatory activities performed pursuant to this Agreement during the previous three-month billing period within forty five (45) days of the end of such previous 3-month billing period. A Participating Organization shall have thirty (30) days from date of invoice to make payment to FINRA on such invoice. The invoice will reflect the Participating Organization's Percentage of Publicly Reported Trades for that billing period.

3. *Disputed Invoices; Interest.* In the event that a Participating Organization disputes an invoice or a portion of an invoice, the Participating Organization shall notify \FINRA in writing of the disputed item(s) within fifteen (15) days of receipt of the invoice. In its notification to FINRA of the disputed invoice, the Participating Organization shall identify the disputed item(s) and provide a brief explanation of why the

Participating Organization disputes the charges. FINRA may charge a Participating Organization interest on any undisputed invoice or the undisputed portions of a disputed invoice that a Participating Organization fails to pay within thirty (30) days of its receipt of such invoice. Such interest shall be assessed monthly. Interest will mean one and one half percent per month, or the maximum allowable under applicable law, whichever is less.

4. *Taxes.* In the event any governmental authority deems the regulatory activities allocated to FINRA to be taxable activities similar to the provision of services in a commercial context, the other Participating Organizations agree that they shall bear full responsibility, on a joint and several basis, for the payment of any such taxes levied on FINRA, or, if such taxes are paid by FINRA directly to the governmental authority, the other Participating Organizations agree that they shall reimburse FINRA for the amount of any such taxes paid.

5. *Audit Right; Record Keeping.*

a. *Audit Right.*

(i) Once every rolling twelve (12) month period, FINRA shall permit no more than one audit (to be performed by one or more Participating Organizations) of the Fees charged by FINRA to the Participating Organizations hereunder and a detailed cost analysis supporting such Fees (the ''Audit''). The Participating Organization or Organizations that conduct this Audit will select a nationally-recognized independent auditing firm (or may use its regular independent auditor, providing it is a nationally-recognized auditing firm) (''Auditing Firm'') to act on its, or their behalf, and will provide reasonable notice to other Participating Organizations of the Audit. FINRA will permit the Auditing Firm reasonable access during FINRA's normal business hours, with reasonable advance notice, to such financial records and supporting documentation as are necessary to permit review of the accuracy of the calculation of the Fees charged to the Participating Organizations. The Participating Organization, or Organizations, as applicable, other than FINRA, shall be responsible for the costs of performing any such audit.

(ii) If, through an Audit, the Exchange Committee determines that FINRA has inaccurately calculated the Fees for any Participating Organization, the Exchange Committee will promptly notify FINRA in writing of the amount of such difference in the Fees, and, if applicable, FINRA shall issue a reimbursement of the overage amount to the relevant Participating Organization(s), less any amount owed by the Participating Organization under any outstanding, undisputed invoice(s). If such an Audit reveals that any Participating Organization paid less than what was required pursuant to the Agreement, then that Participating Organization shall promptly pay FINRA the difference between what the Participating Organization owed pursuant to the Agreement and what that Participating Organization originally paid FINRA. If FINRA disputes the results of an Audit regarding the accuracy of the Fees, it will submit the dispute for resolution pursuant to the dispute resolution procedures in paragraph 12 of the Agreement.

(iii) In the event that through the review of any supporting documentation provided during the Audit, any one or more Participating Organizations desire to discuss with FINRA the supporting documentation and any questions arising therefrom with regard to the manner in which regulation was conducted, the Participating Organization(s) shall call a meeting with FINRA. FINRA shall in turn notify the Exchange Committee of this meeting in advance, and all Participating Organizations shall be welcome to attend (the ''Fee Analysis Meeting''). The parties to this Agreement acknowledge and agree that while FINRA commits to discuss the supporting documentation at the Fee Analysis Meeting, FINRA shall not be subject, by virtue of the above Audit rights or any discussions during the Fee Analysis Meeting or otherwise, to any limitation whatsoever, other than the Increase in Fee provisions set forth in paragraph 1.d. of this Exhibit, on its discretion as to the manner and means by which it conducts its regulatory efforts in its role as the SRO primarily liable for regulatory decisions under this Agreement. To that end, no disagreement among the Participating Organizations as to the manner or means by which FINRA conducts its regulatory efforts hereunder shall be subject to the dispute resolution procedures hereunder, and no Participating Organization shall have the right to compel FINRA to alter the manner or means by which it conducts its regulatory efforts. Further, a Participating Organization shall not have the right to compel a rebate or reassessment of fees for services rendered, on the basis that the Participating Organization would have conducted regulatory efforts in a different manner than FINRA in its professional judgment chose to conduct its regulatory efforts.

b. *Record Keeping.* In anticipation of any audit that may be performed by the Exchange Committee under paragraph 5.a. above, FINRA shall keep accurate financial records and documentation relating to the Fees charged by it under this Agreement.

Exhibit C: Reports

FINRA shall provide the following information in reports to the Exchange Committee, which information covers activity occurring under this Agreement:

1. *Alert Summary Statistics:* Total number of surveillance system alerts generated by quarter along with associated number of reviews and investigations. In addition, this paragraph shall also reflect the number of reviews and investigations originated from a source other than an alert. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

2008	Surveillance alerts	Investigations
1st Quarter		
2nd Quarter		
3rd Quarter		
4th Quarter		
2008 Total		

2. *Aging of Open Matters:* Would reflect the aging for all currently open matters for the quarterly period being reported. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

Example:

	Surveillance alerts	Investigations
0–6 months		
6–9 months		
9–12 months		
12+ months		
Total		

3. *Timeliness of Completed Matters:* Would reflect the total age of those matters that were completed or closed during the quarterly period being reported. FINRA will provide total referrals to the SEC.

Example:

	Surveillance alerts	Investigations
0–6 months		
6–9 months		
9–12 months		
12+ months		
Total		

4. *Disposition of Closed Matters:* Would reflect the disposition of those matters that were completed or closed during the quarterly period being reported. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

Example:

	Surveillance YTD	Investigations YTD
No Further Review		
Letter of Caution/Admonition Fine		
Referred to Legal/Enforcement		
Referred to SEC/SRO		
Merged		
Other		
Total		

5. *Pending Reviews.* In addition to the above reports, the Chief Regulatory Officer (CRO) (or his or her designee) of any Participating Organization that is also a Listing Market may inquire about pending reviews involving stocks listed on that Participating Organization's market. FINRA will respond to such inquiries from a CRO; provided, however, that (a) the CRO must hold any information provided by FINRA in confidence and (b) FINRA will not be compelled to provide information in contradiction of any mandate, directive or order from the SEC, US Attorney's Office, the Office of any State Attorney General or court of competent jurisdiction.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number 4–566 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number 4–566. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all

comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan that are filed with the Commission, and all written communications relating to the proposed plan between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the plan also will be available for inspection and copying at the principal offices of the Participating Organizations. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–566 and should be submitted on or before August 28, 2019.

V. Discussion

The Commission finds that the Plan, as proposed to be amended, is consistent with the factors set forth in Section 17(d) of the Act [14] and Rule 17d–2 thereunder [15] in that it is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. The Commission continues to believe that the Plan, as amended, should reduce unnecessary regulatory duplication by allocating regulatory responsibility for the surveillance, investigation, and enforcement of Common Rules to FINRA. Accordingly, the proposed amendment to the Plan promotes efficiency by consolidating these regulatory functions in a single SRO.

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. The amendment adds LTSE as a Participant to the Plan and reflects the name change of Chicago Stock Exchange, Inc. to NYSE Chicago, Inc.[16] The Commission believes that the current amendment to the Plan does not raise any new regulatory issues that the Commission has not previously considered, and therefore believes that the amended Plan should become effective without any undue delay.

VI. Conclusion

This order gives effect to the amended Plan submitted to the Commission that is contained in File No. 4–566.

It is therefore ordered, pursuant to Section 17(d) of the Act,[17] that the Plan, as amended, filed with the Commission pursuant to Rule 17d–2 on July 15, 2019, is hereby approved and declared effective.

It is further ordered that the Participating Organizations are relieved of those regulatory responsibilities allocated to FINRA under the amended Plan to the extent of such allocation.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16819 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78q(d).

[15] 17 CFR 240.17d–2.

[16] The Commission notes that the most recent prior amendment to the Plan, which, among other things, provided for the adjustment of total trades by separating out bunched or bundled trades by a Participating Organization when determining a Participant's Percentage of Publicly Reported Trades in the calculation of quarterly fees, was published for comment and the Commission did not receive any comments thereon. *See supra* note 11.

[17] 15 U.S.C. 78q(d).

[18] 17 CFR 200.30–3(a)(34).

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–10666; 34–86552; File No. 265–32]

SEC Small Business Capital Formation Advisory Committee

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting.

SUMMARY: The Securities and Exchange Commission Small Business Capital Formation Advisory Committee, established pursuant to Section 40 of the Securities Exchange Act of 1934 as added by the SEC Small Business Advocate Act of 2016, is providing notice that it will hold a public meeting. The public is invited to submit written statements to the Committee.

DATES: The meeting will be held on Tuesday, August 13, 2019, from 9:30 a.m. to 3:30 p.m. (CT) and will be open to the public. Seating will be on a first-come, first-served basis. Written statements should be received on or before August 12, 2019.

ADDRESSES: The meeting will be held at Creighton University, in The President's Fitzgerald Boardroom on the fourth floor of the Mike and Josie Harper Center, located at 602 North 20th Street, Omaha, Nebraska 68178. The meeting will be webcast on the Commission's website at *www.sec.gov.* Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's internet submission form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email message to *rule-comments@sec.gov.* Please include File Number 265–32 on the subject line; or

Paper Statements

- Send paper statements to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–32. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method. The Commission will post all statements on the SEC's website at *www.sec.gov.* Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. (ET). All statements received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Julie Z. Davis, Senior Special Counsel, Office of the Advocate for Small Business Capital Formation, at (202) 551–5407, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Persons needing special accommodations because of a disability should notify the contact person listed in the section above entitled **FOR FURTHER INFORMATION CONTACT**. The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

Dated: August 2, 2019.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2019–16901 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86539; File No. SR–ICEEU–2019–012]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Partial Amendment No. 1 to Proposed Rule Change To Revise the ICE Clear Europe Treasury and Banking Services Policy, Liquidity Management Procedures, Investment Management Procedures and Unsecured Credit Limits Procedures

August 1, 2019.

On July 5, 2019, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] proposed rule change SR–ICEEU 2019–012 to adopt a new Treasury and Banking Services Policy, new Liquidity Management Procedures, new Investment Management Procedures, and revised Unsecured Credit Limits Procedures. The proposed rule change was published for comment in the **Federal Register** on July 25, 2019.[3] On July 30, 2019, ICE Clear Europe filed Partial Amendment No. 1 to the proposed rule change.

Pursuant to Section 19(b)(1) of the Act [4] and Rule 19b–4 thereunder [5] the Commission is publishing notice of this Partial Amendment No.1 to the proposed rule change as described in Item I below. The Commission is publishing this notice to solicit comment on Partial Amendment No. 1 from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of Partial Amendments to the Proposed Rule Change

ICE Clear Europe submits this partial amendment (''Amendment No. 1'') to its previously submitted rule changes to adopt a new Treasury and Banking Services Policy, new Liquidity Management Procedures and Investment Management Procedures and revised Unsecured Credit Limits Procedures (the ''Initial Filing''). Amendment No. 1 is intended to amend a defined term in the confidential Unsecured Credit Limits Procedures in Exhibit 5. The proposed rule changes in the Initial Filing are otherwise unchanged.

II. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2019–012 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2019–012. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2019–012 and should be submitted on or before August 28, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16853 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86546; File No. SR–CboeBZX–2019–068]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the iShares California Short Maturity Muni Bond ETF of the iShares U.S. ETF Trust Under Rule 14.11(i), Managed Fund Shares

August 1, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 19, 2019, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–86413 (July 19, 2019), 84 FR 35892 (July 25, 2019) (SR–ICEEU–2019–012).

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change to list and trade shares of the iShares California Short Maturity Muni Bond ETF (the ''Fund'') of the iShares U.S. ETF Trust (the ''Trust'' or the ''Issuer'') under Rule 14.11(i) (''Managed Fund Shares''). The shares of the Fund are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange.[3] The Fund will be an actively managed fund. The Shares will be offered by the Trust, which was established as a Delaware statutory trust on June 21, 2011. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[4]

Rule 14.11(i)(4)(C)(ii)(a) requires that component fixed income securities that, in the aggregate, account for at least 75% of the fixed income weight of the portfolio must each have a minimum principal amount outstanding of $100 million or more. The Exchange submits this proposal because the Fund will not meet this requirement. The Fund will, however, meet all of the other requirements of Rule 14.11(i).[5]

Description of the Shares and the Fund

BlackRock Fund Advisors is the investment adviser (''BFA'' or ''Adviser'') to the Fund.[6] State Street Bank and Trust Company is the administrator, custodian, and transfer agent (''Administrator,'' ''Custodian,'' and ''Transfer Agent,'' respectively) for the Trust. BlackRock Investments, LLC serves as the distributor (''Distributor'') for the Trust.

Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[7] In addition, Rule 14.11(i)(7) further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. Rule 14.11(i)(7) is similar to Rule 14.11(b)(5)(A)(i), however, Rule 14.11(i)(7) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not a registered broker-dealer, but is affiliated with multiple broker-dealers and has implemented ''fire walls'' with respect to such broker-dealers regarding access to information concerning the composition and/or changes to the Fund's portfolio. In addition, Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with another broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

iShares California Short Maturity Muni Bond ETF

According to the Registration Statement, the Fund will seek to maximize tax-free current income from a portfolio composed of short maturity, investment-grade municipal bonds issued in the State of California. To achieve its objective, the Fund will invest, under Normal Market Conditions,[8] at least 80% of its net

[3] The Commission approved Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[4] *See* Registration Statement on Form N–1A for the Trust, filed on April 11, 2019 (File Nos. 333–179904 and 811–22649). The description of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') (the ''Exemptive Order''). *See* Investment Company Act Release No. 29571 (January 24, 2011) (File No. 812–13601).

[5] The Exchange notes that the Commission has approved several proposals related to the listing and trading of index-based municipal bond funds focused solely on issuers from California as well as several other single-state index-based municipal bond funds. *See, e.g.,* Securities Exchange Act Release Nos. 72464 (June 25, 2014), 79 FR 37373 (July 1, 2014) (SR–NYSEArca–2014–45) (order approving proposed rule change governing the continued listing and trading of shares of the PowerShares Insured California Municipal Bond Portfolio, PowerShares Insured National Municipal Bond Portfolio, and PowerShares Insured New York Municipal Bond Portfolio); and 82295 (December 12, 2017), 82 FR 60056 (December 18, 2017) (SR–NYSEArca–2017–56) (order approving proposed rule change to list and trade shares of twelve series of investment company units, including the iShares California Muni Bond ETF and the iShares New York Muni Bond ETF).

[6] BFA is an indirect wholly owned subsidiary of BlackRock, Inc.

[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[8] The term ''Normal Market Conditions'' includes, but is not limited to, the absence of trading halts in the applicable financial markets generally;

assets in Municipal Securities, as defined below, issued in the State of California by or on behalf of California state or local governments or agencies, whose interest payments are exempt from U.S. federal, including the federal alternative minimum tax, and California state income taxes. The Fund will be classified as a ''non-diversified'' investment company under the 1940 Act.[9]

The Fund intends to qualify each year as a regulated investment company (a ''RIC'') under Subchapter M of the Internal Revenue Code of 1986, as amended. The Fund will invest its assets, and otherwise conduct its operations, in a manner that is intended to satisfy the qualifying income, diversification and distribution requirements necessary to establish and maintain RIC qualification under Subchapter M.

Principal Holdings—Municipal Securities

To achieve its objective, the Fund will invest, under Normal Market Conditions, in U.S.-dollar denominated investment-grade short-term fixed- and floating-rate Municipal Securities, as defined below, with remaining maturities of five years or less. Investment-grade securities are rated BBB- or higher by S&P Global Ratings and/or Fitch Ratings, Inc., or Baa3 or higher by Moody's Investors Service, Inc., or if unrated, determined by the Adviser to be of equivalent quality.[10] Under Normal Market Conditions, the Fund will seek to maintain a weighted average maturity that is less than three years.[11]

Municipal securities (''Municipal Securities'') are fixed and variable rate securities issued in the U.S. by U.S. states and territories, municipalities and other political subdivisions, agencies, authorities, and instrumentalities of states and multi-state agencies and authorities and will include only the following instruments: General obligation bonds,[12] limited obligation bonds (or revenue bonds),[13] municipal notes,[14] municipal commercial paper,[15] tender option bonds,[16] variable rate demand notes and demand obligations (''VRDOs''),[17] municipal lease obligations,[18] stripped securities,[19] structured securities,[20] zero coupon securities,[21] and exchange traded and non-exchange traded investment companies (including investment companies advised by BFA or its affiliates) that invest in such Municipal Securities.[22]

In the absence of Normal Market Conditions, the Fund may temporarily depart from its normal investment process, provided that such departure is, in the opinion of the Adviser, consistent with the Fund's investment objective and in the best interest of the Fund. For example, the Fund may hold a higher than normal proportion of its assets in cash in response to adverse market, economic or political conditions.

The Fund intends to qualify each year as a regulated investment company (a ''RIC'') under Subchapter M of the Internal Revenue Code of 1986, as amended.[23] The Fund will invest its assets, and otherwise conduct its operations, in a manner that is intended to satisfy the qualifying income, diversification and distribution requirements necessary to establish and maintain RIC qualification under Subchapter M.

Other Portfolio Holdings

The Fund may also, to a limited extent (under Normal Market Conditions, less than 20% of the Fund's net assets), invest in certain futures, options and swap contracts,[24] cash and cash equivalents, including shares of money market funds advised by BFA or its affiliates, as well as in Municipal Securities of issuers located outside of California whose interest payments are exempt from regular federal income taxes.[25] The Fund's investments will be consistent with its investment objective and will not be used to achieve leveraged returns (*i.e.* two times or three

operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[9] The diversification standard is set forth in Section 5(b)(1) of the 1940 Act.

[10] According to the Adviser, BFA may determine that unrated securities are of ''equivalent quality'' based on such credit quality factors that it deems appropriate, which may include among other things, performing an analysis similar, to the extent possible, to that performed by a nationally recognized statistical ratings organization when rating similar securities and issuers. In making such a determination, BFA may consider internal analyses and risk ratings, third party research and analysis, and other sources of information, as deemed appropriate by the Adviser.

[11] Weighted average maturity is a U.S. dollar-weighted average of the remaining term to maturity of the underlying securities in the Fund's portfolio. For the purposes of determining the Fund's weighted average maturity, a security's final maturity date will be used for calculation purposes.

[12] General obligation bonds are obligations involving the credit of an issuer possessing taxing power and are payable from such issuer's general revenues and not from any particular source.

[13] Limited obligation bonds are payable only from the revenues derived from a particular facility or class of facilities or, in some cases, from the proceeds of a special excise or other specific revenue source, and also include industrial development bonds issued pursuant to former U.S. federal tax law. Industrial development bonds generally are also revenue bonds and thus are not payable from the issuer's general revenues. The credit and quality of industrial development bonds are usually related to the credit of the corporate user of the facilities. Payment of interest on and repayment of principal of such bonds is the responsibility of the corporate user (and/or any guarantor).

[14] Municipal notes are shorter-term municipal debt obligations that may provide interim financing in anticipation of tax collection, receipt of grants, bond sales, or revenue receipts.

[15] Municipal commercial paper is generally unsecured debt that is issued to meet short-term financing needs.

[16] Tender option bonds are synthetic floating-rate or variable-rate securities issued when long-term bonds are purchased in the primary or secondary market and then deposited into a trust. Custodial receipts are then issued to investors, such as the Fund, evidencing ownership interests in the trust.

[17] VRDOs are tax-exempt obligations that contain a floating or variable interest rate adjustment formula and a right of demand on the part of the holder thereof to receive payment of the unpaid principal balance plus accrued interest upon a short notice period not to exceed seven days.

[18] Municipal lease obligations include certificates of participation issued by government authorities or entities to finance the acquisition or construction of equipment, land, and/or facilities.

[19] Stripped securities are created when an issuer separates the interest and principal components of an instrument and sells them as separate securities. In general, one security is entitled to receive the interest payments on the underlying assets and the other to receive the principal payments.

[20] Structured securities are privately negotiated debt obligations where the principal and/or interest is determined by reference to the performance of an underlying investment, index, or reference obligation, and may be issued by governmental agencies. While structured securities are part of the principal holdings of the Fund, the Issuer represents that such securities, when combined with those instruments held as part of the other portfolio holdings described below, will not exceed 20% of the Fund's net assets.

[21] Zero coupon securities are securities that are sold at a discount to par value and do not pay interest during the life of the security. The discount approximates the total amount of interest the security will accrue and compound over the period until maturity at a rate of interest reflecting the market rate of the security at the time of issuance. Upon maturity, the holder of a zero coupon security is entitled to receive the par value of the security.

[22] The Fund currently anticipates investing in only registered open-end investment companies, including mutual funds and the open-end investment company funds described in Rule 14.11. The Fund may invest in the securities of other investment companies to the extent permitted by law.

[23] 26 U.S.C. 851.

[24] Such futures, options and swap contracts will include only the following: Interest rate futures, interest rate options, and interest rate swaps. The derivatives will be centrally cleared and they will be collateralized. At least 90% of the Fund's net assets that are invested in listed derivatives will be invested in instruments that trade in markets that are members or affiliates of members of the Intermarket Surveillance Group (''ISG'') or are parties to a comprehensive surveillance sharing with the Exchange.

[25] Issuers located outside of California may be states, territories and possessions of the U.S., including the District of Columbia, and their political subdivisions, agencies and instrumentalities.

times the Fund's benchmark, as described in the Registration Statement).

The Fund may also enter into repurchase and reverse repurchase agreements for Municipal Securities (collectively, ''Repurchase Agreements''). Repurchase Agreements involve the sale of securities with an agreement to repurchase the securities at an agreed-upon price, date and interest payment and have the characteristics of borrowing as part of the Fund's principal holdings.[26]

The Fund may also invest in short-term instruments (''Short-Term Instruments''),[27] which includes exchange traded and non-exchange traded investment companies (including investment companies advised by BFA or its affiliates) that invest in money market instruments.

Investment Restrictions

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), as deemed illiquid by the Adviser[28] under the 1940 Act.[29] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets are defined by Rule 22e–4.

The Fund will launch with at least 500,000 Shares outstanding. The portfolio will hold a minimum of 15 different Municipal Securities from at least 15 unique issuers. No single obligor will account for more than 10% of the weight of the Fund's portfolio and no 10 obligors will account for more than 75% of the weight of the Fund's portfolio. The Exchange notes that the California AMT-Free municipal bond market value is estimated to be ~$151 billion and is the second largest as measured by state. As of June 5, 2019, California represented 21.02% of all issuances in the U.S.[30] Additionally, as a registered investment company, no more than 50% of the Fund's assets will be invested in issuers that are more than 5% of the value of the Fund's assets. In addition, the Fund will not invest more than 25% of its assets in any single issuer. As noted above, the Fund will satisfy all of the generic listing requirements for Managed Fund Shares that hold fixed income securities, except for the minimum principal amount outstanding requirement in 14.11(i)(4)(C)(ii)(a).

Availability of Information

The Fund's website, which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The website will include additional quantitative information updated on a daily basis, including: (1) The prior business day's reported NAV, daily trading volume, and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Daily trading volume information for the Shares will also be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson Reuters, and International Data Corporation, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public websites. On each business day, the Fund will disclose on its website the identities and quantities of the portfolio of securities and other assets in the daily disclosed portfolio held by the Fund that formed the basis for the Fund's calculation of NAV at the end of the previous business day. The daily disclosed portfolio will include, as applicable: The ticker symbol; CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security, index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund's portfolio. The website and information will be publicly available at no charge.

In addition, an estimated value, defined in BZX Rule (i)(4)(B)(i) as the intraday indicative value (the ''IIV'') that reflects an estimated intraday value

[26] The Fund's exposure to reverse repurchase agreements will be covered by liquid assets having a value equal to or greater than such commitments. The use of reverse repurchase agreements is a form of leverage because the proceeds derived from reverse repurchase agreements may be invested in additional securities. As further stated below, the Fund's investments will be consistent with its investment objective and will not be used to achieve leveraged returns.

[27] The Fund may invest in Short-Term Instruments, including money market instruments, on an ongoing basis to provide liquidity or for other reasons. Money market instruments are generally short-term investments that include only the following: (i) Shares of money market funds (including those advised by BFA or otherwise affiliated with BFA); (ii) obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities (including government-sponsored enterprises); (iii) negotiable certificates of deposit (''CDs''), bankers' acceptances, fixed-time deposits and other obligations of U.S. and non-U.S. banks (including non-U.S. branches) and similar institutions; (iv) commercial paper, including asset-backed commercial paper; (v) non-convertible corporate debt securities (*e.g.,* bonds and debentures) with remaining maturities at the date of purchase of not more than 397 days and that satisfy the rating requirements set forth in Rule 2a–7 under the 1940 Act; and (vi) short-term U.S. dollar-denominated obligations of non-U.S. banks (including U.S. branches) that, in the opinion of BFA, are of comparable quality to obligations of U.S. banks which may be purchased by the Fund. All money market securities acquired by the Fund will be rated investment grade. The Fund does not intend to invest in any unrated money market securities. However, it may do so, to a limited extent, such as where a rated money market security becomes unrated, if such money market security is determined by the Adviser to be of comparable quality. BFA may determine that unrated securities are of comparable quality based on such credit quality factors that it deems appropriate, which may include, among other things, performing an analysis similar, to the extent possible, to that performed by a nationally recognized statistical rating organization rating similar securities and issuers.

[28] In reaching liquidity decisions, the Adviser may consider factors including: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; the nature of the security and the nature of the marketplace trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer); any legal or contractual restrictions on the ability to transfer the security or asset; significant developments involving the issuer or counterparty specifically (*e.g.,* default, bankruptcy, etc.) or the securities markets generally; and settlement practices, registration procedures, limitations on currency conversion or repatriation, and transfer limitations (for foreign securities or other assets).

[29] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[30] Statistics are based on the universe included in the S&P National AMT-Free Muni Bond Index. New York ($160b) is the largest municipal bond market by state, registering 22.07% of all issuances in the U.S.

of the Fund's portfolio, will be disseminated. Moreover, the IIV will be based upon the current value for the components of the daily disclosed portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Trading Hours.[31] In addition, the quotations of certain of the Fund's holdings may not be updated during U.S. trading hours if updated prices cannot be ascertained.

The dissemination of the IIV, together with the daily disclosed portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and provide a close estimate of that value throughout the trading day.

Quotation and last sale information for the Shares will be available via the CTA high speed line. Price information regarding Municipal Securities and other non-exchange traded assets including certain derivatives, money market funds and other instruments, and repurchase agreements is available from third party pricing services and major market data vendors. Price information regarding Municipal Securities can also be obtained from the Municipal Securities Rulemaking Board's Electronic Municipal Market Access (''EMMA'') system. For exchange-traded assets, including futures, and certain options, such intraday information is available directly from the applicable listing exchange. In addition, price information for U.S. exchange-traded options will be available from the Options Price Reporting Authority.

Initial and Continued Listing

The Shares will be subject to Rule 14.11(i), which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[32] A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

The Trust is required to comply with Rule 10A–3 under the Act for the initial and continued listing of the Shares of the Fund. In addition, the Exchange represents that the Shares of the Fund will continue to comply with all other requirements applicable to Managed Fund Shares, which include the dissemination of key information such as the Disclosed Portfolio,[33] Net Asset Value,[34] and the Intraday Indicative Value,[35] suspension of trading or removal,[36] trading halts,[37] surveillance,[38] minimum price variation for quoting and order entry,[39] the information circular,[40] and firewalls [41] as set forth in Exchange rules applicable to Managed Fund Shares and the orders approving such rules. All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of reference asset and intraday indicative values (as applicable), or the applicability of Exchange listing rules specified in this filing shall constitute continued listing requirements for the Shares. The Fund has represented to the Exchange that it will advise the Exchange of any failure by the Fund or Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. The Financial Industry Regulatory Authority (''FINRA'') conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures with respect to the Fund under Exchange Rule 14.12.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. The Exchange will halt trading in the Shares under the conditions specified in Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which trading in the Shares of the Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange will allow trading in the Shares from 8:00 a.m. until 5:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in Rule 11.11(a), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price variation for order entry is $0.0001.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by FINRA on behalf of the Exchange, or by regulatory staff of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets

[31] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available IIVs published via the CTA or other data feeds.

[32] *See* 17 CFR 240.10A–3.

[33] *See* Rule 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[34] *See* Rule 14.11(i)(4)(A)(ii).

[35] *See* Rule 14.11(i)(4)(B)(i).

[36] *See* Rule 14.11(i)(4)(B)(iii).

[37] *See* Rule 14.11(i)(4)(B)(iv).

[38] *See* Rule 14.11(i)(2)(C).

[39] *See* Rule 14.11(i)(2)(B).

[40] *See* Rule 14.11(i)(6).

[41] *See* Rule 14.11(i)(7).

and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). FINRA also can access data obtained from the Municipal Securities Rulemaking Board's EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [42] in general and Section 6(b)(5) of the Act [43] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 14.11(i). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. The Adviser is not a registered broker-dealer, but is affiliated with multiple broker-dealers and has implemented ''fire walls'' with respect to such broker-dealers regarding access to information concerning the composition and/or changes to a Fund's portfolio. In addition, Adviser personnel who make decisions regarding a Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. The Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange traded equity securities via the ISG, from other exchanges that are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, the Exchange, or FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income instruments reported to TRACE and Municipal Securities reported to MSRB. FINRA also can access data obtained from the MSRB relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. The Fund will launch with at least 500,000 Shares outstanding. The portfolio will hold a minimum of 15 different Municipal Securities from at least 15 unique issuers. No single obligor will account for more than 10% of the weight of the Fund's portfolio and no 10 obligors will account for more than 75% of the weight of the Fund's portfolio. The Exchange notes that the California AMT-Free municipal bond market value is estimated to be ~$151 billion and is the second largest as measured by state. As of June 5, 2019, California represented 21.02% of all issuances in the U.S.[44] Additionally, as a registered investment company, no more than 50% of the Fund's assets will be invested in issuers that are more than 5% of the value of the Fund's assets. In addition, the Fund will not invest more than 25% of its assets in any single issuer.

Further, the Exchange represents that: (1) Except for Rule 14.11(i)(4)(C)(ii)(a), the Fund will satisfy all of the generic listing standards under Rule 14.11(i)(4); (2) the continued listing standards under Rule 14.11(i), as applicable to Managed Fund Shares that hold fixed income securities, will apply to the Shares of the Fund; and (3) the issuer of the Fund is required to comply with Rule 10A–3 [45] under the Act for the initial and continued listing of the Shares. In addition, the Exchange represents that the Fund will meet and be subject to all other requirements of the Generic Listing Rules and other applicable continued listing requirements for Managed Fund Shares under Exchange Rule 14.11(i), including those requirements regarding the Disclosed Portfolio (as defined in the Exchange rules) and the requirement that the Disclosed Portfolio and the net asset value (''NAV'') will be made available to all market participants at the same time,[46] intraday indicative value,[47] suspension of trading or removal,[48] trading halts,[49] disclosure,[50] and firewalls.[51] Further, at least 100,000 Shares will be outstanding upon the commencement of trading of the Fund.[52]

The Fund will invest, under Normal Market Conditions, at least 80% of its net assets in Municipal Securities, as defined below, issued in the State of California by or on behalf of California state or local governments or agencies, whose interest payments are exempt from U.S. federal, including the federal alternative minimum tax, and California state income taxes. Additionally, the Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), as deemed illiquid by the Adviser under the 1940 Act. The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets are defined by Rule 22e–4.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value will be disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours.

[42] 15 U.S.C. 78f.

[43] 15 U.S.C. 78f(b)(5).

[44] Statistics are based on the universe included in the S&P National AMT-Free Muni Bond Index. New York ($160b) is the largest municipal bond market by state, registering 22.07% of all issuances in the U.S.

[45] 17 CFR 240.10A–3.

[46] *See* Exchange Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[47] *See* Exchange Rule 14.11(i)(4)(B)(i).

[48] *See* Exchange Rule 14.11(i)(4)(B)(iii).

[49] *See* Exchange Rule 14.11(i)(4)(B)(iv).

[50] *See* Exchange Rule 14.11(i)(6).

[51] *See* Exchange Rule 14.11(i)(7).

[52] *See* Exchange Rule 14.11(i)(4)(A)(i).

On each business day, before commencement of trading in Shares during Regular Trading Hours, the Fund will disclose on its website the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Pricing information will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's NAV and the market closing price or mid-point of the Bid/Ask Price,[53] and a calculation of the premium or discount of the market closing price or Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily market closing price or Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Additionally, information regarding market price and trading of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available on the facilities of the CTA. The website for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of a Fund will be halted under the conditions specified in Rule 11.18. Trading may also be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Finally, trading in the Shares will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

Intraday, executable price quotations on assets held by the Fund are available from major broker-dealer firms and for exchange-traded assets, including investment companies, such intraday information is available directly from the applicable listing exchange. All such intraday price information is available through subscription services, such as Bloomberg, Thomson Reuters and International Data Corporation, which can be accessed by authorized participants and other investors.

[53] The Bid/Ask Price of a Fund will be determined using the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund or its service providers.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG, from other exchanges that are members of ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, the Exchange, or FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income instruments reported to TRACE and Municipal Securities reported to MSRB. FINRA also can access data obtained from the MSRB relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. As noted above, investors will also have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comment

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2019–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2019–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All

submissions should refer to File Number SR–CboeBZX–2019–068 and should be submitted on or before August 28, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[54]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16855 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86550; File No. SR–NYSE–2019–41]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Price List Related to Co-location Services

August 1, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 18, 2019, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Price List related to co-location services to amend the Partial Cabinet Solution bundles. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Price List related to co-location[4] services offered by the Exchange to amend two of the Partial Cabinet Solution (''PCS'') bundles that the Exchange offers Users.[5] The proposed change would have the effect of lowering the latency in the Liquidity Center Network (''LCN'') connection included in two of the PCS bundles. This is not a fee filing: There is no proposed change to the fee for the PCS bundles.

The Exchange plans to implement the change during the fourth quarter of 2019. It will announce the implementation date through a customer notice.

Proposed Change to the Option C and Option D PCS Bundles

There are four PCS bundles, Options A through D. Each PCS bundle option includes a partial cabinet; access to the LCN and internet protocol (''IP'') network, the local area networks available in the data center; two fiber cross connections; and connectivity to one of two time feeds.[6] The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[7]

Currently, the Options C and D PCS bundles include 10 Gigabit (''Gb'') LCN connections. The Exchange proposes to change each 10 Gb LCN connection to a lower-latency 10 Gb LCN connection, referred to as the ''LCN 10 Gb LX.''[8] As a result of this change, Users will benefit from a lower latency LCN connection in the Options C and D PCS bundles at the same cost.

The sole change to the Price List would be to add ''LX'' to the reference to the 10 Gb LCN connection in the description of Option C and Option D in the Price List. The revised text would read as follows (proposed additions underlined):

- *For Option C:* 1 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.
- *For Option D:* 2 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.

Application and Impact of the Proposed Change

The proposed change would apply to all Option C and Option D PCS bundles, including those that Users currently have.[9] Those current Users would benefit immediately from the lower latency connection. The Exchange believes that would be the only consequence for them, as (a) the current Users would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the prices they pay for their Option C and Option D PCS bundles.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. All Users that order an Option C or D

[54] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE National, Inc. (''NYSE National'' and together with NYSE American, NYSE Arca, and NYSE Chicago, Inc., the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59).

[6] *See* Securities Exchange Act Release No. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53).

[7] *Id.,* at 7396.

[8] *See* Securities Exchange Act Release No. 70888 (November 15, 2013), 78 FR 69907 (November 21, 2013) (SR–NYSE–2013–73) (notice of filing and immediate effectiveness of proposed rule change to offer LCN 10 Gb LX connection).

[9] The Exchange does not propose to make a change to the Option A or B PCS bundles. The Option A and B PCS bundles include 1 Gb LCN connections, and the Exchange does not offer a 1 Gb LCN connection with a lower latency than that in the current bundles.

bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List is applied uniformly to all Users.

Competitive Environment

A User may host another entity in its space within the data center. Such Users are called ''Hosting Users,'' and their customers are ''Hosted Customers.'' [10]

Based on conversations with Users and potential customers, the Exchange believes that Hosting Users offer bundles (''Hosting User Bundles'') that include cabinet space and space on shared LCN and IP network connections—and that the Hosting User Bundles provide their end users with a service similar to that of the PCS bundles, but with a lower cost and latency.[11]

The proposed change is intended to create a more level playing field between the Exchange and the Hosting Users, who compete for Hosted Customer business. Based on the above conversations, the Exchange understands that, given the choice, customers may choose a Hosting User Bundle over a PCS bundle, with the latency of the 10 Gb LCN connection being a major factor in the choice. The Exchange believes that, by reducing the latency of the LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. Importantly, the change would provide potential Users with a wider range of attractive choices, which would be a benefit to the competitive environment, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[12]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [14] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[15]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[18] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Not Unfairly Discriminatory

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that in the future order or currently use an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit

[10] A Hosting User is required to be a User, but because only Users can be Hosting Users, a Hosted Customer is not able to provide hosting services to any other entities in the space in which it is hosted. The Exchange allows Users to act as Hosting Users for a monthly fee. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40).

[11] Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public or disclose it to the Exchange. The Exchange therefore does not have direct visibility into the specific range of options, or cost thereof, offered by Hosting Users, and relies on third parties for information.

[12] *See supra* note 7.

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies, as compared to Users that are not co-located, in sending orders to, and receiving market data from, the Exchange.

[15] *See* 78 FR 51765, *supra* note 5, at 51766. NYSE American, NYSE Arca and NYSE National have submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEAmer–2019–28, SR–NYSEArca–2019–54, and SR–NYSENAT–2019–17.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(4).

of a lower latency LCN connection immediately. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

As a result of the proposed change, the latency of the LCN connection in the Option C and D bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The changes would continue to make it more cost effective for Users to utilize co-location by offering a cost effective, convenient way to create a colocation environment, through the choice among PCS bundles with different cabinet footprints and network connections options. The Exchange expects that such Users would include those with minimal power or cabinet space demands and Users for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.

The Proposed Change is Reasonable and Equitable

The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who may otherwise opt to become Hosted Customers, and thus enhance the competitive environment for potential Users (who would then have more options from which to select).

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[19]

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users and potential Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency connection immediately. The Exchange believes that would be the only effect of this change for current Users as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

[19] *See supra* note 7.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[20] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because, in addition to the proposed services being completely voluntary, they are available to all Users on an equal basis: All Users that order an Option C or Option D bundle would receive an LCN 10 Gb LX connection as part of that bundle. The Exchange believes that the proposed changes are reasonable and designed to be fair and equitable, and therefore, will not unduly burden any particular group of Users. Under the proposed change the Exchange will continue to offer cost effective options for Users to create a colocation environment through the PCS bundles.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate. The purpose of this filing is not to change any fees, but rather to make a change to the contents of the Option C and D PCS bundles that would give current and future Users of those bundles more efficient connections for the same costs. As a result of the proposed change, the latency of the LCN connection in the Option C and D PCS bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The proposed change would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that have an Option C or D PCS bundle—including those that already have one—would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could

[20] 15 U.S.C. 78f(b)(8).

still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both.

The current Users would receive the benefit of a lower latency connection at the same cost. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

Intermarket Competition

The Exchange does not believe that the proposed fee would impose any burden on intermarket competition that is not necessary or appropriate. The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. At the same time, however, no potential User would be obligated to purchase a PCS bundle, and it would still have the options offered by Hosting Users.

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[21]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22]

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[25]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [26] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2019–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2019–41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2019–41 and should be submitted on or beforeAugust 28, 2019.

[21] *See supra* note 7.

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16859 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86549; File No. SR–NYSENAT–2019–17]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Price List Related to Co-location Services

August 1, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 18, 2019, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Price List related to co-location services to amend the Partial Cabinet Solution bundles. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Price List related to co-location [4] services offered by the Exchange to amend two of the Partial Cabinet Solution (''PCS'') bundles that the Exchange offers Users.[5] The proposed change would have the effect of lowering the latency in the Liquidity Center Network (''LCN'') connection included in two of the PCS bundles. This is not a fee filing: there is no proposed change to the fee for the PCS bundles.

The Exchange plans to implement the change during the fourth quarter of 2019. It will announce the implementation date through a customer notice.

Proposed Change to the Option C and Option D PCS Bundles

There are four PCS bundles, Options A through D. Each PCS bundle option includes a partial cabinet; access to the LCN and internet protocol (''IP'') network, the local area networks available in the data center; two fiber cross connections; and connectivity to one of two time feeds.[6] The PCS bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[7]

Currently, the Options C and D PCS bundles include 10 Gigabit (''Gb'') LCN connections. The Exchange proposes to change each 10 Gb LCN connection to a lower-latency 10 Gb LCN connection, referred to as the ''LCN 10 Gb LX.'' [8] As a result of this change, Users will benefit from a lower latency LCN connection in the Options C and D PCS bundles at the same cost.

The sole change to the Price List would be to add ''LX'' to the reference to the 10 Gb LCN connection in the description of Option C and Option D in the Price List. The revised text would read as follows (proposed additions underlined):

- *For Option C:* 1 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.
- *For Option D:* 2 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.

Application and Impact of the Proposed Change

The proposed change would apply to all Option C and Option D PCS bundles, including those that Users currently have.[9] Those current Users would benefit immediately from the lower latency connection. The Exchange believes that would be the only consequence for them, as (a) the current Users would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the prices they pay for their Option C and Option D PCS bundles.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and

[27] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in May 2018. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See id.* at note 9. As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates the New York Stock Exchange (''NYSE''), NYSE American LLC (''NYSE American''), and NYSE Arca, Inc. (''NYSE Arca'' and together with NYSE, NYSE American, and NYSE Chicago, Inc., the ''Affiliate SROs''). *See id.* at note 11.

[6] *See id.* at 26317.

[7] See *id.* and Securities Exchange Act Release No. 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53).

[8] *See* 83 FR 26314, *supra* note 4, at 26317.

[9] The Exchange does not propose to make a change to the Option A or B PCS bundles. The Option A and B PCS bundles include 1 Gb LCN connections, and the Exchange does not offer a 1 Gb LCN connection with a lower latency than that in the current bundles.

the Price List is applied uniformly to all Users.

Competitive Environment

A User may host another entity in its space within the data center. Such Users are called ''Hosting Users,'' and their customers are ''Hosted Customers.'' [10]

Based on conversations with Users and potential customers, the Exchange believes that Hosting Users offer bundles (''Hosting User Bundles'') that include cabinet space and space on shared LCN and IP network connections—and that the Hosting User Bundles provide their end users with a service similar to that of the PCS bundles, but with a lower cost and latency.[11]

The proposed change is intended to create a more level playing field between the Exchange and the Hosting Users, who compete for Hosted Customer business. Based on the above conversations, the Exchange understands that, given the choice, customers may choose a Hosting User Bundle over a PCS bundle, with the latency of the 10 Gb LCN connection being a major factor in the choice. The Exchange believes that, by reducing the latency of the LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. Importantly, the change would provide potential Users with a wider range of attractive choices, which would be a benefit to the competitive environment, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[12]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis;[14] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[15]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[18] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Not Unfairly Discriminatory

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that in the future order or currently use an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency LCN connection immediately. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

As a result of the proposed change, the latency of the LCN connection in the Option C and D bundles would be

[10] A Hosting User is required to be a User, but because only Users can be Hosting Users, a Hosted Customer is not able to provide hosting services to any other entities in the space in which it is hosted. The Exchange allows Users to act as Hosting Users for a monthly fee. *See* 83 FR 26314, *supra* note 4.

[11] Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public or disclose it to the Exchange. The Exchange therefore does not have direct visibility into the specific range of options, or cost thereof, offered by Hosting Users, and relies on third parties for information.

[12] *See supra* note 7.

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies, as compared to Users that are not co-located, in sending orders to, and receiving market data from, the Exchange.

[15] *See* 83 FR 26314, *supra* note 4, at 26314. The NYSE, NYSE American, and NYSE Arca have submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2019–41, SR–NYSEAmer–2019–28, and SR–NYSEArca–2019–54.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(4).

reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The changes would continue to make it more cost effective for Users to utilize co-location by offering a cost effective, convenient way to create a colocation environment, through the choice among PCS bundles with different cabinet footprints and network connections options. The Exchange expects that such Users would include those with minimal power or cabinet space demands and Users for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.

The Proposed Change Is Reasonable and Equitable

The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who may otherwise opt to become Hosted Customers, and thus enhance the competitive environment for potential Users (who would then have more options from which to select).

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[19]

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users and potential Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency connection immediately. The Exchange believes that would be the only effect of this change for current Users as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[20] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because, in addition to the proposed services being completely voluntary, they are available to all Users on an equal basis: All Users that order an Option C or Option D bundle would receive an LCN 10 Gb LX connection as part of that bundle. The Exchange believes that the proposed changes are reasonable and designed to be fair and equitable, and therefore, will not unduly burden any particular group of Users. Under the proposed change the Exchange will continue to offer cost effective options for Users to create a colocation environment through the PCS bundles.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate. The purpose of this filing is not to change any fees, but rather to make a change to the contents of the Option C and D PCS bundles that would give current and future Users of those bundles more efficient connections for the same costs. As a result of the proposed change, the latency of the LCN connection in the Option C and D PCS bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The proposed change would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that have an Option C or D PCS bundle—including those that already have one—would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both.

The current Users would receive the benefit of a lower latency connection at the same cost. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

[19] *See supra* note 7.

[20] 15 U.S.C. 78f(b)(8).

Intermarket Competition

The Exchange does not believe that the proposed fee would impose any burden on intermarket competition that is not necessary or appropriate. The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. At the same time, however, no potential User would be obligated to purchase a PCS bundle, and it would still have the options offered by Hosting Users.

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[21]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22]

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[25]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [26] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2019–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2019–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2019–17 and should be submitted on or before August 28, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16858 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

[21] *See supra* note 7.

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 15 U.S.C. 78s(b)(2)(B).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86545; File No. SR–NASDAQ–2019–049]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change To Amend the Definition of Family Member in Listing Rule 5605(a)(2) for Purposes of the Definition of Independent Director

August 1, 2019.

On May 29, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposal to modify the definition of a ''Family Member'', for purposes of the independence of directors, under Nasdaq Rule 5605(a)(2). The proposed rule change was published for comment in the **Federal Register** on June 18, 2019.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is August 2, 2019.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates September 16, 2019 as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2019–049).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16854 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86095 (June 12, 2019), 84 FR 28379.

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86548; File No. SR–NYSEAMER–2019–28]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its NYSE American Equities Price List and the NYSE American Options Fee Schedule Related to Co-location Services

August 1, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b-4 thereunder,[3] notice is hereby given that on July 18, 2019, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its NYSE American Equities Price List (''Price List'') and the NYSE American Options Fee Schedule (''Fee Schedule'') related to co-location services to amend the Partial Cabinet Solution bundles. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Price List and Fee Schedule related to co-location [4] services offered by the Exchange to amend two of the Partial Cabinet Solution (''PCS'') bundles that the Exchange offers Users.[5] The proposed change would have the effect of lowering the latency in the Liquidity Center Network (''LCN'') connection included in two of the PCS bundles. This is not a fee filing: there is no proposed change to the fee for the PCS bundles.

The Exchange plans to implement the change during the fourth quarter of 2019. It will announce the implementation date through a customer notice.

Proposed Change to the Option C and Option D PCS Bundles

There are four PCS bundles, Options A through D. Each PCS bundle option includes a partial cabinet; access to the LCN and internet protocol (''IP'') network, the local area networks available in the data center; two fiber cross connections; and connectivity to one of two time feeds.[6] The PCS

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex-2010–80). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Price List and Fee Schedule, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE''), NYSE Arca, Inc. (''NYSE Arca'') and NYSE National, Inc. (''NYSE National'' and together with NYSE, NYSE Arca, and NYSE Chicago, Inc., the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67).

[6] *See* Securities Exchange Act Release No. 77071 (February 5, 2016), 81 FR 7382 (February 11, 2016) (SR–NYSEMKT–2015–89).

bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[7]

Currently, the Options C and D PCS bundles include 10 Gigabit (''Gb'') LCN connections. The Exchange proposes to change each 10 Gb LCN connection to a lower-latency 10 Gb LCN connection, referred to as the ''LCN 10 Gb LX.'' [8] As a result of this change, Users will benefit from a lower latency LCN connection in the Options C and D PCS bundles at the same cost.

The sole change to the Price List and Fee Schedule would be to add ''LX'' to the reference to the 10 Gb LCN connection in the description of Option C and Option D in the Price List and Fee Schedule. The revised text would read as follows (proposed additions underlined):

- *For Option C:* 1 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.
- *For Option D:* 2 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.

Application and Impact of the Proposed Change

The proposed change would apply to all Option C and Option D PCS bundles, including those that Users currently have.[9] Those current Users would benefit immediately from the lower latency connection. The Exchange believes that would be the only consequence for them, as (a) the current Users would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the prices they pay for their Option C and Option D PCS bundles.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Price List and Fee Schedule are applied uniformly to all Users.

Competitive Environment

A User may host another entity in its space within the data center. Such Users are called ''Hosting Users,'' and their customers are ''Hosted Customers.'' [10]

Based on conversations with Users and potential customers, the Exchange believes that Hosting Users offer bundles (''Hosting User Bundles'') that include cabinet space and space on shared LCN and IP network connections—and that the Hosting User Bundles provide their end users with a service similar to that of the PCS bundles, but with a lower cost and latency.[11]

The proposed change is intended to create a more level playing field between the Exchange and the Hosting Users, who compete for Hosted Customer business. Based on the above conversations, the Exchange understands that, given the choice, customers may choose a Hosting User Bundle over a PCS bundle, with the latency of the 10 Gb LCN connection being a major factor in the choice. The Exchange believes that, by reducing the latency of the LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. Importantly, the change would provide potential Users with a wider range of attractive choices, which would be a benefit to the competitive environment, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[12]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis;[14] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[15]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or

[7] *Id.,* at 7384.

[8] *See* Securities Exchange Act Release No. 70886 (November 15, 2013), 78 FR 69904 (November 21, 2013) (SR–NYSEMKT–2013–92) (notice of filing and immediate effectiveness of proposed rule change to offer LCN 10 Gb LX connection).

[9] The Exchange does not propose to make a change to the Option A or B PCS bundles. The Option A and B PCS bundles include 1 Gb LCN connections, and the Exchange does not offer a 1 Gb LCN connection with a lower latency than that in the current bundles.

[10] A Hosting User is required to be a User, but because only Users can be Hosting Users, a Hosted Customer is not able to provide hosting services to any other entities in the space in which it is hosted. The Exchange allows Users to act as Hosting Users for a monthly fee. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67).

[11] Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public or disclose it to the Exchange. The Exchange therefore does not have direct visibility into the specific range of options, or cost thereof, offered by Hosting Users, and relies on third parties for information.

[12] *See supra* note 7.

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies, as compared to Users that are not co-located, in sending orders to, and receiving market data from, the Exchange.

[15] *See* 78 FR 50471, *supra* note 5, at 50471. NYSE, NYSE Arca and NYSE National have submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2019–41, SR–NYSEArca-2019–54, and SR–NYSENAT–2019–17.

related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[18] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Not Unfairly Discriminatory

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that in the future order or currently use an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency LCN connection immediately. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

As a result of the proposed change, the latency of the LCN connection in the Option C and D bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The changes would continue to make it more cost effective for Users to utilize co-location by offering a cost effective, convenient way to create a colocation environment, through the choice among PCS bundles with different cabinet footprints and network connections options. The Exchange expects that such Users would include those with minimal power or cabinet space demands and Users for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.

The Proposed Change Is Reasonable and Equitable

The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who may otherwise opt to become Hosted Customers, and thus enhance the competitive environment for potential Users (who would then have more options from which to select).

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[19]

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users and potential Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency connection immediately. The Exchange believes that would be the only effect of this change for current Users as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(4).

[19] *See supra* note 7.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[20] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because, in addition to the proposed services being completely voluntary, they are available to all Users on an equal basis: all Users that order an Option C or Option D bundle would receive an LCN 10 Gb LX connection as part of that bundle. The Exchange believes that the proposed changes are reasonable and designed to be fair and equitable, and therefore, will not unduly burden any particular group of Users. Under the proposed change the Exchange will continue to offer cost effective options for Users to create a colocation environment through the PCS bundles.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate. The purpose of this filing is not to change any fees, but rather to make a change to the contents of the Option C and D PCS bundles that would give current and future Users of those bundles more efficient connections for the same costs. As a result of the proposed change, the latency of the LCN connection in the Option C and D PCS bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The proposed change would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that have an Option C or D PCS bundle—including those that already have one—would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both.

The current Users would receive the benefit of a lower latency connection at the same cost. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

Intermarket Competition

The Exchange does not believe that the proposed fee would impose any burden on intermarket competition that is not necessary or appropriate. The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. At the same time, however, no potential User would be obligated to purchase a PCS bundle, and it would still have the options offered by Hosting Users.

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[21]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22]

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.[25]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [26] of the Act to

[20] 15 U.S.C. 78f(b)(8).

[21] *See supra* note 7.

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 15 U.S.C. 78s(b)(2)(B).

determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2019–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2019–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2019–28 and should be submitted on or before August 28, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16857 Filed 8–6–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86547; File No. SR–NYSEARCA–2019–54]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges Related to Co-Location Services

August 1, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 18, 2019, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fees and Charges (the ''Options Fee Schedule'') and the NYSE Arca Equities Fees and Charges (the ''Equities Fee Schedule'' and, together with the Options Fee Schedule, the ''Fee Schedules'') related to co-location services to amend the Partial Cabinet Solution bundles. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedules related to co-location[4] services offered by the Exchange to amend two of the Partial Cabinet Solution (''PCS'') bundles that the Exchange offers Users.[5] The proposed change would have the effect of lowering the latency in the Liquidity Center Network (''LCN'') connection included in two of the PCS bundles. This is not a fee filing: There is no proposed change to the fee for the PCS bundles.

The Exchange plans to implement the change during the fourth quarter of 2019. It will announce the implementation date through a customer notice.

Proposed Change to the Option C and Option D PCS Bundles

There are four PCS bundles, Options A through D. Each PCS bundle option includes a partial cabinet; access to the LCN and internet protocol (''IP'') network, the local area networks available in the data center; two fiber cross connections; and connectivity to one of two time feeds.[6] The PCS

[27] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedules, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), and NYSE National, Inc. (''NYSE National'' and, together with NYSE, NYSE American and NYSE Chicago, Inc., the ''Affiliate SROs'').*See* Securities Exchange Act Release No. 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80).

[6] *See* Securities Exchange Act Release No. 77070 (February 5, 2016)), 81 FR 7401 (February 11, 2016) (SR–NYSEArca-2015–102).

bundles were designed to attract smaller Users, including those with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[7]

Currently, the Options C and D PCS bundles include 10 Gigabit (''Gb'') LCN connections. The Exchange proposes to change each 10 Gb LCN connection to a lower-latency 10 Gb LCN connection, referred to as the ''LCN 10 Gb LX.'' [8] As a result of this change, Users will benefit from a lower latency LCN connection in the Options C and D PCS bundles at the same cost.

The sole change to the Fee Schedules would be to add ''LX'' to the reference to the 10 Gb LCN connection in the description of Option C and Option D in the Fee Schedules. The revised text would read as follows (proposed additions underlined):

- *For Option C:* 1 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.
- *For Option D:* 2 kW partial cabinet, 1 LCN connection (10 Gb *LX*), 1 IP network connection (10 Gb), 2 fiber cross connections and either the Network Time Protocol Feed or Precision Timing Protocol.

Application and Impact of the Proposed Change

The proposed change would apply to all Option C and Option D PCS bundles, including those that Users currently have.[9] Those current Users would benefit immediately from the lower latency connection. The Exchange believes that would be the only consequence for them, as (a) the current Users would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the prices they pay for their Option C and Option D PCS bundles.

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary and the Fee Schedules are applied uniformly to all Users.

Competitive Environment

A User may host another entity in its space within the data center. Such Users are called ''Hosting Users,'' and their customers are ''Hosted Customers.'' [10]

Based on conversations with Users and potential customers, the Exchange believes that Hosting Users offer bundles (''Hosting User Bundles'') that include cabinet space and space on shared LCN and IP network connections—and that the Hosting User Bundles provide their end users with a service similar to that of the PCS bundles, but with a lower cost and latency.[11]

The proposed change is intended to create a more level playing field between the Exchange and the Hosting Users, who compete for Hosted Customer business. Based on the above conversations, the Exchange understands that, given the choice, customers may choose a Hosting User Bundle over a PCS bundle, with the latency of the 10 Gb LCN connection being a major factor in the choice. The Exchange believes that, by reducing the latency of the LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. Importantly, the change would provide potential Users with a wider range of attractive choices, which would be a benefit to the competitive environment, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[12]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [13]

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [14] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[15]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not

[7] *Id.,* at 7396.

[8] *See* Securities Exchange Act Release No. 70887 (November 15, 2013), 78 FR 69897 (November 21, 2013) (SR–NYSEArca–2013–123) (notice of filing and immediate effectiveness of proposed rule change to offer LCN 10 Gb LX connection).

[9] The Exchange does not propose to make a change to the Option A or B PCS bundles. The Option A and B PCS bundles include 1 Gb LCN connections, and the Exchange does not offer a 1 Gb LCN connection with a lower latency than that in the current bundles.

[10] A Hosting User is required to be a User, but because only Users can be Hosting Users, a Hosted Customer is not able to provide hosting services to any other entities in the space in which it is hosted. The Exchange allows Users to act as Hosting Users for a monthly fee. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82).

[11] Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public or disclose it to the Exchange. The Exchange therefore does not have direct visibility into the specific range of options, or cost thereof, offered by Hosting Users, and relies on third parties for information.

[12] *See supra* note 7.

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[14] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies, as compared to Users that are not co-located, in sending orders to, and receiving market data from, the Exchange.

[15] *See* 78 FR 50459, *supra* note 5, at 50459. NYSE, NYSE American and NYSE National have submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2019–41, SR–NYSEAmer–2019–28, and SR–NYSENAT–2019–17.

aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and does not unfairly discriminate between customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[18] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Not Unfairly Discriminatory

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that in the future order or currently use an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency LCN connection immediately. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

As a result of the proposed change, the latency of the LCN connection in the Option C and D bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The changes would continue to make it more cost effective for Users to utilize co-location by offering a cost effective, convenient way to create a colocation environment, through the choice among PCS bundles with different cabinet footprints and network connections options. The Exchange expects that such Users would include those with minimal power or cabinet space demands and Users for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.

The Proposed Change Is Reasonable and Equitable

The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who may otherwise opt to become Hosted Customers, and thus enhance the competitive environment for potential Users (who would then have more options from which to select).

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[19]

The proposed change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users and potential Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that order an Option C or D bundle would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both. As is currently the case, the purchase of any colocation service, including PCS bundles, is completely voluntary.

Having the change apply to all Option C and D PCS bundles, including those that Users already have, would ensure that all Users with Option C and D PCS bundles receive the same services no matter when they purchased them. The current Users would receive the benefit of a lower latency LCN connection immediately. The Exchange believes that would be the only effect of this change for current Users as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(4).

[19] *See supra* note 7.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[20] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because, in addition to the proposed services being completely voluntary, they are available to all Users on an equal basis: All Users that order an Option C or Option D bundle would receive an LCN 10 Gb LX connection as part of that bundle. The Exchange believes that the proposed changes are reasonable and designed to be fair and equitable, and therefore, will not unduly burden any particular group of Users. Under the proposed change the Exchange will continue to offer cost effective options for Users to create a colocation environment through the PCS bundles.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate. The purpose of this filing is not to change any fees, but rather to make a change to the contents of the Option C and D PCS bundles that would give current and future Users of those bundles more efficient connections for the same costs. As a result of the proposed change, the latency of the LCN connection in the Option C and D PCS bundles would be reduced. The proposed change would assist Users in making their network connectivity more efficient by reducing the time that messaging (*e.g.,* orders and quotes) takes to reach the Exchange's trading and execution system once sent from their co-located servers and also the time that market data takes to reach their co-located servers. The Exchange believes that the reduction in latencies attributed to the LCN 10 Gb LX connection would provide Users with a more efficient means of processing their messages sent to the Exchange's trading and execution system from the data center.

The proposed change would apply to all Users equally. The Exchange would continue to offer the four different PCS bundles with different cabinet footprints and network connections options. All Users that have an Option C or D PCS bundle—including those that already have one—would receive an LCN 10 Gb LX connection as part of that bundle. Users that require other sizes or combinations of cabinets, network connections and cross connects could still request them, and would still have the choice of purchasing a 10 Gb LCN connection, an LCN 10 Gb LX connection, or both.

The current Users would receive the benefit of a lower latency connection at the same cost. The Exchange believes that would be the only effect of this change for current Users, as (a) they would not be required to change their equipment to accommodate the change, and so would not incur equipment costs, and (b) there would be no change in the initial charge or MRC for the applicable PCS bundles.

Intermarket Competition

The Exchange does not believe that the proposed fee would impose any burden on intermarket competition that is not necessary or appropriate. The Exchange believes that the proposed change is a reasonable attempt to create a more level playing field between the Exchange and Hosting Users. Because Hosting Users' services are not regulated, they may offer differentiated pricing and are not required to make their pricing public. The Exchange believes that, by reducing the latency in the included LCN connection, the proposed change may make Option C and D PCS bundles more attractive to potential Users who might otherwise opt to become Hosted Customers. At the same time, however, no potential User would be obligated to purchase a PCS bundle, and it would still have the options offered by Hosting Users.

Without this proposed rule change, potential Users choosing between a PCS bundle and a Hosting User Bundle would have fewer attractive options. This would be a detriment for them, especially for potential Users with minimal power or cabinet space demands or those for which the costs attendant with having a dedicated cabinet or greater network connection bandwidth are too burdensome.[21]

The Exchange operates in a highly competitive market in which exchanges and other vendors (*i.e.,* Hosting Users) offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [22]

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[25]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [26] of the Act to

[20] 15 U.S.C. 78f(b)(8).

[21] *See supra* note 7.

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 15 U.S.C. 78s(b)(2)(B).

determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2019–54 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2019–54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2019–54 and should be submitted on or before August 28, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–16856 Filed 8–6–19; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16052 and #16053; Kansas Disaster Number KS–00125]

Administrative Declaration of a Disaster for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of KANSAS dated 07/31/2019.

Incident: Flooding.

Incident Period: 06/22/2019 through 07/06/2019.

DATES: 07/31/2019.

Physical Loan Application Deadline Date: 09/30/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 05/01/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Marion.

Contiguous Counties:

KANSAS: Butler, Chase, Dickinson, Harvey, McPherson, Morris, Saline

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.875
Homeowners Without Credit Available Elsewhere	1.938
Businesses With Credit Available Elsewhere	8.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16052 6 and for economic injury is 16053 0.

The States which received an EIDL Declaration # are Kansas.

(Catalog of Federal Domestic Assistance Number 59008)

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–16866 Filed 8–6–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 16056 and # 16057; Missouri Disaster Number MO–00099]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of MISSOURI (FEMA—4451—DR), dated 07/29/2019.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 04/29/2019 through 07/05/2019.

DATES: Issued on 07/29/2019.

Physical Loan Application Deadline Date: 09/27/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 04/29/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on

[27] 17 CFR 200.30–3(a)(12).

07/29/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adair, Andrew, Atchison, Barry, Barton, Bates, Bollinger, Buchanan, Caldwell, Camden, Cape Girardeau, Carroll, Cedar, Chariton, Clark, Cole, Dade, Dallas, Daviess, Douglas, Gentry, Grundy, Harrison, Henry, Hickory, Holt, Howell, Jackson, Jasper, Knox, Laclede, Lewis, Linn, Livingston, Macon, Maries, Marion, McDonald, Mercer, Miller, Mississippi, Monroe, Montgomery, New Madrid, Newton, Nodaway, Ozark, Pemiscot, Perry, Pike, Putnam, Ralls, Randolph, Ray, Sainte Genevieve, Saline, Schuyler, Scotland, Shannon, Shelby, Stoddard, Sullivan, Taney, Texas, Vernon, Wayne, Webster, Wright.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16056C and for economic injury is 160570.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator, For Disaster Assistance.

[FR Doc. 2019–16867 Filed 8–6–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16054 and #16055; Minnesota Disaster Number MN–00069]

Administrative Declaration of a Disaster for the State of Minnesota

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Minnesota dated 08/01/2019.

Incident: Severe Weather and Flooding.

Incident Period: 06/27/2019 through 07/07/2019.

DATES: Issued on 08/01/2019.

Physical Loan Application Deadline Date: 09/30/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 05/01/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Dodge

Contiguous Counties:

Minnesota: Goodhue, Mower, Olmsted, Rice, Steele.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.875
Homeowners without Credit Available Elsewhere	1.938
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16054 6 and for economic injury is 16055 0.

The State which received an EIDL Declaration # is Minnesota.

(Catalog of Federal Domestic Assistance Number 59008)

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–16864 Filed 8–6–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16058 and #16059; Idaho Disaster Number ID–00076]

Administrative Declaration of a Disaster for the State of Idaho

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of IDAHO dated 08/01/2019.

Incident: Severe Storms, Flooding, Landslides and Mudslides.

Incident Period: 04/07/2019 through 04/13/2019.

DATES: Issued on 08/01/2019.

Physical Loan Application Deadline Date: 09/30/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 05/01/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Idaho.

Contiguous Counties:

IDAHO: Adams, Clearwater, Lemhi, Lewis, Nez Perce, Valley.

MONTANA: Missoula, Ravalli.

OREGON: Wallowa.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.125
Homeowners without Credit Available Elsewhere	2.063
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere ...	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000

	Percent
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16058 6 and for economic injury is 16059 0.

The States which received an EIDL Declaration # are Idaho, Montana, Oregon.

(Catalog of Federal Domestic Assistance Number 59008)

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–16865 Filed 8–6–19; 8:45 am]

BILLING CODE 8026–03–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2019–0035]

Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2019–0031].

SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than September 6, 2019. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Application for Lump Sum Death Payment—20 CFR 404.390–404.392—0960–0013. SSA uses Form SSA–8 to collect information needed to authorize payment of the lump sum death payment (LSDP) to a widow, widower, or children as defined in section 202(i) of the Social Security Act (Act). Respondents complete the application for this one-time payment through use of the paper form, or person interview with an SSA employee either via telephone, or in person in a field office. For all personal interviews (either telephone or in-person), we collect the information in our electronic Modernized Claim System (MCS) or via our Intranet-based Preliminary Claims System (PCS) which mirrors the MCS screens. Respondents are applicants for the LSDP.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–8—MCS or PCS Screens	656,623	1	9	98,493
SSA–8—Paper Form	5,484	1	10	914
Total	662,107			99,407

2. Statement for Determining Continuing Eligibility, Supplemental Security Income Payment(s)—416.204—0960–0416. To determine whether SSI recipients (1) have met and continue to meet all statutory and regulatory requirements for SSI eligibility and (2) are receiving the correct SSI payment amount, SSA conducts redeterminations of disability. Periodic collection of this information using Form SSA–8203BK is the only way SSA can make these redeterminations, and collection of this information is mandatory under the law. We routinely collect the information in field offices via personal contact (face-to-face or telephone interview) using the automated SSI Claims System. The respondents are SSI recipients or their representative payees.

Type of Request: Revision on an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSI Claims System	1,468,220	1	19	464,936
Paper	135,357	1	20	45,119
Total	1,603,577			510,055

3. Statement for Determining Continuing Entitlement for Special Veterans Benefits (SVB)—0960–0782. Title VIII of the Act provides for the payment of Special Veterans benefits (SVB) to certain World War II veterans who reside outside of the United States. SSA regularly reviews individuals' claims for SVB to determine their continued eligibility and correct payment amounts. Individuals living outside the United States receiving SVB must report to SSA any changes that may affect their benefits. These include changes such as: (1) A change in mailing

address or residence; (2) an increase or decrease in a pension, annuity, or other recurring benefit; (3) a return or visit to the United States for a calendar month or longer; or (4) an inability to manage benefits. SSA uses Form SSA–2010, to collect this information. Beneficiaries under age 90 receive notification of their benefit review along with the form every two years, and beneficiaries age 90 or older have face-to-face interviews with the Foreign Service Post every year who assist them in completing this form. Currently, the average respondent is over age 90, and very few respondents are under age 90. Respondents are beneficiaries living outside the United States collecting SVB.

Type of Request: Revision on an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–2010	382	1	20	127

Dated: August 1, 2019.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2019–16805 Filed 8–6–19; 8:45 am]

BILLING CODE 4191–02–P

SUSQUEHANNA RIVER BASIN COMMISSION

Grandfathering (GF) Registration Notice

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Grandfathering Registration for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: June 1–30, 2019.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries May be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists GF Registration for projects, described below, pursuant to 18 CFR 806, Subpart E for the time period specified above:

Grandfathering Registration Under 18 CFR Part 806, Subpart E

1. Borough of Akron, GF Certificate No. GF–201906033, Borough of Akron, Lancaster County, Pa.; Well 1, Well 2, and the Spring; Issue Date: June 14, 2019.

2. Leola Sewer Authority, GF Certificate No. GF–201906034, Upper Leacock Township, Lancaster County, Pa.; Wells 6, 9, and 12; Issue Date: June 14, 2019.

3. Martinsburg Municipal Authority, GF Certificate No. GF–201906035, Martinsburg Borough, Blair County, Pa.; Hershberger Well; Issue Date: June 17, 2019.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: August 1, 2019.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2019–16820 Filed 8–6–19; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold its regular business meeting on September 6, 2019, in Big Flats, New York. Details concerning the matters to be addressed at the business meeting are contained in the Supplementary Information section of this notice. Also the Commission published a document in the **Federal Register** on July 3, 2019, concerning its public hearing on August 1, 2019, in Harrisburg, Pennsylvania.

DATES: The meeting will be held on Friday, September 6, 2019, at 9 a.m.

ADDRESSES: The meeting will be held at the Big Flats Community Center, 476 Maple Street, Big Flats, NY 14814.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: 717–238–0423; fax: 717–238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Informational presentation of interest to the upper Susquehanna River region; (2) proposed rulemaking on consumptive use regulation; (3) ratification/approval of contracts/grants; (4) a report on delegated settlements; (5) Regulatory Program projects; and (6) approval of a settlement with Sunoco Pipeline, L.P.

This agenda is complete at the time of issuance, but other items may be added, and some stricken without further notice. The list of an item on the agenda does not necessarily mean that the Commission will take final action on it at this meeting. When the Commission does take final action, notice of these actions will be published in the **Federal Register** after the meeting. Any actions specific to projects will also be provided in writing directly to project sponsors.

Regulatory Program projects listed for Commission action were those that were the subject of public hearings conducted by the Commission on August 1, 2019, and identified in the notices for such hearings, which was published in 84 FR 31976, July 3, 2019.

The public is invited to attend the Commission's business meeting. Comments on the Regulatory Program projects are subject to a deadline of August 12, 2019. Written comments pertaining to other items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *www.srbc.net/about/meetings-events/business-meeting.html.* Such comments are due to the Commission on or before September 2, 2019. Comments will not be accepted at the business meeting noticed herein.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: August 1, 2019.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2019–16816 Filed 8–6–19; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Rescinded for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the approved by rule projects rescinded by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: June 1–30, 2019.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address. See also Commission website at *www.srbc.net.*

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, being rescinded for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Rescinded ABRs Issued

1. SWEPI LP; Pad ID: Allen 620; ABR–20100623.R1; Charleston Township, Tioga County, Pa.; Rescinded Date: June 10, 2019.

2. SWEPI LP; Pad ID: Baker 1105; ABR–201101011.R1; Deerfield Township, Tioga County, Pa.; Rescinded Date: June 14, 2019.

3. SWEPI LP; Pad ID: Davis 841; ABR–201505002; Chatham Township, Tioga County, Pa.; Rescinded Date: June 19, 2019.

4. SWEPI LP; Pad ID: Dietz 490; ABR–201010030.R1; Richmond Township, Tioga County, Pa.; Rescinded Date: June 18, 2019.

5. SWEPI LP; Pad ID: Harman 565; ABR–201010028.R1; Charleston Township, Tioga County, Pa.; Rescinded Date: June 18, 2019.

6. SWEPI LP; Pad ID: Williams 889; ABR–201009051.R1; Deerfield Township, Tioga County, Pa.; Rescinded Date: June 10, 2019.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: August 1, 2019.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2019–16818 Filed 8–6–19; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in ''DATES.''

DATES: May 1–June 30, 2019.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(e) and § 806.22 (f) for the time period specified above:

Water Source Approvals Issued Under 18 CFR 806.22(f)(13):

1. Repsol Oil & Gas USA, LLC.; Pad ID: ALEXANDER (01 124); ABR–201905003; Armenia Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: May 9, 2019.

2. Chesapeake Appalachia, L.L.C.; Pad ID: Benscoter; ABR–20090601.R2; Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 3, 2019.

3. Chesapeake Appalachia, L.L.C.; Pad ID: Strom; ABR–20090602.R2; Monroe Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 3, 2019.

4. Chesapeake Appalachia, L.L.C.; Pad ID: Evanchick; ABR–20090604.R2; Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 3, 2019.

5. Chesapeake Appalachia, L.L.C.; Pad ID: Vargson; ABR–20090605.R2; Granville Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 3, 2019.

6. Chief Oil & Gas, LLC.; Pad ID: Baumunk North B Drilling Pad; ABR–201406004.R1; Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 4, 2019.

7. Chief Oil & Gas, LLC.; Pad ID: Wissler Drilling Pad; ABR–201406005.R1; McNett Township, Lycoming County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 4, 2019.

8. Chief Oil & Gas, LLC.; Pad ID: IDC–INNES UNIT PAD; ABR–201906004; Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 7, 2019.

9. Seneca Resources Company, LLC; Pad ID: Gamble Pad G; ABR–201906005; Gamble Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 7, 2019.

10. Repsol Oil & Gas USA, LLC; Pad ID: SHEDDEN (01 013/043) D; ABR–20090603.R2; Troy Township, Bradford County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: June 10, 2019.

11. Chief Oil & Gas, LLC.; Pad ID: SGL 12 O Pad; ABR–2019006002; Franklin Township, Bradford County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 11, 2019.

12. Seneca Resources Company, LLC; Pad ID: CRV D08-Pad G; ABR–201406007.R1; Norwich Township, McKean County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 13, 2019.

13. Chief Oil & Gas, LLC.; Pad ID: Clark Drilling Pad; ABR–201406008.R1; Springville Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 13, 2019.

14. Repsol Oil & Gas USA, LLC; Pad ID: WARNER (05 121) W; ABR–201906001; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: June 17, 2019.

15. Chesapeake Appalachia, L.L.C.; Pad ID: MTL; ABR–201906003; Wyalusing Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 17, 2019.

16. ARD Operating, LLC; Pad ID: C.O.P. Tract 285 (1000); ABR–20190406.R2; Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: June 17, 2019.

17. Repsol Oil & Gas USA, LLC; DCNR 587 (02 001); ABR–20090609.R2; Ward Township, Tioga County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: June 17, 2019.

18. ARD Operating, LLC; Pad ID: COP Tract 285 (1001H, 1002H); ABR–20190413.R2; Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: June 17, 2019.

19. ARD Operating, LLC; Pad ID: COP Tr 252 #1000H; ABR–20190444.R2;

Grugan Township, Clinton County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: June 17, 2019.

20. Chesapeake Appalachia, L.L.C.; Pad ID: Welles 1; ABR–20090610.R2; Terry Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: June 18, 2019.

21. Chief Oil & Gas, LLC; Pad ID: Czop Drilling Pad; ABR–201406009.R1; Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: June 19, 2019.

22. Repsol Oil & Gas USA, LLC; Pad ID: WILLIAMS (01 041/042) R; ABR–20090611.R2; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.0000 mgd; Approval Date: June 24, 2019.

23. Seneca Resources Company, LLC; Pad ID: CRV Pad C08–X; ABR–201406010.R1; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: June 26, 2019.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: August 1, 2019.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2019–16817 Filed 8–6–19; 8:45 am]

BILLING CODE 7040–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of product exclusions.

SUMMARY: Effective September 24, 2018, the U.S. Trade Representative (Trade Representative) imposed additional duties on goods of China with an annual trade value of approximately $200 billion (the $200 billion action) as part of the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation. The Trade Representative's subsequent modification in May 2019 included a decision to establish a product exclusion process. The Trade Representative initiated the exclusion process in June 2019, and stakeholders have submitted requests for the exclusion of specific products. This notice announces the Trade Representative's determination to grant certain exclusion requests, as specified in the Annex to this notice. The Trade Representative will continue to issue decisions on pending requests on a periodic basis.

DATES: The product exclusions announced in this notice will apply as of the September 24, 2018 effective date of the $200 billion action, and will extend for one year after the publication of this notice. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Assistant General Counsels Philip Butler or Megan Grimball, or Director of Industrial Goods Justin Hoffmann at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

For background on the proceedings in this investigation, please see the prior notices issued in the investigation, including 82 FR 40213 (August 23, 2017), 83 FR 14906 (April 6, 2018), 83 FR 28710 (June 20, 2018), 83 FR 33608 (July 17, 2018), 83 FR 38760 (August 7, 2018), 83 FR 47974 (September 21, 2018), 83 FR 49153 (September 28, 2018), 83 FR 65198 (December 19, 2018), 84 FR 7966 (March 5, 2019), 84 FR 20459 (May 9, 2019), and 84 FR 29576 (June 24, 2019).

Effective September 24, 2018, the Trade Representative imposed additional 10 percent duties on goods of China classified in [5,745] 8-digit subheadings of the Harmonized Tariff Schedule of the United States (HTSUS), with an approximate annual trade value of $200 billion. *See* 83 FR 47974. The Trade Representative's subsequent modification increased the additional duty to 25 percent and decided to establish a process by which U.S. stakeholders may request exclusion of particular products classified within an 8-digit HTSUS subheading covered by the $200 billion action from the additional duties. *See* 84 FR 20459. The Trade Representative issued a notice setting out the process for the product exclusions, and opened a public docket. *See* 84 FR 29576 (the June 24 notice).

Under the June 24 notice, requests for exclusion had to identify the product subject to the request in terms of the physical characteristics that distinguish the product from other products within the relevant 8-digit subheading covered by the $200 billion action. Requestors also had to provide the 10-digit subheading of the HTSUS most applicable to the particular product requested for exclusion, and could submit information on the ability of U.S. Customs and Border Protection to administer the requested exclusion. Requestors were asked to provide the quantity and value of the Chinese-origin product that the requestor purchased in the last three years. With regard to the rationale for the requested exclusion, requests had to address the following factors:

- Whether the particular product is available only from China and specifically whether the particular product and/or a comparable product is available from sources in the United States and/or third countries.
- Whether the imposition of additional duties on the particular product would cause severe economic harm to the requestor or other U.S. interests.
- Whether the particular product is strategically important or related to ''Made in China 2025'' or other Chinese industrial programs.

The June 24 notice stated that the Trade Representative would take into account whether an exclusion would undermine the objective of the Section 301 investigation.

The June 24 notice required submission of requests for exclusion from the $200 billion action no later than September 30, 2019, and noted that the Trade Representative would periodically announce decisions. The Office of the United States Trade Representative regularly updates the status of each pending request and posts the status within the web pages for the respective tariff action they apply to at *https://ustr.gov/issue-areas/enforcement/section-301-investigations/tariff-actions.*

B. Determination To Grant Certain Exclusions

Based on the evaluation of the factors set out in the June 24 notice, which are summarized above, pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, and in accordance with the advice of the interagency Section 301 Committee, the Trade Representative has determined to grant the product exclusions set out in the Annex to this notice. The Trade Representative's determination also takes into account advice from advisory committees and any public comments on the pertinent exclusion requests.

As set out in the Annex to this notice, the exclusions are reflected in 10 specially prepared product descriptions,

which cover 15 separate exclusion requests.

In accordance with the June 24 notice, the exclusions are available for any product that meets the description in the Annex, regardless of whether the importer filed an exclusion request. Further, the scope of each exclusion is governed by the scope of the product descriptions in the Annex to this notice, and not by the product descriptions set out in any particular request for exclusion.

Paragraph A, subparagraphs (3)–(5) are conforming amendments to the HTSUS reflecting the modification made by the Annex to this notice.

As stated in the June 24 notice, the exclusions will apply as of the September 24, 2018 effective date of the $200 billion action, and extend for one year after the publication of this notice. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

The Trade Representative will continue to issue determinations on pending requests on a periodic basis.

Joseph Barloon,

General Counsel, Office of the U.S. Trade Representative.

Annex

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on September 24, 2018, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. By inserting the following new heading 9903.88.13 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled ''Heading/Subheading'', ''Article Description'', and ''Rates of Duty 1-General'', respectively:

Heading/ subheading	Article description	Rates of duty		
		1		2
		General	Special	
''9903.88.13	Articles the product of China, as provided for in U.S. note 20(p) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative.	The duty provided in the applicable subheading''		

2. By inserting the following new U.S. note 20(p) to subchapter III of chapter 99 in numerical sequence:

''(p) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.03 and provided for in U.S. notes 20(e) and (f) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.03. See 83 FR 47974 (September 21, 2018) and 84 FR 29576 (June 24, 2019). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that the additional duties provided for in heading 9903.88.03 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

(1) Container units of plastics, each comprising a tub and lid therefore, configured or fitted for the conveyance, packing, or dispensing of wet wipes (described in statistical reporting number 3923.10.9000)

(2) Injection molded polypropylene plastic caps or lids each weighing not over 24 grams designed for dispensing wet wipes (described in statistical reporting number 3923.50.0000)

(3) Kayak paddles, double ended, with shafts of aluminum and blades of fiberglass reinforced nylon (described in statistical reporting number 3926.90.3000)

(4) High tenacity polyester yarn not over 600 decitex (described in statistical reporting number 5402.20.3010)

(5) Nonwovens weighing more than 25 g/m² but not more than 70 g/m² in rolls, not impregnated coated or covered (described in statistical reporting number 5603.92.0090)

(6) Pet cages of steel (described in statistical reporting number 7323.99.9080)

(7) Carts, not mechanically propelled, each with three or four wheels, of the kind used for household shopping (described in statistical reporting number 8716.80.5090)

(8) Truck trailer skirt brackets, other than parts of general use of Section XV (described in statistical reporting number 8716.90.5060)

(9) Inflatable boats, other than kayaks and canoes, with over 20 gauge polyvinyl chloride (PVC), each valued at $500 or less and weighing not over 52 kg (described in statistical reporting number 8903.10.0060)

(10) Inflatable kayaks and canoes, with over 20 gauge polyvinyl chloride (PVC), each valued at $500 or less and weighing not over 22 kg (described in statistical reporting number 8903.10.0060)''

3. by amending the last sentence of the first paragraph of U.S. note 20(e) to subchapter III of chapter 99 by inserting after the phrase ''imposed by heading 9903.88.03'':

'', except products of China granted an exclusion by the U.S. Trade Representative and provided for in heading 9903.88.13 and U.S. note 20(p) to subchapter III of chapter 99'';

4. by amending the first sentence of U.S. note 20(f) to subchapter III of chapter 99 by inserting after the phrase ''the following 8-digit subheadings'' the following phrase:

'', except products of China granted an exclusion by the U.S. Trade Representative and provided for in heading 9903.88.13 and U.S. note 20(p) to subchapter III of chapter 99''; and

5. by amending the Article Description of heading 9903.88.03:

a. by deleting ''''Articles the product of China,'' and

b. by inserting in lieu thereof: ''Except as provided in heading 9903.88.13, articles the product of China,''.

[FR Doc. 2019–16886 Filed 8–6–19; 8:45 am]

BILLING CODE 3290–F9–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2017–0975]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Information Collection 2120–0768, Part 107 Authorizations and Waivers Under 14 CFR Part 107

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The Federal Aviation Agency is seeking approval from the Office of Management and Budget (OMB) for a renewal of the existing Information Collection 2120–0768. As required by the Paperwork Reduction Act of 1995 (PRA), the purpose of this notice is to allow 60 days for public comment.

The FAA proposes collecting information related to requests to operate Unmanned Aircraft Systems (UAS) in controlled airspace pursuant to regulations contained in the code of federal regulations. FAA will use the collected information to make determinations whether to authorize or deny the requested operation of UAS in controlled airspace. The proposed information collection is necessary to issue such authorizations or denials consistent with the FAA's mandate to ensure safe and efficient use of national airspace.

DATES: Written comments should be submitted by October 7, 2019.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

By fax: 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Casey Nair, FAA's Unmanned Aircraft Systems (UAS) Low Altitude Authorization and Notification Capability (LAANC) Program Manager, by email at *Casey.Nair@faa.gov*; phone: 202–267–0369.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0768.

Title: Requests for Comments; Clearance of Renewed Approval of Information Collection: Information Collection 2120–0768, Part 107 Authorizations and Waivers under 14 CFR part 107.

Form Numbers: There are no forms associated with this collection.

Type of Review: Renewal of existing Information Collection.

Background: The FAA has seen increased operations of small Unmanned Aircraft Systems (UAS) flying under 14 CFR part 107. Section 107.41 states that ''no person may operate a small unmanned aircraft in Class B, Class C, or Class D airspace or within the lateral boundaries of the surface area of Class E airspace designated for an airport unless that person has prior authorization from Air Traffic Control (ATC).'' Such authorization may be obtained in the form of either an airspace authorization issued by the FAA or a waiver of the authorization requirements of 14 CFR 107.41 (airspace waiver). Additionally, operators may request waivers of the other operational requirements listed in § 107.205 (operational waivers).

In order to process authorization and airspace waiver requests, the FAA requires the operator's name, the operator's contact information, and information related to the date, place, and time of the requested small UAS operation. This information is necessary for the FAA to meet its statutory mandate of maintaining a safe and efficient national airspace. See 49 U.S.C. 40103 and 44701; Public Law 112–95, Section 333.

Additionally, if the operator is seeking an operational waiver from one of the other regulations listed in 14 CFR 107.205, further information is required related to the proposed waiver and any necessary mitigations. The FAA will use the requested information to determine if the proposed UAS operation can be conducted safely.

The FAA proposes to use LAANC and a web portal to process authorization requests from the public to conduct Part 107 flight operations pursuant to § 107.41. The FAA also proposes to use the web portal to process requests from the public to conduct Part 107 flight operations that require an operational waiver or an airspace waiver.

Respondents: Small UAS operators seeking to conduct flight operations under 14 CFR part 107 within controlled airspace or flight operations that require waiver from certain provisions of Part 107. Between 2020–2022, the FAA estimates that it will receive a total of 346,917 requests for airspace authorization, 27,831 requests for airspace waivers, and 9,000 requests for operational waivers.

Frequency: The requested information will need to be provided each time a respondent requests an airspace authorization to operate a small UAS under 14 CFR part 107 in controlled airspace. A respondent may reduce the frequency by seeking and obtaining an airspace waiver to conduct recurring operations. For requests for operational waivers, a respondent will need to provide the information once at the time of the request for the waiver. If granted, operational waivers may be valid for up to four (4) years.

Estimated Average Burden per Response: The FAA estimates the respondents using LAANC will take five (5) minutes per request and those using the web portal will take thirty (30) minutes per request. For those submitting requests for airspace or operational waivers through the web portal, the FAA estimates each request will take thirty (30) minutes.

Estimated Total Annual Burden: For airspace authorizations, the FAA estimates that the average annual burden will be 15,834 hours for respondents submitting requests. This includes 8,446 burden hours for 101,762 LAANC respondents and 6,938 hours for 13,877 web portal respondents. For airspace waivers, the FAA estimates that the average annual burden will be 4,639 hours for respondents. For operational waivers, the FAA estimates that the average annual burden will be 1,950 hours for respondents.

Issued in Washington, DC, on August 1, 2019.

Victoria Gallagher,

UAS LAANC Acting Program Manager.

[FR Doc. 2019–16797 Filed 8–6–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by TxDOT and Federal Agencies.

SUMMARY: This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to an assignment agreement executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway projects will be barred unless the claim is filed on or before the deadline. For the projects listed below, the deadline is January 4, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416–2734; email: *carlos.swonke@txdot.gov.* TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 16, 2014, and executed by FHWA and TxDOT.

Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Air: Clean Air Act, 42 U.S.C. 7401–7671(q).

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. Wetlands and Water Resources: Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)–300(j)(6); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287; Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931; TEA–21 Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(11); Flood Disaster Protection Act, 42 U.S.C. 4001–4128.

8. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. FM 2252 from Evans Road to FM 3009, Bexar and Comal Counties. This project includes widening FM 2252 from a two-lane roadway to a four-lane roadway with a raised median or a continuous left turn lane plus bike lanes and sidewalks. The project will replace the existing bridge over Cibolo Creek and also provide an overpass at the Union Pacific Railroad crossing. The project is approximately 2.8 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on May 6, 2019 and other documents in the TxDOT project file. The Categorical Exclusion determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

2. I–410 from SH 16 to Ingram Road, Bexar County. The project includes additional capacity improvements, frontage road improvements, interchange improvements and bicycle and pedestrian accommodations. The project is approximately 14.9 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on May 8, 2019 and other documents in the TxDOT project file. The Categorical Exclusion determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

3. State Highway (SH) 146 from Farm-to-Market 519 to Loop 197 in Galveston County, Texas. The 1.4 mile long project will widen SH 146 from two-lanes to four lanes and will replace the SH 146 railroad bridge over the Texas City Terminal and Union Pacific Railroads with a four lane bridge. The project will also reconfigure the existing intersection at SH 146 and SH 3. The actions by

TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on May 16, 2019 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

4. US 75 from FM 1417 to FM 120, in Grayson County, Texas. The purpose of the proposed project is to improve mobility on US 75 to accommodate current and future traffic volumes by reconstructing and widening the freeway from four to six lanes and removing the Texas Northeastern Division Railroad bridge crossing US 75 and the Union Pacific Railroad bridge crossing Texoma Parkway (SH 91). The proposed project would also include reconfigurations of intersections, ramp modifications, and improvements to pedestrian facilities along US 75. The proposed project length is approximately 12.7 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion approved on May 22, 2019 and other documents in the TxDOT project file. The Categorical Exclusion and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Paris District Office at 1365 N Main St., Paris, Texas, 75460; telephone (903) 737–9213.

5. FM 549 from SH 205 to SH 276 in Rockwall County, Texas. The proposed improvements would include widening the existing FM 549 to a four-lane roadway with a 20-foot center turn lane with median. In addition to widening, the project would construct a new segment of FM 549 extending from south of FM 1139 to SH 205. The proposed project would include 12 to 14-foot wide lanes with 2-foot wide shoulders and 5-foot wide sidewalks on both sides of the road. At specific locations, 12-foot wide turn lanes would be added as well and a bridge would be constructed for the crossing of Long Branch. The length of the proposed project is approximately 2.08 miles. The purpose of the FM 549 roadway widening is to improve safety, mobility, capacity, and to accommodate future traffic demand in the area. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on May 30, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

6. IH 20 Overpass and Ramps at CR 1250. The construction limits are from Loop 250 to FM 1788 in Midland County, Texas. The proposed project consists of the construction of an overpass at the intersection of IH 20 and CR 1250, reconstruction of the IH 20 at CR 1250 frontage road intersection, eastbound and westbound U-turns, removal of ramps east of FM 1788, and addition of eight new ramps (four entrance and four exit) west of Loop 250. The frontage road improvements will include full reconstruction with curbs and gutters, as well as drainage improvements at both FM 1788 and Loop 250. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on June 11, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Odessa District Office at 3901 East Highway 80, Odessa, Texas 79761; telephone (432) 498–4746.

7. Farm-to-Market (FM) 2100 from Huffman-Cleveland Road (North) to FM 1960 in Harris County, Texas. The 4.5 mile long project will reconstruct and widen the existing roadway from two lanes to four lanes with a raised median. The project would also include sidewalks, a storm sewer drainage system and detention ponds. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on June 12, 2019 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

8. US 75 at Ridgeview Drive in Collin County, Texas. The proposed project would reconstruct the Ridgeview interchange at US 75. The proposed US 75 at Ridgeview Drive would consist of four to five 11-foot to 12-foot wide general-purpose lanes in each direction with 10-foot wide outside shoulders and 13-foot to 16-foot wide inside shoulders separated. Auxiliary lanes would be 12 feet wide. The US 75 general purpose lanes would cross over Ridgeview Drive. There are frontage road lanes in each direction and would consist of one 14-foot wide outside shared-use lane and one to two 12-foot wide inside lanes with curb and gutter. There would be two frontage road bypass lanes in each direction including bridge replacement at Ridgeview Drive. The length of the proposed project is approximately 1.2 miles. The purpose of the proposed project is to address safety and mobility issues in the project area. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on June 20, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

9. FM 545 from FM 2933 to Business State Highway 78D (BS–78D) in Collin County, Texas. The proposed project would include widening FM 545 to accommodate twelve-foot travel lanes with ten foot shoulders and the improvement of four curves by shifting the center line of each curve to improve safety. The length of the proposed project is approximately 7.4 miles. The purpose of the proposed project is to improve safety and meet current design standards. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on June 27, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

10. US 287 from IH 45 to Intersection of US 287 and CR 2040 in Navarro County, Texas. The proposed project involves the full reconstruction of the existing rural roadway to a four-lane divided highway with sidewalk. The proposed roadway would consist generally of 4 lanes with curb & gutter, plus an 18-foot flush median. The length of the proposed project is approximately 5.77 miles. The purpose of the proposed project is to meet local and regional future travel demand by

upgrading the transportation infrastructure to meet current design standards for interstates, bridges, and frontage roads, and to improve the operation of the roadway by correcting access conflicts. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on July 10, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

11. FM 148 from South of FM 3039 to US 175 in Kaufman County, Texas. The proposed project would construct a new location rural roadway connecting FM 148 with US 175. The proposed roadway would consist of two 12-foot wide travel lanes (one in each direction) with 8-foot wide shoulders and turn lanes. Approximately 3,850 feet of US 175 would be reconstructed to create an overpass crossing of the FM 148 bypass. The length of the proposed project is approximately 1.6 miles. The purpose of the proposed project is to improve operations along FM 148, improve mobility and access between FM 148 and US 175, and accommodate future traffic demand on the corridor in a manner compatible with local and regional thoroughfare plans. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on March 26, 2019, Finding of No Significant Impact (FONSI) issued on June 3, 2019 and other documents in the TxDOT project file. The EA and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

12. IH 35E from US 77 South to US 77 North in Ellis County, Texas. The proposed project would reconstruct and widen the existing frontage roads, convert all two-way frontage roads to one-way operations and make all of the frontage roads continuous along the entire project limits. The length of the proposed project is approximately 11 miles. The purpose of the proposed project is to improve mobility on IH 35E within the city of Waxahachie in Ellis County, Texas. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on June 26, 2019, Finding of No Significant Impact (FONSI) issued on June 26, 2019 and other documents in the TxDOT project file. The EA and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

13. SH 71 at FM 1209, Bastrop County, Texas. This project includes constructing new frontage roads, a grade separation over FM 1209 and shared use paths. The project is approximately 2.5 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on June 25, 2019, the Finding of No Significant Impact (FONSI) issued on June 25, 2019, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office at 7901 North I–35, Austin, Texas, 78753; telephone (512) 832–7000.

14. FM 548 from North of US 80 to SH 205 in Kaufman and Rockwall Counties, Texas. There are two segments to the proposed project. Segment 1 would involve the expansion from a two-lane roadway to a six-lane divided urban minor arterial from US 80 to Windmill Farms Boulevard. Segment 2 would involve the expansion from a two-lane rural roadway to a four-lane divided urban arterial (six-lane ultimate) from Windmill Farms Boulevard to SH 205. The length of the proposed project is approximately 7.84 miles. The purpose of the proposed project is to bring the roadway up to current design standards and to reduce congestion and improve mobility within the project limits. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on July 3, 2019, Finding of No Significant Impact (FONSI) issued on July 3, 2019 and other documents in the TxDOT project file. The EA and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

Authority: 23 U.S.C. 139(l)(1).

Issued on: July 26, 2019.

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2019–16397 Filed 8–6–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2019–0012]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the extension of a currently approved information collection: 49 U.S.C. Section 5337 State of Good Repair Program.

DATES: Comments must be submitted before October 7, 2019.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Website: www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202–366–7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-

addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to *www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *www.regulations.gov.* Docket: For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Eric Hu, Office of Program Management (202) 366–0870, or email: *eric.hu@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: 49 U.S.C. Section 5337 State of Good Repair Program

(OMB Number: 2132–0550)

Background: 49 U.S.C. Section 5337, the State of Good Repair Grants Program was authorized by Moving Ahead for Progress in the 21st Century (MAP–21). It was reauthorized under the Fixing America's Surface Transportation (FAST) Act Section 3015. This program authorizes the Secretary of Transportation to make grants to designated recipients to maintain, replace, and rehabilitate high intensity fixed guideway systems and high intensity motorbus systems in a state of good repair. Projects that are eligible for the State of Good Repair Program funds must be in the priority list of a recipient's Transit Asset Management plan. Eligible recipients include state and local government authorities in urbanized areas with high intensity fixed guideway systems and/or high intensity motorbus systems operating for at least seven years. Projects are funded at 80 percent federal with a 20 percent local match requirement by statute. FTA will apportion funds to designated recipients. The designated recipients will then allocate funds as appropriate to recipients that are public entities in the urbanized areas. FTA can make grants to direct recipients after sub- allocation of funds. Recipients apply for grants electronically, and FTA collects milestone and financial status reports from designated recipients on a quarterly basis. The information submitted ensures FTA's compliance with applicable federal laws.

Respondents: State and local governments.

Estimated Annual Number of Respondents: 1,044.

Estimated Total Annual Burden: 13,224 hours.

Frequency: Annual.

Nadine Pembleton,

Director Office of Management Planning.

[FR Doc. 2019–16906 Filed 8–6–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 3520

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 3520, Annual Return To Report Transactions With Foreign Trusts and Receipts of Certain Foreign Gifts.

DATES: Written comments should be received on or before October 7, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Annual Return To Report Transactions With Foreign Trusts and Receipts of Certain Foreign Gifts.

OMB Number: 1545–0159.

Form Number: Form 3520.

Abstract: U.S. persons who create a foreign trust or transfer property to a foreign trust must file Form 3520 to report the establishment of the trust or the transfer of property to the trust. Form 3520 must also be filed by U.S. persons who are treated as owners of any part of the assets of a trust under subpart E of Part I or subchapter J of Chapter 1; who received a distribution from a foreign trust; or who received large gifts during the tax year from a foreign person.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 1,320.

Estimated Time per Respondent: 54.35 hours.

Estimated Total Annual Burden Hours: 71,742.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the

information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 24, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–16803 Filed 8–6–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Proposed Collections; Comment Requests

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on revisions of an information collection that are proposed for approval by the Office of Management and Budget. The Office of International Affairs within the Department of the Treasury is soliciting comments concerning Treasury International Capital Forms CQ–1 and CQ–2, ''Financial and Commercial Liabilities to, and Claims on, Unaffiliated Foreign Residents.''

DATES: Written comments should be received on or before October 7, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International Portfolio Investment Data Systems, Department of the Treasury, Room 5422, 1500 Pennsylvania Avenue NW, Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Wolkow at the email or telephone contact mentioned in the next section.

FOR FURTHER INFORMATION CONTACT: Copies of the proposed forms and instructions are available on the Treasury's TIC web page for forms, *http://www.treasury.gov/resource-center/data-chart-center/tic/Pages/forms.aspx.* Requests for additional information should be directed to Mr. Wolkow by email (*comments2TIC@treasury.gov*) or telephone (202–622–1276).

SUPPLEMENTARY INFORMATION:

Title: Treasury International Capital Form CQ–1, ''Financial Liabilities to, and Claims on, Unaffiliated Foreign Residents;'' and Treasury International Capital Form CQ–2, ''Commercial Liabilities to, and Claims on, Unaffiliated Foreign Residents.''

OMB Number: 1505–0024.

Abstract: Forms CQ–1 and CQ–2 are part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR 128), and is designed to collect timely information on international portfolio capital movements. Forms CQ–1 and CQ–2 are quarterly reports filed by non-financial enterprises in the U.S. to report their international portfolio transactions with unaffiliated foreign residents. This information is necessary for compiling the U.S. balance of payments accounts and the U.S. international investment position, and for use in formulating U.S. international financial and monetary policies.

Current Actions: No changes in the forms are being proposed at this time. The proposed changes in the instructions are: (1) The section I.C ''Who Must Report'' is updated to list out separately Intermediate Holding Companies (IHCs), as defined by Regulation YY, 12 CFR 252, and to clarify that IHCs should follow the same consolidation rules that are applicable to Bank Holding Companies (BHCs), Financial Holding Companies (FHCs), and Savings and Loan Holding Companies. Regulation YY was effective by January 1, 2015, and IHCs are filing TIC reports; this update will formalize their reporting requirements. (2) In section I.C ''Who Must Report'', the last item in the list of entities that must file, ''State and local government'', has been expanded to clarify that it means ''State and local government agencies and instrumentalities such as utilities that produce goods or non-financial services that are not strictly governmental in nature in exchange for money.'' (3) The glossaries for all Treasury International Capital (''TIC'') reports are consolidated into a single document which will provide more consistency across the TIC system. As a result, the TIC C reporting instructions will not include a glossary but new Appendix D will point to the separate consolidated TIC Glossary document on the Treasury website. See the March 2018 version and later versions. (4) In section I.B.5 ''Other Statistical Reports'', some descriptions are updated. (5) The contact information is updated in section F.2, ''Submission of Reports.'' (6) Some other clarifications and format changes may be made to improve the instructions.

Type of Review: Revision of a currently approved data collection.

Affected Public: Business or other for-profit organizations.

Forms: CQ–1 and CQ–2 (1505–0024).

Estimated Number of Respondents: 135.

Estimated Average Time per Respondent: Six and seven-tenths (6.7) hours per respondent per filing.

Estimated Total Annual Burden Hours: 3,620 hours, based on four reporting periods per year.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) Whether Forms CQ–1 and CQ–2 are necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Systems.

[FR Doc. 2019–16360 Filed 8–6–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Proposed Collections; Comment Requests

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on revisions of an information collection that are proposed for approval by the Office of Management and Budget. The Office of International Affairs within the Department of the Treasury is soliciting comments concerning the revisions of the Treasury International Capital (TIC) Forms BC, BL–1, BL–2, BQ–1, BQ–2, and BQ–3 (called the ''TIC B forms'').

DATES: Written comments should be received on or before October 7, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International Portfolio Investment Data Systems, Department of the Treasury, Room 5422, 1500 Pennsylvania Avenue NW,

Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Wolkow at the email or telephone contact mentioned in the next section.

FOR FURTHER INFORMATION CONTACT: Copies of the proposed forms and instructions are available on the Treasury's TIC Forms web page, *http://www.treasury.gov/resource-center/data-chart-center/tic/Pages/forms.aspx.* Requests for additional information should be directed to Mr. Wolkow by email (*comments2TIC@treasury.gov*) or telephone (202–622–1276).

SUPPLEMENTARY INFORMATION:

Titles: Treasury International Capital (TIC) Form BC ''Monthly Report of U.S. Dollar Claims of Financial Institutions on Foreign Residents;'' TIC BL–1 ''Monthly Report of U.S. Dollar Liabilities of Financial Institutions to Foreign Residents;'' TIC BL–2 ''Monthly Report of Customers' U.S. Dollar Liabilities to Foreign Residents;'' TIC BQ–1 ''Quarterly Report of Customers' U.S. Dollar Claims on Foreign Residents;'' TIC BQ–2 ''Part 1: Quarterly Report of Foreign Currency Liabilities and Claims of Financial Institutions and of their Domestic Customers' Foreign Currency Claims with Foreign Residents'' and ''Part 2: the Report of Customers' Foreign Currency Liabilities to Foreign Residents;'' and TIC BQ–3 ''Quarterly Report of Maturities of Selected Liabilities and Claims of Financial Institutions with Foreign Residents.''

OMB Numbers: 1505–0017 (TIC BC), 1505–0019 (TIC BL–1), 1505–0018 (TIC BL–2), 1505–0016 (TIC BQ–1), 1505–0020 (TIC BQ–2), and 1505–0189 (TIC BQ–3).

Abstract: Forms BC, BL–1, BL–2, BQ–1, BQ–2, BQ–3 are part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR 128) and are designed to collect timely information on international portfolio capital movements. These forms are filed by all U.S.-resident financial institutions. On the monthly forms, these organizations report their own claims on (BC), their own liabilities to (BL–1), and their U.S. customers' liabilities to (BL–2) foreign residents, denominated in U.S. dollars. On the quarterly forms, these organizations report their U.S.-resident customers' U.S. dollar claims on foreign residents (BQ–1), and their own and their domestic customers' claims and liabilities with foreign residents, where all claims and liabilities are denominated in foreign currencies (BQ–2). On the quarterly BQ–3 form, these organizations report the remaining maturities of all their own U.S. dollar and foreign currency liabilities and claims (excluding securities) with foreign residents. This information is necessary for compiling the U.S. balance of payments accounts and the U.S. international investment position, and for use in formulating U.S. international financial and monetary policies.

Current Actions: Changes in forms BC and BQ–1 are proposed. No changes to the other Forms are proposed. (a) In Form BQ–1, a new line titled ''Brokerage Balances'' is added in the ''Of Which'' Items section. The amount of brokerage balances included in the form's first column ''Non-Negotiable Foreign Deposits'' is needed to implement new estimates that will help bring the U.S. balance of payments into better compliance with the international reporting standards in the Balance of Payments Manual, 6th Edition (BPM6). (b) In Form BC, the title of the ''Of Which'' line 8132–9 is expanded to read ''Unpaid Insurance Claims And Prepaid Insurance Premiums.'' This clarifies that prepaid insurance premiums are to be reported in this line. (c) In Form BC, the extra text in parenthesis ''(Please . . .)'' is removed in the title box of the ''Of Which'' line 8200–9 ''Assets Written Off This Reporting Period''. The following are all changes in the instructions. (d) Section II.C.3 in the instructions is clarified to indicate prepaid insurance premiums are included in the ''Of Which'' line 8132–9 of the TIC BC form. (e) Section V.C.4 is added to the instructions for reporting the new ''Of Which'' row called ''Brokerage Balances'' in the TIC BQ–1 form.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Forms: BC, BL–1, BL–2, BQ–1, BQ–2, and BQ–3.

Estimated Number of Respondents: BC, 320; BL–1, 360; BL–2, 110; BQ–1, 85; BQ–2, 190 and BQ–3, 155.

Estimated Average Time per Respondent per Filing: BC, 11.2 hours; BL–1, 7.7 hours; BL–2, 8.9 hours; BQ–1, 3.8 hours; BQ–2, 7.8 hours; and BQ–3, 10.5 hours. The average time varies, and is estimated to be generally twice as many hours for major data reporters as for other reporters.

Estimated Total Annual Burden Hours: BC, 43,170 hours for 12 reports per year; BL–1, 33,440 hours for 12 reports per year; BL–2, 11,760 hours for 12 reports per year; BQ–1, 1,290 hours for 4 reports per year, BQ–2, 5,960 hours for 4 reports per year; and BQ–3, 6,510 hours for 4 reports per year.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) Whether Forms BC, BL–1, BL–2, BQ–1, BQ–2, and BQ–3 are necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Systems.

[FR Doc. 2019–16359 Filed 8–6–19; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 413

[CMS–1718–F]

RIN 0938–AT75

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2020

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

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2020. We also are making minor revisions to the regulation text to reflect the revised assessment schedule under the Patient Driven Payment Model (PDPM). Additionally, we are revising the definition of group therapy under the SNF PPS, and are implementing a subregulatory process for updating the code lists (International Classification of Diseases, Tenth Version (ICD–10) codes) used under PDPM. In addition, the final rule updates requirements for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program.

DATES: These regulations are effective on October 1, 2019.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

Anthony Hodge, (410) 786–6645, for information related to payment for SNF-level swing-bed services.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes, and general information.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations and consolidated billing.

Casey Freeman, (410) 786–4354, for information related to the skilled nursing facility quality reporting program.

Lang Le, (410) 786–5693, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for fiscal year (FY) 2020 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this final rule) in the **Federal Register**, before the August 1 that precedes the start of each FY. This final rule also revises the definition of group therapy under the SNF PPS and implements a subregulatory process for updating ICD–10 code lists used under the PDPM. Finally, this rule updates requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP).

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832), which reflects the SNF market basket update, as adjusted by the multifactor productivity (MFP) adjustment, for FY 2020. In addition, we are revising the definition of group therapy under the SNF PPS and implementing a subregulatory process for updating ICD–10 code lists used under the PDPM.

This final rule updates requirements for the SNF QRP, including the adoption of two Transfer of Health Information quality measures and standardized patient assessment data elements that SNFs would be required to begin reporting with respect to admissions and discharges that occur on or after October 1, 2020. We also are finalizing our proposal to exclude baseline nursing home residents from the Discharge to Community Measure. Further, we also are finalizing our proposal to publicly display the quality measure, Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP). We also are finalizing our proposal to revise references in the regulations text to reflect enhancements to the system used for the submission of data. Finally, we requested information on quality measures and standardized resident assessment data elements under consideration for future years, and we have summarized the information we received. In contrast, we are not finalizing our proposal to expand data collection for SNF QRP quality measures to all SNF residents, regardless of their payer.

In accordance with section 1888(h) of the Act, this rule updates certain policies for the SNF VBP Program.

C. Summary of Cost and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total transfers
FY 2020 SNF PPS payment rate update.	The overall economic impact of this final rule is an estimated increase of $851 million in aggregate payments to SNFs during FY 2020.
FY 2020 Updates to the SNF QRP.	The overall annual cost for SNFs to submit data for the SNF QRP for the provisions in this final rule is $29 million.
FY 2020 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $213.6 million in aggregate payments to SNFs during FY 2020.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in post-acute care, we developed a Data Element Library (DEL) to serve as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the DEL (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (the Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. In another important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices. In March 2019, ONC and CMS published the proposed rules, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,'' (84 FR 7424) and ''Interoperability and Patient Access'' (84 FR 7610) to promote secure and more immediate access to health information for patients and healthcare providers through the implementation of information blocking provisions of the Cures Act and the use of standardized application programming interfaces (APIs) that enable easier access to electronic health information. These two rules were open for public comment at *www.regulations.gov*. We invited providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf*.

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2019 (83 FR 39162), as corrected in the FY 2019 SNF PPS correction notice (83 FR 49832).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule will provide the required annual updates to the per diem payment rates for SNFs for FY 2020.

III. Analysis and Responses to Public Comments on the FY 2020 SNF PPS Proposed Rule

In response to the publication of the FY 2020 SNF PPS proposed rule, we received 63 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2020 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the

following, more general, observations on the SNF PPS and SNF care generally, as well as on aspects of PDPM that were finalized in the FY 2019 SNF PPS final rule. A discussion of these comments, along with our responses, appears below.

Comment: Many commenters expressed their continued support for implementation of PDPM. Many commenters also offered suggestions and recommendations for how to improve aspects of PDPM finalized in the FY 2019 SNF PPS final rule. Several commenters raised concerns regarding the impact of PDPM on other payers, such as on Medicare Advantage plans and on Medicaid programs, as well as on other CMS payment models, such as the Bundled Payment for Care Initiative and Accountable Care Organizations. A few commenters requested clarification on how PDPM would align with a unified post-acute payment system. Finally, several commenters raised concerns with certain structural elements of PDPM finalized in the FY 2019 final rule, such as the data used in developing the case-mix indexes under PDPM, the use of section GG on the MDS, and the effect of the variable per diem adjustment, specifically that used under the NTA component, on care provision.

Response: We appreciate all of the comments we received supporting PDPM implementation. We also appreciate all of the comments and suggestions on ways to improve PDPM in the future, including comments regarding changes in the structural elements of PDPM, such as the variable per diem adjustment or use of section GG on the MDS. However, because we consider these comments to be outside the scope of the current rulemaking, we are not addressing them in this final rule. We will consider all of these recommendations as we consider future rulemaking.

For comments on the impact of PDPM on other payers, we have worked with each of these groups to provide education and training to aid in understanding the impact of PDPM implementation on the respective group. Most notably, we have worked closely with states to aid in navigating the transition to PDPM, while maintaining support for legacy case-mix systems necessary for certain state Medicaid programs. With regard to the impact of PDPM on alternative payment models, we have worked with the teams responsible for these policies to provide education on how PDPM changes payment under the SNF PPS and will ensure that evaluating the impact of PDPM on these models is a component of our monitoring program after implementation.

In terms of how PDPM would align with a unified post-acute payment system, we believe that PDPM represents an important step in aligning the SNF PPS with other post-acute payment systems, in anticipation of a unified post-acute payment system. Many of the aspects of PDPM finalized in the FY 2019 final rule, such as the use of patient characteristics as the basis for payment, and our revision in this final rule to the definition of group therapy (as discussed in section III.D.1. of this final rule), better align SNF PPS payment policies with those used in other post-acute settings.

Comment: Many commenters suggested that CMS monitor closely the financial, clinical, and outcome-related impacts of PDPM implementation. Several commenters requested clarification on contingency plans in case of assessment and/or claims submission and processing errors in the early stages of PDPM implementation. A few commenters requested that CMS consider convening a stakeholder workgroup to review data derived from the aforementioned monitoring activities and consider ways of sharing the data collected with stakeholders.

Response: We agree with commenters that close, real-time monitoring will be essential once PDPM is implemented. We are developing a robust monitoring program that will incorporate data from patient assessments, claims, cost reports, and quality measurement programs to identify any adverse or positive trends associated with PDPM implementation. With respect to sharing this data or convening a stakeholder workgroup, we are still in the process of determining the best way to share the data collected during our monitoring activities and the best way to engage with stakeholders to ensure a collective understanding of the data collected.

Regarding contingency plans for any issues in assessment or claims submission and/or processing after PDPM is implemented, CMS and its contractors intend to put adequate risk mitigation strategies in place to identify potential risk areas pre-emptively and ensure adequate testing to eliminate such risk. If any issues are identified after PDPM is implemented, we request that stakeholders alert us as soon as possible, so that the issue can be addressed.

Comment: A few commenters requested that CMS finalize the Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies proposed rule (80 FR 68126–68155), to ensure that hospitals provide SNFs with the necessary medical records and documentation used for both care planning and coding purposes in as timely a manner as possible. These commenters stated that the lack of such information represents a potentially serious program risk, as they often do not have the hospital information in as timely a manner as necessary for capturing such information on the MDS.

Response: We appreciate this comment and have shared with the appropriate CMS staff responsible for the proposed rule referenced above.

B. SNF PPS Rate Setting Methodology and FY 2020 Update

1. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we revised and rebased the market basket index, which included updating the base year from FY 2010 to 2014.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.2.d. of this final rule. For the FY 2020 proposed rule, the growth rate of the 2014-based SNF market basket was estimated to be 3.0 percent, based on the IHS Global Insight, Inc. (IGI) first quarter 2019 forecast with historical data through fourth quarter 2018, before the multifactor productivity adjustment is applied. However, as discussed in the FY 2020 proposed rule (84 FR 17624), our policy is that if more recent data become available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule. Since the proposed rule, we have updated the FY 2020 market basket percentage increase based on the IGI second quarter 2019 forecast, with historical data through first quarter 2019. The revised SNF market basket growth rate based on this updated data is 2.8 percent.

In section III.B.2.e. of this final rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

b. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2020. This factor is based on the FY 2020 percentage increase in the 2014-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. In this final rule, the SNF market basket percentage is estimated to be 2.8 percent for FY 2020 based on IGI's second quarter 2019 forecast (with historical data through first quarter 2019). Finally, as discussed in section II.B.2. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2018 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.6 percentage points, and the actual increase for FY 2018 is 2.6 percentage points, resulting in the actual increase being the same as the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 2.8 percent would not be adjusted to account for the forecast error correction. Table 2 shows the forecasted and actual market basket amounts for FY 2018.

TABLE 2—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2018

Index	Forecasted FY 2018 increase *	Actual FY 2018 increase **	FY 2018 difference
SNF	2.6	2.6	0.0

* Published in **Federal Register**; based on second quarter 2017 IGI forecast (2014-based index).
** Based on the second quarter 2019 IGI forecast, with historical data through the first quarter 2019 (2014-based index).

d. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the multifactor productivity (MFP) adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period). The Bureau of Labor Statistics

(BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

(1) Incorporating the MFP Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

In the FY 2020 proposed rule, the MFP adjustment, calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2020, was estimated to be 0.5 percent based on IGI's first quarter 2019 forecast. However, in the FY 2020 proposed rule (84 FR 17624), we stated that if more recent data became available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the final rule. Since that time, we have updated the FY 2020 MFP adjustment based on the IGI second quarter 2019 forecast. The revised MFP adjustment based on updated data is 0.4 percent.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), the market basket percentage for FY 2020 for the SNF PPS is based on IGI's second quarter 2019 forecast of the SNF market basket percentage, which is estimated to be 2.8 percent. In accordance with section 1888(e)(5)(B)(ii) of the Act and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment which, as discussed above, is 0.4 percent. The resulting MFP-adjusted SNF market basket update is equal to 2.4 percent, or 2.8 percent less 0.4 percentage point.

e. Market Basket Update Factor for FY 2020

Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(i) of the Act require that the update factor used to establish the FY 2020 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2018, through September 30, 2019 to the average market basket level for the period of October 1, 2019, through September 30, 2020. This process yields a percentage change in the 2014-based SNF market basket of 2.8 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the difference between the forecasted FY 2018 SNF market basket percentage change and the actual FY 2018 SNF market basket percentage change (FY 2018 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2020 market basket percentage change of 2.8 percent is not adjusted by the forecast error correction.

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (10-year moving average of changes in MFP for the period ending September 30, 2020) which is 0.4 percent, as described in section III.B.2.d. of this final rule. The resulting net SNF market basket update would equal 2.4 percent, or 2.8 percent less the 0.4 percentage point MFP adjustment.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than 0.0 for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only with respect to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

As discussed above and in the proposed rule, we proposed to apply the FY 2020 SNF market basket increase factor of 2.5 percent in our determination of the FY 2020 SNF PPS unadjusted federal per diem rates, which reflected a market basket increase factor of 3.0 percent, less a 0.5 percentage point MFP adjustment. However, as noted previously in this final rule, based on updated data, we are revising the FY 2020 SNF market basket update factor used in our determination

of the FY 2020 SNF PPS unadjusted federal per diem rates, to 2.4 percent, which reflects a revised market basket percentage increase of 2.8 percent, less the revised 0.4 percentage point MFP adjustment.

We did not receive any comments regarding the calculation of the SNF market basket percentage increase or the MFP adjustment. Accordingly, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing the SNF market basket update factor of 2.4 percent, which reflects the updated SNF market basket percentage increase of 2.8 percent less the updated MFP adjustment of 0.4 percentage point.

f. Unadjusted Federal per Diem Rates for FY 2020

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), we are implementing a new case-mix classification system to classify SNF patients under the SNF PPS, beginning in FY 2020, called the Patient Driven Payment Model (PDPM). As discussed in section V.B of that final rule, under PDPM, the unadjusted federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as exists under RUG–IV. In calculating the FY 2020 unadjusted federal per diem rates that would be used under PDPM in FY 2020, we applied the FY 2020 MFP-adjusted market basket increase factor to the unadjusted federal per diem rates provided in Tables 4 and 5 of the FY 2019 SNF PPS final rule (83 FR 39169) and then applied the methodology for separating the RUG–IV base rates into the PDPM base rates, as discussed and finalized in section V.B.3 of the FY 2019 SNF PPS final rule (83 FR 39191 through 39194).

Tables 3 and 4 reflect the updated unadjusted federal rates for FY 2020, prior to adjustment for case-mix.

TABLE 3—FY 2020 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$60.75	$56.55	$22.68	$105.92	$79.91	$94.84

TABLE 4—FY 2020 UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$69.25	$63.60	$28.57	$101.20	$76.34	$96.59

Commenters submitted the following comments related to the proposed rule's discussion of the Unadjusted Federal Per Diem rates for FY 2020. A discussion of these comments, along with our responses, appears below.

Comment: We received a number of comments in relation to applying the FY 2020 SNF market basket update factor in the determination of the FY 2020 unadjusted federal per diem rates, with most commenters supporting its application in determining the FY 2020 unadjusted per diem rates, while a few commenters opposed its application. In their March 2019 report (available at *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf*) and in their comment on the FY 2020 SNF PPS proposed rule, MedPAC recommended that we eliminate the market basket update for SNFs altogether for FY 2020.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2020. In response to those comments opposing the application of the FY 2020 market basket update factor in determining the FY 2020 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs, we are required to update the unadjusted federal per diem rates for FY 2020 by the SNF market basket percentage change in accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act.

Comment: Several commenters raised concerns regarding the calculation of the proposed unadjusted federal per diem rates. These commenters believe that the unadjusted federal per diem rates were calculated using an increase factor greater than the proposed 2.5 percent and requested clarification on exactly how the unadjusted federal per diem rates for FY 2020 were calculated.

Response: We appreciate the commenters highlighting this concern regarding the calculation of the unadjusted federal per diem rates for FY 2020, but we believe the commenters did not account for the effect of an additional factor used in calculating the FY 2020 unadjusted federal per diem rates.

As discussed in the FY 2020 proposed rule (84 FR 17630), section 1888(e)(4)(G)(ii) of the Act requires that we apply the wage index adjustment in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. To accomplish this, as in prior years, we multiply each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2019 to the weighted average wage adjustment factor for FY 2020. In the FY 2020 proposed rule, this wage adjustment budget neutrality factor was 1.0060. As noted below, due to an update in the data used for this calculation, this adjustment factor has been revised to be 1.0002.

Comment: One commenter raised concerns with how the base rates used under the SNF PPS, which have been adjusted by the SNF market basket each year, are based on cost reports from 1995. The commenters requested that CMS update the cost reporting base year used in deriving the unadjusted federal rates.

Response: We appreciate the commenter's suggestion regarding updating the cost reporting base year used for deriving the unadjusted federal per diem rates. However, section 1888(e)(4)(A) of the Act requires that we use the ''allowable costs of extended care services (excluding exception payments) for the facility for cost reporting periods beginning in 1995.'' As such, we do not have the statutory authority to update the cost reporting base year used to derive the SNF PPS federal per diem rates.

Comment: Two commenters requested that CMS consider a cost of living adjustment, or COLA, for Hawaii and Alaska, stating that the absence of a COLA differentiates SNFs from hospitals, which do receive a COLA on non-labor costs. These commenters stated that providing care in these states is more expensive than others due to their unique circumstances.

Response: While the law specifically authorizes a COLA for Hawaii and Alaska for hospitals, it does not provide such an adjustment for SNFs in these states. Specifically, section 1886(d)(5)(H) of the Act authorizes the Secretary to make appropriate adjustments to reflect the unique circumstances of *hospitals* located in Alaska and Hawaii.

Accordingly, after considering the comments received, for the reasons specified in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing the unadjusted federal per diem rates set forth above, which were derived in accordance with the methodology proposed in the FY 2020 SNF PPS proposed rule (84 FR 17624 through 17625) (as discussed above), using the revised SNF market basket update of 2.4 percent and the revised wage index budget neutrality factor of 1.0002 (as discussed later in this preamble).

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, to take effect beginning October 1, 2019. The RUG–IV model classifies most patients into a therapy payment group and primarily uses the volume of therapy services provided to the patient as the basis for payment classification, thus inadvertently creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS. As discussed in section III.C.1. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html*.

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2020 payment rates set forth in this final rule reflect the use of the PDPM case-mix classification system from October 1, 2019, through September 30, 2020. In the FY 2020 SNF PPS proposed rule (84 FR 17627 through 17628), we listed the proposed case-mix adjusted PDPM payment rates for FY 2020, provided separately for urban and rural SNFs, in Tables A6 and A7 with corresponding case-mix values.

As discussed in the FY 2019 SNF PPS final rule (83 FR 39255 through 39256), we finalized the implementation of PDPM in a budget neutral manner. To accomplish this, as discussed in the FY 2019 SNF PPS final rule (83 FR 39256), the unadjusted PDPM case mix indexes (CMIs) were multiplied by 1.46 so that the total estimated payments under the PDPM would be equal to the total actual payments under RUG–IV. Further, section 3.11.2 of the PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/PDPM_Technical_Report_508.pdf*, provided additional detail on the calculation of the PDPM CMIs in order to achieve budget neutrality. In that section, it states that ''to align the distribution of resources across components with the statutory base rates, Acumen set CMIs such that the average product of the CMI and the variable per diem adjustment factor for a day of care is the same (set to 1) for each of the five case-mix-adjusted components in PDPM. To do this, Acumen first calculated the product of the CMI and the adjustment factor for every utilization day for each component. Then, we calculated the average of this product for each component. Finally, Acumen calculated the ratio of 1 divided by the average product for each component. This ratio is the standardization multiplier.'' As discussed in section 3.11.2 of the PDPM Technical Report, the standardization multiplier is used to align the distribution of resources across components with the statutory base rates by setting the CMIs such that the average product of the component CMI and the variable per diem adjustment factor for that component for a day of care is the same. Effectively, the standardization multiplier is used to mitigate the effect of the variable per diem adjustment when calculating budget neutrality. The CMIs were adjusted such that total payments under PDPM, if it had been in effect in FY 2017, equal total actual payments made under RUG–IV in FY 2017.

In the proposed rule, we proposed to update the payment year used as the basis for the calculation of the standardization multiplier and budget neutrality multiplier, in order to best ensure that PDPM will be implemented in a budget neutral manner, as finalized in the FY 2019 SNF PPS Final Rule. We stated in the proposed rule that the only difference in methodology between that used to calculate these multipliers and CMIs in the FY 2019 SNF PPS final rule and that used to calculate the multipliers and CMIs in the proposed rule is that, in the proposed rule, we updated the data used from FY 2017 data to FY 2018 data. The impact of using the updated FY 2018 data and the proposed updated adjustment multipliers for standardization and budget neutrality, was provided in Table 5 of the proposed rule (84 FR 17626). We note that while the multipliers discussed in the FY 2019 SNF PPS final rule and in the PDPM Technical Report are given to the hundredths place, in order to make clear the effect of this change in data, the multipliers in Table 5 are shown to the thousandths place. The standardization

and budget neutrality multipliers for this final rule are set forth in Table 5.

TABLE 5—PDPM STANDARDIZATION AND BUDGET NEUTRALITY MULTIPLIERS

Component	FY 2017 data		FY 2018 data	
	Standardization multiplier	Budget neutrality multiplier	Standardization multiplier	Budget neutrality multiplier
PT	1.031	1.458	1.028	1.463
OT	1.030	1.458	1.028	1.463
SLP	0.995	1.458	0.996	1.463
Nursing	0.995	1.458	0.996	1.463
NTA	0.817	1.458	0.811	1.463

We did not receive any comments regarding our proposed calculation of the PDPM standardization and budget neutrality multipliers. Accordingly, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing the standardization and budget neutrality multipliers, as proposed, without modification, calculated based on FY 2018 data as set forth in Table 5. The CMIs provided in Tables 6 and 7 of this final rule reflect the use of the final multipliers in Table 5, which are based on FY 2018 data.

We stated in the proposed rule that given the differences between RUG–IV and PDPM in terms of patient classification and billing, it was important that the format of Tables 6 and 7 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim in order to bill for covered SNF services. Under RUG–IV, the HIPPS code includes the three character RUG–IV group into which the patient classifies as well as a two character assessment indicator code that represents the assessment used to generate this code. Under PDPM, while providers would still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Therefore, we stated in the proposed rule that we were modifying the format of Tables A6 and A7 from what we have used for similar tables in prior SNF PPS rulemaking, such as Tables A6 and A7 of the FY 2019 SNF PPS final rule (83 FR 39170 through 39172). We stated in the proposed rule that Column 1 of modified Tables A6 and A7 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group. We received no comments on the revised format of these tables.

Tables A6 and A7 reflect the final PDPM case-mix adjusted rates and case-mix indexes for FY 2020.Tables A6 and A7 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section III.E.1. of this final rule, or the SNF VBP program, discussed in section III.E.2. of this final rule, or other adjustments, such as the variable per diem adjustment. Further, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility.

TABLE 6—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.53	$92.95	1.49	$84.26	0.68	$15.42	ES3	4.06	$430.04	3.24	$258.91
B	1.70	103.28	1.63	92.18	1.82	41.28	ES2	3.07	325.17	2.53	202.17
C	1.88	114.21	1.69	95.57	2.67	60.56	ES1	2.93	310.35	1.84	147.03
D	1.92	116.64	1.53	86.52	1.46	33.11	HDE2	2.40	254.21	1.33	106.28
E	1.42	86.27	1.41	79.74	2.34	53.07	HDE1	1.99	210.78	0.96	76.71
F	1.61	97.81	1.60	90.48	2.98	67.59	HBC2	2.24	237.26	0.72	57.54
G	1.67	101.45	1.64	92.74	2.04	46.27	HBC1	1.86	197.01	.....	.....
H	1.16	70.47	1.15	65.03	2.86	64.86	LDE2	2.08	220.31	.....	.....
I	1.13	68.65	1.18	66.73	3.53	80.06	LDE1	1.73	183.24	.....	.....
J	1.42	86.27	1.45	82.00	2.99	67.81	LBC2	1.72	182.18	.....	.....
K	1.52	92.34	1.54	87.09	3.70	83.92	LBC1	1.43	151.47	.....	.....
L	1.09	66.22	1.11	62.77	4.21	95.48	CDE2	1.87	198.07	.....	.....

TABLE 6—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN—Continued

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
M	1.27	77.15	1.30	73.52			CDE1	1.62	171.59		
N	1.48	89.91	1.50	84.83			CBC2	1.55	164.18		
O	1.55	94.16	1.55	87.65			CA2	1.09	115.45		
P	1.08	65.61	1.09	61.64			CBC1	1.34	141.93		
Q							CA1	0.94	99.56		
R							BAB2	1.04	110.16		
S							BAB1	0.99	104.86		
T							PDE2	1.57	166.29		
U							PDE1	1.47	155.70		
V							PBC2	1.22	129.22		
W							PA2	0.71	75.20		
X							PBC1	1.13	119.69		
Y							PA1	0.66	69.91		

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.53	$105.95	1.49	$94.76	0.68	$19.43	ES3	4.06	$410.87	3.24	$247.34
B	1.70	117.73	1.63	103.67	1.82	52.00	ES2	3.07	310.68	2.53	193.14
C	1.88	130.19	1.69	107.48	2.67	76.28	ES1	2.93	296.52	1.84	140.47
D	1.92	132.96	1.53	97.31	1.46	41.71	HDE2	2.40	242.88	1.33	101.53
E	1.42	98.34	1.41	89.68	2.34	66.85	HDE1	1.99	201.39	0.96	73.29
F	1.61	111.49	1.60	101.76	2.98	85.14	HBC2	2.24	226.69	0.72	54.96
G	1.67	115.65	1.64	104.30	2.04	58.28	HBC1	1.86	188.23		
H	1.16	80.33	1.15	73.14	2.86	81.71	LDE2	2.08	210.50		
I	1.13	78.25	1.18	75.05	3.53	100.85	LDE1	1.73	175.08		
J	1.42	98.34	1.45	92.22	2.99	85.42	LBC2	1.72	174.06		
K	1.52	105.26	1.54	97.94	3.70	105.71	LBC1	1.43	144.72		
L	1.09	75.48	1.11	70.60	4.21	120.28	CDE2	1.87	189.24		
M	1.27	87.95	1.30	82.68			CDE1	1.62	163.94		
N	1.48	102.49	1.50	95.40			CBC2	1.55	156.86		
O	1.55	107.34	1.55	98.58			CA2	1.09	110.31		
P	1.08	74.79	1.09	69.32			CBC1	1.34	135.61		
Q							CA1	0.94	95.13		
R							BAB2	1.04	105.25		
S							BAB1	0.99	100.19		
T							PDE2	1.57	158.88		
U							PDE1	1.47	148.76		
V							PBC2	1.22	123.46		
W							PA2	0.71	71.85		
X							PBC1	1.13	114.36		
Y							PA1	0.66	66.79		

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2020, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, unadjusted for occupational mix and the rural floor, as the basis for the SNF PPS wage index. For FY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (FY 2016 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. As discussed in

greater detail later in this section, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible at this time.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2020 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we stated we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2020, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we stated we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we stated we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2020, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

We note that after the publication of the FY 2020 SNF PPS proposed rule, we were made aware of a minor calculation error in the file used to compute the SNF wage index values. Specifically, the wage and hour data for CBSA 31084 were inadvertently doubled. This caused an error in the national average hourly wage, which factors into the calculation of all wage index values. We have changed the programming logic to correct this error. In addition, we corrected the classification of one provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency. The correction to the proposed rule wage index data was not completed until after the comment period closed on June 18, 2019. This final rule reflects the corrected and updated wage index. The final wage index applicable to FY 2020 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300). As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we wish to note that this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index.

We stated in the proposed rule that, once calculated, we would apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2020. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2020 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2020 in four steps. First, we compute the FY 2020 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2020 price index level for that cost category by the total market basket price index level. Third, we determine the FY

2020 relative importance for each cost category by multiplying this ratio by the base year (2014) weight. Finally, we add the FY 2020 relative importance for each of the labor-related cost categories (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related services, and a portion of Capital-Related expenses) to produce the FY 2020 labor-related relative importance.

In the FY 2020 SNF PPS proposed rule, the labor-related share calculation was based on IGI's first quarter 2019 forecast with historical data through fourth quarter 2018. However, as discussed in the FY 2020 SNF PPS proposed rule (84 FR 17624), our policy is if more recent data become available (for example, a more recent estimate of the 2014-based SNF market basket or MFP adjustment), we would use such data, if appropriate, to determine the FY 2020 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the final rule. Since that time, we revised the FY 2020 labor-related share calculation to reflect the IGI second quarter 2019 forecast, with historical data through first quarter 2019. Table 8 summarizes the final, revised labor-related share for FY 2020, based on the updated data, compared to the labor-related share that was used for the FY 2019 SNF PPS final rule.

TABLE 8—LABOR-RELATED RELATIVE IMPORTANCE, FY 2019 AND FY 2020

	Relative importance, labor-related, FY 2019 18:2 forecast [1]	Relative importance, labor-related, FY 2020 19:2 forecast [2]
Wages and salaries	50.2	50.6
Employee benefits	10.1	10.0
Professional Fees: Labor-Related	3.7	3.7
Administrative and facilities support services	0.5	0.5
Installation, Maintenance and Repair Services	0.6	0.6
All Other: Labor Related Services	2.5	2.6
Capital-related (.391)	2.9	2.9
Total	70.5	70.9

[1] Published in the **Federal Register**; based on second quarter 2018 IGI forecast.
[2] Based on second quarter 2019 IGI forecast, with historical data through first quarter 2019.

In the proposed rule (84 FR 17630), we stated that in order to calculate the labor portion of the case-mix adjusted per diem rate, we would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2020 labor-related share percentage provided in Table 8. The remaining portion of the rate would be the non-labor portion. In prior years, we have included tables which provide the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the proposed rule (84 FR 17630), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that have existed in prior rulemaking.

Therefore, to aid stakeholders in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a revised hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2020 (federal rates effective October 1, 2019), we would apply an adjustment to fulfill the budget neutrality requirement. We would meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2019 to the weighted average wage adjustment factor for FY 2020. For this calculation, we would use the same FY 2018 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component.

We note that in the FY 2020 SNF PPS proposed rule, the budget neutrality factor calculation was based on the wage and cost data available at the time of the proposed rule. As a result of correcting the wage index error discussed above, the budget neutrality factor that was calculated for the proposed rule has been revised. The proposed FY 2020 budget neutrality factor was 1.0060. The revised and final FY 2020 budget neutrality factor, which was used in calculating the final unadjusted FY 2020 federal per diem rates, is 1.0002.

Commenters submitted the following comments related to our proposed calculation of the SNF wage index. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters raised concerns with the use of the inpatient hospital wage index in lieu of a SNF-specific wage index. These commenters provided suggested revisions to the manner in which CMS uses the inpatient hospital wage index under the SNF PPS. One commenter suggested that CMS apply the average state wage index in areas where all of the hospitals within that CBSA have been reclassified under the hospital wage index to a different CBSA, similar to how the average wage index is used in areas where no hospitals exist within a CBSA. A few commenters suggested that CMS consider modifying the current hospital wage data that are used to construct the SNF PPS wage index, in order to reflect more closely the SNF environment, by trimming hospital wage data to reflect positions staffed in nursing homes, as well as using an occupational mix adjustment specific to SNFs and/or rural

floor under the SNF PPS. A few commenters also requested that CMS develop a SNF-specific wage index, which would allow for the possibility of a reclassification methodology under the SNF PPS.

Response: We appreciate all of the suggestions and comments on the SNF PPS wage index. With regard to the suggestion that CMS develop a SNF-specific wage index, which would allow for the possibility of a reclassification methodology under the SNF PPS, as we discussed in the FY 2020 SNF PPS proposed rule (84 FR 17628) and in prior rules (most recently in the FY 2019 SNF PPS final rule (83 FR 39177 through 39178)), section 315 of BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, the development of a SNF-specific wage index has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. In addition, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible at this time. While we continue to review all available data and contemplate potential methodological approaches for a SNF-specific wage index in the future, we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS.

With regard to those comments on modifying the current hospital wage data that are used to construct the SNF PPS wage index, in order to reflect more closely the SNF environment, by trimming hospital wage data to reflect positions staffed in nursing homes, applying an occupational mix adjustment, and other such suggestions, we believe it would be appropriate to consider such changes in future rulemaking. However, while we consider whether or not such approaches would improve the SNF PPS wage index, we would note that other provider types also use the hospital wage index as the basis for their associated wage index. As such, we believe that such a recommendation should be part of a broader discussion on wage index reform across Medicare payment systems.

With regard to using an occupational mix adjustment for the SNF PPS wage index, as discussed above and in the FY 2020 SNF PPS proposed rule (84 FR 17628), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the hospital occupational wage data excludes any wage data related to SNFs. Therefore, we believe that using the updated hospital wage data exclusive of the IPPS occupational mix adjustment continues to be appropriate for SNF payments. With regard to developing a SNF-specific occupational mix adjustment, we appreciate this suggestion and may consider this in future rulemaking.

With regard to implementing a rural floor under the SNF PPS, we do not believe it would be prudent at this time to adopt such a policy, particularly because MedPAC has recommended eliminating the rural floor policy from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://www.medpac.gov/docs/default-source/reports/mar13_ch03.pdf*, which notes on page 65 that, in 2007, MedPAC had recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b)). If we adopted the rural floor policy at this time, the SNF PPS wage index could become vulnerable to problems similar to those MedPAC identified in its March 2013 Report to Congress.

Finally, with regard to the suggestion that CMS use the average state wage index for areas where all of the hospitals within a CBSA have reclassified under the IPPS out of the CBSA to a different CBSA, we believe that such circumstances are different from those in which there are no hospitals located within the CBSA, specifically CBSA 25980, Hinesville-Fort Stewart, GA, where we use the average wage index for all urban areas in the state. In the circumstance where all hospitals in a CBSA have reclassified under the IPPS to a different CBSA, there still are hospitals geographically located in the CBSA and we would have hospital data for the associated CBSA, even if the hospitals subsequently reclassify out of the CBSA. Therefore, we would have data upon which to base our calculation of the SNF PPS wage index for that CBSA, and we think it would be appropriate to use that data to determine the SNF PPS wage index as we do in other CBSAs.

After consideration of the comments received, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing, without modification, our proposed policies discussed above relating to the wage index and the labor-related share. The final wage index applicable to FY 2020 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

5. Wage Index Comment Solicitation

As discussed above, historically, we have calculated the SNF PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the SNF PPS wage index values and their impact on payments. In the FY 2020 SNF PPS proposed rule, we solicited comments on concerns stakeholders may have regarding the wage index used to adjust SNF PPS payments and suggestions for possible updates and improvements to the geographic adjustment of SNF PPS payments.

Commenters submitted the following comments related to the wage index comment solicitation. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters raised concerns with the wage index related proposals contained in the FY 2020 Inpatient Prospective Payment System proposed rule, specifically the proposal related to those hospitals whose wage indexes are in the bottom 25 percent of all wage index values. Several commenters also raised issues with the manner in which the hospital wage index was calculated. These commenters also highlighted discrepancies between the SNF PPS wage index values posted on the CMS

website and those calculated using public use files made available by CMS. A few commenters stated concerns with the improper exclusion of seven hospitals in California. One commenter stated that Part B wages should be removed from the calculation of the hospital wage index.

Response: We appreciate these comments on the inpatient hospital wage index and associated proposed changes and will pass these comments to our colleagues responsible for the hospital wage index. With respect to the highlighted discrepancies between the posted proposed SNF PPS wage index values and those calculated using the public use file, as stated above, there was a minor error in the file used to compute the proposed SNF wage index values. We have corrected this error in computing the SNF wage index values and payment rates for this final rule.

Comment: One commenter stated that CMS has the statutory authority to implement geographically-specific updates associated with rising state and/or regional minimum wage standards. The commenter requested that such updates be made at the Core-Based Statistical Area (CBSA) levels.

Response: With regard to rising minimum wage standards, we would note that such increases will likely be reflected in future data used to create the SNF wage index, as these changes to state minimum wage standards would be reflected in increased wages to SNF staff. Therefore, we already incorporate such standards into the calculation of the SNF PPS wage index to the extent that these standards have an impact on facility wages.

6. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section III.E.2. of this final rule for a further discussion of our policies for the SNF VBP Program.

7. Adjusted Rate Computation Example

The following tables provide examples generally illustrating payment calculations during FY 2020 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 43524), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 9 shows the adjustments made to the federal per diem rates (prior to application of any adjustments under the SNF QRP and SNF VBP programs as discussed above) to compute the provider's case-mix adjusted per diem rate for FY 2020, based on the patient's PDPM classification, as well as how the VPD adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 10 shows the adjustments made to the case-mix adjusted per diem rate from Table 9 to account for the provider's wage index. The wage index used in this example is based on the FY 2020 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*. Finally, Table 11 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 11 also includes the variable per diem (VPD) adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 11, SNF XYZ's total PPS payment for this particular patient's stay would equal $19,975.62.

TABLE 9—PDPM CASE-MIX ADJUSTED RATE COMPUTATION EXAMPLE

[Per diem rate calculation]

Component	Component group	Component rate	VPD adjustment factor	VPD adjustment rate
PT	TN	$89.91	1.00	$89.91
OT	TN	84.83	1.00	84.83
SLP	SH	64.86		64.86
Nursing	CBC2	164.18		164.18
NTA	NC	147.03	3.00	441.09
Non-Case-Mix		94.84		94.84
Total PDPM Case-Mix Adj. Per Diem				939.71

TABLE 10—WAGE INDEX ADJUSTED RATE COMPUTATION EXAMPLE

[PDPM wage index adjustment calculation]

HIPPS code	PDPM case-mix adjusted per diem	Labor portion	Wage index	Wage index adjusted rate	Non-labor portion	Total case mix and wage index adjustment rate
NHNC1	$939.71	$666.25	0.9839	$655.53	$273.46	$928.98

TABLE 11—ADJUSTED RATE COMPUTATION EXAMPLE

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage index adjusted per diem rate
1	3.0	1.0	$928.98
2	3.0	1.0	928.98
3	3.0	1.0	928.98
4	1.0	1.0	638.28
5	1.0	1.0	638.28
6	1.0	1.0	638.28
7	1.0	1.0	638.28
8	1.0	1.0	638.28
9	1.0	1.0	638.28
10	1.0	1.0	638.28
11	1.0	1.0	638.28
12	1.0	1.0	638.28
13	1.0	1.0	638.28
14	1.0	1.0	638.28
15	1.0	1.0	638.28
16	1.0	1.0	638.28
17	1.0	1.0	638.28
18	1.0	1.0	638.28
19	1.0	1.0	638.28
20	1.0	1.0	638.28
21	1.0	0.98	634.83
22	1.0	0.98	634.83
23	1.0	0.98	634.83
24	1.0	0.98	634.83
25	1.0	0.98	634.83
26	1.0	0.98	634.83
27	1.0	0.98	634.83
28	1.0	0.96	631.37
29	1.0	0.96	631.37
30	1.0	0.96	631.37
Total Payment	.....	.....	19,975.62

C. Additional Aspects of the SNF PPS

1. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in § 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to make changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix

classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the initial Medicare assessment (as discussed further in section III.D.3 of this final rule). Finally, regarding the new set of case-mix classifiers designated under the PDPM for this purpose, we noted in the FY 2019 SNF PPS final rule (83 FR 39252, August 8, 2018) our intent ''. . . to review the new designations going forward and make further adjustments over time as we gain actual operating experience under the new classification model.'' Accordingly, to the extent that it may become evident in actual practice that these new criteria are not accurately performing their intended role (for example, by capturing cases that do not actually require an SNF level of care), we would propose appropriate adjustments to correct them.

Commenters submitted the following comments related to the proposed rule's discussion of the administrative level of care presumption. A discussion of these comments, along with our responses, appears below.

Comment: Commenters expressed support for CMS' intent to ''review the new designations going forward and make further adjustments over time as we gain actual operating experience under the new classification model'' (84 FR 17632). One commenter specifically endorsed CMS' longstanding position that under PDPM, SNFs are still required to make decisions related to level of care appropriately and in a timely manner and to monitor for changes in patients' conditions related to the continuing need for Part A SNF benefits after the assessment reference date of the initial assessment.

Response: We appreciate the support for our position, and note that our ongoing review of the administrative presumption will include careful monitoring of the newly-designated classifiers under the PDPM to ensure that they are not inappropriately capturing significant numbers of nonskilled cases in actual practice. In that context, we have repeatedly noted—most recently, in the FY 2019 SNF PPS final rule (83 FR 39251)—that the actual purpose of the level of care presumption has always been to afford a streamlined and simplified administrative procedure for readily identifying those beneficiaries with the *greatest likelihood* of meeting the level of care criteria that in no way serves to disadvantage *other* beneficiaries who may *also* meet the level of care criteria. Accordingly, in view of the presumption's intended role of identifying only the most *clearly qualified* cases, once a particular classifier has been found in actual practice to capture a significant number of *nonskilled* cases, we believe that it would be inappropriate to continue to designate such a classifier for use in triggering the coverage that the presumption provides.

2. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113, enacted November 29, 1999) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of the specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: They must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high

cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791). In the proposed rule, we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We stated in the proposed rule that we may consider excluding a particular service if it meets our criteria for exclusion as specified above. We requested that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, we stated in the proposed rule that, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2019). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

Commenters submitted the following comments related to the proposed rule's discussion of consolidated billing. A discussion of these comments, along with our responses, appears below.

Comment: One commenter expressed support for the overall concept of consolidated billing, but cautioned that problems in its practical application can create difficulties for suppliers in obtaining payment for those services that are subject to this provision. The commenter noted that when a MAC denies separate payment to a supplier for a bundled SNF service, the denial notice may not specify the particular SNF involved; even after the supplier has identified the SNF in question, the latter may be reluctant to pay the supplier, especially if the SNF itself did not directly order the service. The commenter suggested that the consolidated billing edits should deny separate payment to the supplier only for those services that are directly ordered by the practitioner who is responsible for the patient in the SNF.

Response: Sections 1862(a)(18) and 1866(a)(1)(H)(ii) of the Act specifically require the SNF itself to be responsible for furnishing the *entire range* of covered SNF services (the bundled services)—either directly with its own resources, or under an ''arrangement'' with an outside supplier in which the supplier's payment would come from the SNF (rather than from Part B or the beneficiary). Further, as noted in Section 70.4 of the Medicare Benefit Policy Manual, Chapter 8 (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c08.pdf*), while

> . . . the specific details of the ensuing payment arrangement between the SNF and the outside supplier (such as the actual payment amount and timeframe) represent a private, ''marketplace'' transaction that is negotiated between the parties themselves . . . in order for the arrangement itself to be valid, the SNF must, in fact, make payment to its supplier for services rendered.

In that context, the Medicare Claims Processing Manual, Chapter 6 (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf*) discusses in Sections 10.4ff. the importance of establishing written agreements between SNFs and their suppliers—preferably *before* services are actually rendered—to ensure that both parties have arrived at a common understanding of the specific terms of payment and also to help resolve any disputes that may arise regarding them, and it describes some additional steps that both SNFs and suppliers can take to prevent problems from developing. For example, with reference to suppliers, Section 10.4.2 specifies that

> . . . prior to furnishing services to a Medicare beneficiary, the supplier should routinely ascertain whether the beneficiary is currently receiving any comprehensive Medicare benefits (such as SNF or home health benefits) for which Medicare makes a bundled payment that could potentially include the supplier's services. If the supplier ascertains that a particular beneficiary is, in fact, a resident of an SNF with which the supplier does not have a valid arrangement in place, then the supplier should contact the SNF before actually furnishing any services to that beneficiary that are subject to the consolidated billing provision.

Notwithstanding such precautions, if a supplier nevertheless continues to encounter difficulties either in identifying the particular SNF involved or in securing that SNF's compliance with the consolidated billing requirement, the supplier's appropriate contact at that point would be with its servicing MAC, which is responsible for providing technical assistance and support to the entities that it serves. In addition, the Medicare fee-for-service operations component of the servicing CMS Regional Office is available to assist as needed in helping to resolve such situations.

Comment: Commenters urged CMS to create an exclusion from consolidated billing for clotting factor and non-factor medication therapies for patients with hemophilia, similar to the existing exclusions for chemotherapy and its administration, radioisotope services, and certain customized prosthetic devices.

Response: We note that the item/service categories cited by the commenters (chemotherapy and its administration, radioisotope services, and certain customized prosthetic devices) are in statute at section 1888(e)(2)(A)(iii) of the Act (as enacted through section 103 of the BBRA). As we indicated previously in the FY 2012 SNF PPS final rule (76 FR 48531), hemophilia treatments are outside the particular service categories that the statute authorizes for exclusion, and establishing an exclusion category for hemophilia treatment services, or any other service categories that are not specified in the statute, would require legislation by Congress to amend this statutory provision. Thus, we decline to adopt the commenter's suggestion.

Comment: In terms of considering new chemotherapy drugs for exclusion, one commenter suggested that CMS should focus specifically on their cost, noting that such drugs do not always have their own HCPCS code. Another commenter expressed support for expanding the list of chemotherapy exclusions from consolidated billing as helping to ''ensure that life-saving treatment is not interoperated during a

patient's transition to sub-acute rehab,'' but suggested that ''rather than focusing on specific HCPCS for the expansion list,'' CMS should instead ''. . . set a dollar amount ceiling on Medicare *approved* chemotherapy medications and administration'' in order to ''. . . help reduce burden on providers and patients involved in this important care transition.'' Still another commenter reiterated a recommendation from previous years to exclude the oral chemotherapy drug REVLIMID®.

Response: We note that as enacted by section 103 of the BBRA, section 1888(e)(2)(A)(iii) of the Act does not authorize or provide for setting an overall cap on chemotherapy expenditures in this context, and instead establishes the existing approach of designating by HCPCS code those individual ''high-cost, low probability'' chemotherapy items and services that qualify for exclusion. Accordingly, as we noted previously in the FY 2016 SNF PPS final rule (80 FR 46407), we are unable to designate a chemotherapy drug for exclusion from consolidated billing prior to the point at which it is actually assigned its own J code. We further explained in the FY 2015 SNF PPS final rule (79 FR 45642) that

> . . . the assignment of such a code has been an essential element of identifying certain chemotherapy drugs for exclusion ever since the BBRA first created the statutory exclusion in 1999, as reflected in the drafting of the statutory provision itself as well as in our periodic solicitation of ''codes'' that might meet the criteria for exclusion.

Regarding the oral chemotherapy drug REVLIMID®, we note that this drug has been recommended for exclusion during several previous rulemaking cycles—most recently, in the one for FY 2019, when commenters recommended its exclusion along with three other Part-D-only oral chemotherapy drugs: ZYTIGA®, ERLEADA®, and GLEEVEC®. In the FY 2019 SNF PPS final rule (83 FR 39181 through 39182), we stated that because the particular drugs at issue here would not be covered under Part B, the applicable provisions at section 1888(e)(2)(A) of the Act may not provide a basis for excluding them from consolidated billing (emphasis added), but we also cited ''the need for further consideration of this issue.'' After further consideration, we continue to believe that the applicable provisions at section 1888(e)(2)(A) of the Act *do not* provide a basis for excluding Part-D-only chemotherapy drugs from consolidated billing. While the chemotherapy item exclusion itself (at section 1888(e)(2)(A)(iii)(II) of the Act) contains no language that would serve to restrict its scope to only those items that are payable under Part B, such restrictive language is, in fact, set forth more broadly in section 1888(e)(2)(A)(i) of the Act, which defines the ''covered skilled nursing facility services'' that are included in the SNF PPS per diem rate. Under section 1888(e)(1) of the Act, the payment for all costs of ''covered skilled nursing facility services'' furnished by a SNF is equal to (and thus included in) the SNF PPS adjusted per diem rate. Section 1888(e)(2)(A)(i) of the Act, in turn, defines the term ''covered skilled nursing facility services'' in subclause (I) as Part A post-hospital extended care services (SNF services) as defined in section 1861(i) of the Act, and in subclause (II) as ''all items and services (other than items and services described in clauses (ii), (iii), and (iv)) *for which payment may be made under Part B*'' and which are furnished during the course of a Medicare-covered SNF stay (emphasis added). Accordingly, while therapeutic drugs such as the ones at issue here would fall within the scope of the Part A SNF bundle as referenced in subclause (I) above, the only items and services that potentially could be carved out from that bundle under subclause (II) above would be those that otherwise would be separately payable *under Part B.* Further, as noted in the FY 2019 SNF PPS final rule (83 FR 39181), while section 1861(s)(2)(Q) of the Act does include a specific Part B benefit category for oral chemotherapy drugs, coverage under that benefit is restricted to those with the same indication and active ingredient(s) as a covered non-oral anti-cancer drug, which is not the case for the specific drugs in question. Moreover, as noted in the FY 2006 SNF PPS final rule (70 FR 45049), expanding the existing statutory drug coverage available under Part B to include such drugs is not within our authority. In this context, we further note that section 410 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003)—the same legislation that created the Part D drug benefit—also amended section 1888(e)(2)(A) of the Act by adding a new subclause (iv) that excluded certain Part B Rural Health Clinic and Federally Qualified Health Center services from consolidated billing. At the same time, the accompanying legislative history (House Ways and Means Comm. Rep. No. 108–178, Part 2 at 209) specifically *reaffirmed* the Part-B-only nature of the consolidated billing exclusions by noting that ''Certain services and items provided a SNF resident . . . are excluded from the SNF PPS and paid separately *under Part B*'' (emphasis added). Similar language also appears in the MMA's Conference Report (H. Conf. Rep. No. 108–391 at 640–41). Finally, it is also worth bearing in mind in this context that the PDPM will introduce for the first time a separate SNF payment component specifically for non-therapy ancillary (NTA) services. As we noted in the FY 2019 SNF PPS final rule (83 FR 39180), in accounting more accurately for the costs of NTA services such as drugs, the PDPM model has the potential to ameliorate some of the concerns about the adequacy of payment for drugs furnished in the SNF setting.

3. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment in order to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *http://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.

A commenter submitted the following comment related to the proposed rule's discussion of payment for SNF-level swing-bed services. A discussion of that comment, along with our response, appears below.

Comment: One commenter suggested that exempting the swing-bed services of CAHs from the SNF PPS creates a discrepancy in payment for comparable services between the CAH and any area SNFs which are not so exempted, to the SNF's disadvantage. The commenter urged CMS to seek statutory authority either to pay for CAH swing-bed services under the SNF PPS, or to adjust Medicare payments for those rural SNFs located in the same geographic area as a swing-bed CAH.

Response: We note that as originally enacted in section 4432 of the BBA 1997, the SNF PPS applied uniformly to *all* providers of extended care services under Part A, including SNFs themselves along with swing-bed CAHs as well as rural (non-CAH) swing-bed hospitals. However, the Congress subsequently enacted legislation in section 203 of the BIPA that specifically excluded swing-bed CAHs from the SNF PPS (see § 1888)(e)(7)(C) of the Act), thus establishing that swing-bed CAHs are to be exempted from the SNF PPS while leaving this payment methodology in place for the other facilities, including rural SNFs. Accordingly, CMS cannot adjust Medicare payments for rural SNFs located in the same geographic area as a swing-bed CAH to provide for similar payments.

D. Issues Relating to PDPM Implementation

1. Revised Group Therapy Definition

As set forth in the FY 2019 SNF PPS final rule (83 FR 39162), effective October 1, 2019 under the PDPM, patients will be classified into case-mix groups under each therapy component based on patient characteristics rather than using the volume of therapy services furnished to the patient as the basis for classification. Additionally, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39243), we finalized a combined limit on concurrent and group therapy furnished to a patient, specifically that, for each therapy discipline, no more than 25 percent of the therapy services furnished to a patient in a covered Medicare Part A stay may be in a group or concurrent setting. Given these policy changes relating to therapy classification and therapy provision under the PDPM, as well as recent efforts to increase standardization across PAC settings, we believed it was appropriate to evaluate other policies associated with therapy under PDPM to determine if other policies should be revised as well.

In the FY 2012 SNF PPS final rule (76 FR 48511 through 48517), we finalized changes relating to the definition of group therapy and payment of group therapy services, specifically to define group therapy as the practice of one therapist or therapy assistant treating four patients at the same time while the patients are performing either the same or similar activities. In the FY 2012 SNF PPS final rule (76 FR 48511), we noted that, using our STRIVE data as a baseline, we identified under RUG–IV two significant changes in provider behavior related to the provision of therapy services to Medicare beneficiaries in SNFs. First, we saw a major decrease in the amount of concurrent therapy (that is, therapy provided to two patients by one therapist or therapy assistant doing different activities) performed in SNFs, the minutes for which are divided between the two concurrent therapy participants when determining the patient's appropriate RUG classification. At the same time, we found a significant increase in the amount of group therapy services, which were not subject to the allocation requirement. Given this increase in group therapy services, we expressed concern that the method for reporting group therapy on the MDS created an inappropriate payment incentive to perform the group therapy in place of individual therapy, because the method of reporting group therapy time did not require allocation among patients.

As we stated in the FY 2012 SNF PPS final rule (76 FR 48511), because in group therapy, patients are performing similar activities, in contrast to concurrent therapy, group therapy gives patients the opportunity to benefit from each other's therapy regimen by observing and interacting with one another and applying the lessons learned from others to one's own therapy program in order to progress. At that time, we stated that large groups, such as those of five or more participants, can make it difficult for the participants to engage with one another over the course of the session. In addition, we have long believed that individual therapists could not adequately supervise large groups, and since the inception of the SNF PPS in July 1998, we have capped the number of residents at four. Furthermore, we believed that groups of fewer than four participants did not maximize the group therapy benefit for the participants. As we stated in the FY 2012 final rule (76 FR 48511), we believed that in groups of two or three participants, the opportunities for patients in the group to interact and learn from each other are significantly diminished given the small size of the group. Thus, we revised the definition of group therapy to require a group size for the SNF setting of exactly four patients, which we believed was the size that permits the therapy participants to derive the maximum benefit from the group therapy setting.

Since that time, we have monitored group therapy utilization and found that, as discussed in the FY 2019 SNF PPS final rule (83 FR 39237 through 39238), group therapy represents a very small proportion of therapy provided to SNF patients. Further, as discussed in the FY 2019 SNF PPS final rule (83 FR 39240 through 39241), some commenters suggested that we revise the definition of group therapy to include two to six participants doing the same or similar activities, as this would better align with the Inpatient Rehabilitation Facility (IRF) setting and allow increased flexibility so that patients in smaller SNFs, presumably where a group of exactly four patients may be difficult to attain, could utilize and benefit from group therapy. In our response to these comments, in the FY 2019 SNF PPS final rule (83 FR 39241), we stated that we may consider changing the definition of group therapy in future rulemaking.

In the past we stated our concern that a group that consisted of more than 4 participants would not allow for adequate supervision of each participant as well as cause difficulty for participants to engage with one another in the most effective way. Conversely, we maintained that a group of fewer than 4 participants would not allow for effective interaction to best achieve the goals of a group. For these reasons, we defined group therapy as exactly 4 participants. However, as we noted in the FY 2020 SNF PPS proposed rule (84 FR 17634), based on our review of the use of group therapy in the IRF and outpatient settings where the definition of group therapy is less restrictive than the current definition under the SNF PPS, we have found that therapists do seem capable of managing groups of various sizes. We stated that, based on this review, we believe therapists have the clinical judgment to determine whether groups of different sizes would clinically benefit their patients, which they should be able to demonstrate with adequate documentation. We stated in the proposed rule that patients can often

benefit from the psycho-social aspect of groups, and in some situations, a group of six participants is not too large to provide that benefit to participants. For example, a cooking activity which will provide very functional therapy for patients planning to return home can be done in a group of six that will enhance the patient's psycho-social experience in the SNF.

Alternatively, we stated that a group of 2–3 patients can be clinically useful for certain patients as well. For example, a group of 2–3 patients who have pragmatic language difficulties following a stroke or head injury could very well benefit from a small communication group to work on the social aspects of language together without the concern of distraction that a larger group might cause. Thus, we stated in the proposed rule that while we continue to maintain minimal concerns that some groups may be either too small or too large to allow for effective interaction, we believe that the potential clinical benefits of various size groups outweigh our concerns, and that it would be appropriate to allow therapists greater flexibility to perform therapy in groups of different sizes.

In light of our discussion above and the comments in the FY 2019 SNF PPS final rule, and to align the SNF PPS more closely with other settings, in the FY 2020 SNF PPS proposed rule (84 FR 17634), we proposed to adopt a new definition of group therapy for use under PDPM, effective October 1, 2019, as further discussed below. As discussed in the FY 2020 SNF PPS proposed rule, in an effort to support CMS' crosssetting initiatives under the IMPACT Act and Meaningful Measures Initiative, we looked at ways to align the definition of group therapy used under the SNF PPS more closely with the definitions used within the outpatient setting covered under Medicare Part B and under the IRF PPS, as this type of standardization would reduce administrative burden on providers by utilizing the same or similar definitions across settings. For group therapy in the outpatient setting, the Medicare Benefit Policy Manual, Chapter 15, Section 230 states that contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (CPT code 97150). This manual section further states that the individuals can be, but need not be, performing the same activity. In addition, this section states that the physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required. Under the IRF PPS, the definition of group therapy (found in Section 2 of the IRF PAI Training Manual, *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/InpatientRehabFacPPS/Downloads/IRFPAI-1_5-2_0.zip*) is the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) treating two to six patients at the same time who are performing the same or similar activities.

As discussed in the FY 2020 SNF PPS proposed rule (84 FR 17634), we considered using the same definition as used in the outpatient setting covered under Medicare Part B, which is two or more patients performing either the same or different activity, as opposed to the IRF definition of two to six patients performing the same or similar activities. However, we stated that given the greater degree of similarity between the IRF and SNF settings in terms of the intensity of therapy and patient acuity, we believe that the IRF PPS definition would be more appropriate in the SNF setting. Thus, for the reasons discussed previously and in the FY 2020 SNF PPS proposed rule (84 FR 17634), we proposed to define group therapy in the SNF Part A setting as a qualified rehabilitation therapist or therapy assistant treating two to six patients at the same time who are performing the same or similar activities. We stated in the proposed rule that we believe this definition would offer therapists more clinical flexibility when determining the appropriate number for a group, without compromising the therapist's ability to manage the group and the patient's ability to interact effectively and benefit from group therapy.

In the FY 2020 SNF PPS proposed rule (84 FR 17635), we stated that we continue to believe that individual therapy is the preferred mode of therapy provision and offers the most tailored service for patients. As we stated in the FY 2012 proposed rule (76 FR 26387), while group therapy can play an important role in SNF patient care, group therapy is not appropriate for either all patients or for all conditions, and is primarily effective as a supplement to individual therapy, which we maintain should be considered the primary therapy mode and standard of care in therapy services provided to SNF residents. Additionally, we stated that we continue to maintain that when group therapy is used in a SNF, therapists must document its use in order to demonstrate why it is the most appropriate mode of therapy for the patient who is receiving it. As stated in the FY 2012 SNF PPS proposed rule (76 FR 26388) regarding group therapy documentation, because group therapy is not appropriate for either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

Commenters submitted the following comments related to the proposed rule's discussion of the Revised Group Therapy Definition. A discussion of these comments, along with our responses, appears below.

Comment: The majority of the comments received supported changing the definition of group therapy to treatment by a qualified therapist or therapy assistant of two to six patients at the same time who are performing the same or similar activities. Several commenters noted agreement that the increased flexibility afforded by the revised definition will offer therapists more clinical flexibility when determining what mode of therapy would best suit their patients. Other commenters stated that the revised definition would allow smaller SNFs with fewer patients to treat a smaller group in a therapy session (for example, two patients) and that they believe they were unable to provide this when group therapy was defined as four patients. Commenters approved of the standardization across post-acute care settings and appreciated the synchronization between the Inpatient Rehabilitation Facility (IRF) definition and the proposed SNF definition of group therapy. Additionally, one commenter pointed out that the increased latitude in the provision of group therapy will better allow patients to gradually progress from one-to-one

treatment into a family or community setting which better simulates a typical living environment and will better provide a transition model from the short term SNF stay. Several of the commenters who supported the proposal noted that individual therapy is still the most preferred mode of therapy to provide to SNF patients and expressed that although they were in agreement with the change in definition of group therapy, their support should not be conflated with any thought that individual therapy isn't the most appropriate mode of therapy.

Response: We are pleased that so many commenters supported the change to the definition of group therapy in the SNF setting. We agree that the increased flexibility for therapists to determine the appropriate number of patients in a group is appropriate and will allow therapists to better meet the clinical needs of their patients. Further, we believe that this change is a positive part of CMS' mission to reduce administrative burden on providers by utilizing the same or similar definitions across settings. We agree with the commenter who discussed that the ability to use different modes of therapy may better simulate real-life situations for many patients. We do, however, believe that, as with all clinical situations, there should not be a one-size-fits-all approach—which is entirely consistent with our emphasis on the critical importance of addressing each patient's specific condition and individualized treatment needs. While utilizing different modes of therapy may be a good way to transition some patients back to their home environments, it may be inappropriate for other patients. We continue to believe and agree with the commenters who stated that individual therapy is the most preferred mode of therapy to use in the SNF. While group therapy can play an important role in SNF patient care for certain patients or for certain conditions, it is primarily a supplement to individual therapy, and we continue to maintain that a therapist providing one-to-one care with his or her full attention on one patient should be considered the primary mode of therapy and standard of care.

Comment: One commenter requested further clarification regarding documentation requirements described in the proposed rule. This commenter questioned whether documentation requires a new plan of care to incorporate group therapy after an evaluation.

Response: We note that there are no new documentation requirements regarding group therapy. In the proposed rule, we simply reiterated existing CMS policy pertaining to documentation. As stated in the FY 2012 proposed rule (76 FR 26388) regarding group therapy documentation,

> . . . because group therapy is not appropriate for either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

If there is a change in the need for group therapy after a plan of care is completed, we would expect that this would be reflected in the medical record with whatever progress notes a facility requires to adequately capture the clinical status of a patient.

Comment: Many commenters discussed the increased value in providing all different modes of therapy (that is, individual, concurrent, and group therapy) to patients based on their different clinical needs. They believe that in the strictest sense, the definition of group therapy in the SNF setting is for payment purposes rather than clinical purposes and that ultimately clinicians should be the ones to determine which mode of therapy is in the best interest of each patient.

Response: We agree that the ability to provide different modes of therapy increases the possibility that patients will receive therapy that is most appropriate for their individual needs based on the sound clinical judgment of SNF therapists and therapy assistants. We also agree that clinicians should be the ultimate deciders of which mode of therapy is appropriate for each patient, but as we stated previously, we continue to maintain that individual therapy should be the primary mode of therapy and the standard of care for SNF patients. Furthermore, we believe the implementation of PDPM will bring with it incentives to provide less therapy in general because payment will no longer be based on the volume of service provided, and for the sake of patients and their needs, we have placed some limits on the size of the group to help assure that patients are not placed in groups that are too large and that patients continue to receive the individualized care that is the most appropriate for them. Thus, even though the proposed definition of group therapy is technically being used for payment purposes, the proposed definition is also based on clinical considerations, as we believe it is necessary to assure that patients are receiving the best clinical care possible.

Comment: Several commenters pointed out that because the definition of group therapy will change simultaneously with the implementation of PDPM, there cannot be a direct comparison between group therapy utilization under RUG–IV and group therapy under PDPM. They noted that, under RUG–IV, when the definition of group therapy was exactly four patients, it was possible that patients who might have benefitted from group therapy but whose sessions did not qualify for the strict definition would have received individual or concurrent therapy in its place. These commenters cautioned CMS against assuming a correlation between an increase in group therapy usage and the implementation of PDPM. Further, one commenter suggested that CMS delay the change in definition of group therapy for at least 3 years until the impact of the PDPM transition has been adequately monitored and analyzed.

Response: We recognize that the simultaneous implementation of PDPM and the change to the definition of group therapy means that it will be difficult to compare RUG–IV and PDPM in terms of the impact of the PDPM on group therapy utilization. However, we think it is important and appropriate to move forward with the change in definition. This change will benefit SNF patients by providing therapists with increased flexibility to determine the size of groups thereby enhancing the therapists' ability to accommodate the needs of different patients with different conditions. We do not believe a delay in implementation of the definition change is an appropriate solution. Given the significant behavioral changes that may be seen under PDPM, specifically a reduction in therapy provision generally and an increase in use of group therapy, we put in place several safeguards or monitoring mechanisms, such as the required PPS discharge assessment that will record the amount of therapy provided during a SNF stay as well as act as a tool that will calculate the percentage of group therapy provided. We continue to expect that therapists will use clinical judgment to determine the appropriate frequency, duration, and

modality of therapy services for SNF patients and will do so based on sound clinical reasoning and not financial motives. We also expect that these therapists will document the use of group therapy for each patient they treat in a group in a way that clearly shows that group therapy is the most appropriate mode of therapy to be used in each case. Finally, we plan to monitor closely how the provision of therapy changes under PDPM and may consider additional policy development in the future to address any adverse trends we identify.

Comment: Several commenters did not support the proposal to change the definition of group therapy. These commenters believe that this definition goes against the long held CMS belief that individual therapists cannot supervise large groups of patients and that small groups of two or three patients do not provide an adequate opportunity for patients to interact with each other to maximize the benefit of a group. This group of commenters urged CMS to keep the current definition of group therapy. These commenters also expressed concern that the revised definition of group therapy will incentivize SNFs to provide more group therapy, possibly to the detriment of their patients. In general, these commenters are concerned that with the PDPM changes, SNFs already have too many incentives to provide group therapy in place of individual therapy and that the change in the definition of group therapy is one more factor that will result in care decisions being made for financial reasons rather than clinical reasons. They stated that PDPM will incentivize SNFs to provide less therapy in general and the additional change to group therapy will inhibit SNFs from providing the individualized therapy that the majority of SNF patients require. These commenters requested that CMS closely monitor the 25 percent combined cap on group and concurrent therapy that will go into effect upon implementation of PDPM to protect patients from receiving inappropriate amounts of group and concurrent therapy and to consider adding a penalty to providers who do not comply with the limit.

Response: We appreciate the concern that the commenters expressed with regard to the change in definition of group therapy. We are aware that in the past, we maintained the position that large groups were difficult to supervise and could make it difficult for patients to engage with one another and that small groups did not offer adequate opportunity to effectively interact or maximize the benefit of the group. However, as we discussed in the FY 2020 SNF PPS proposed rule (84 FR 17634), we reviewed the usage of group therapy sizes in the IRF setting and we found that therapists are capable of using their clinical judgment to determine whether a group is too large or small and can manage groups of various sizes, and we expect therapists to adequately document the basis for their clinical decisions. Additionally, as we stated in the proposed rule, groups of various sizes can provide psycho-social benefits to patients, and thus we believe the increased flexibility provided to therapists to furnish therapy through different size groups will be clinically beneficial to patients.

We understand that in some SNFs, staffing issues may make it difficult to adequately and effectively supervise larger groups. However, there are many cases where this is not an issue and we do not want to prohibit SNFs from providing valuable therapy in larger groups if they can appropriately staff them. Additionally, these larger groups are an opportunity to utilize therapy students as extra sets of hands, eyes, and observers and can work as a way to offer therapy students valuable teaching and patient care time to assist them in maximal learning. Conversely, we do not want to prevent SNFs that have fewer patients with similar or the same needs from providing group therapy in smaller groups because the definition is currently set at four patients.

We recognize that the change in the way we are paying for therapy under PDPM may incentivize providers to furnish more group therapy for financial, rather than clinical reasons, and for this reason, we put the 25 percent combined cap into place effective October 1, 2019 as a limit on the amount of group and concurrent therapy that may be provided under PDPM. Ultimately though, we expect the decision on group size (within the revised definition) will be made by qualified therapists and therapy assistants and we expect their judgment on this matter to be based on sound clinical rationale and not financial gain. We believe that the judgment of the therapists and therapy assistants will allow for appropriate decision making regarding the number of group participants, and the combined 25 percent cap on group and concurrent therapy will help prevent an overutilization of group therapy under PDPM. We plan to implement a robust monitoring program to assess compliance with the 25 percent cap, and based on our findings, we may propose taking additional action in future rulemaking.

Comment: Several commenters expressed concern that the definition of group therapy as two to six patients will give providers an incentive to place the maximum number of patients in a group in order to exploit the financial incentives that would accompany doing so. One commenter expressed concern that corporate rehabilitation companies will disregard the clinical judgment of their therapists and therapy assistants and pressure them into providing groups of five or six at all times for financial gain. This commenter also stated the concern that rehabilitation companies may relax their standards for what is considered a group and pressure their therapists into providing groups that are less than clinically sound.

Response: We appreciate the commenters' concern that the proposed change in the definition of group therapy may give providers an incentive to place the maximum number of patients in a group for financial reasons. We also appreciate the concern of the commenter who stated that it is possible that corporate rehabilitation companies will pressure therapists into providing group therapy in groups with as many patients as possible and that this might not be appropriate as group therapy at all times. As we have stated previously, therapists treating SNF patients should use their own clinical judgment to determine the appropriate frequency, duration, and modality of therapy services and the size of a therapy group based on the individual needs of each patient. Financial motives should not override the clinical judgment of a therapist or therapy assistant or pressure a therapist or therapy assistant to provide less than appropriate therapy, including putting patients in large groups that are not clinically appropriate for those patients.

Comment: Several commenters suggested that CMS consider revising the definition of group therapy to two to four patients doing the same or similar activity. These commenters explained that doing so would still provide therapists an appropriate level of clinical flexibility while preventing SNFs from including a very large number of patients in a group only for financial reasons.

Response: We appreciate the suggestion of revising the definition of a group to two to four patients. If, after monitoring the provision of group therapy under the PDPM, we believe this policy would be more appropriate in the SNF setting, we will consider it for future rule-making. As stated above and the in the FY 2020 SNF PPS proposed rule (84 FR 17634), we believe that defining group therapy as therapy

provided to groups of 2 to 6 patients at the same time who are performing the same or similar activities would provide therapists with an appropriate amount of flexibility to meet the clinical needs of their patients without compromising the therapist's ability to manage groups and the patient's ability to interact effectively and benefit from the group. We expect that therapists will use their professional judgment to determine the most appropriate group size within the bounds of that definition to maximize the benefit to each patient in the group session.

Comment: Several commenters noted that revising the definition of group therapy to better align with other post-acute care settings is ''misguided''. These commenters stated that the post-acute care settings provide different levels of care and that the IRF setting, specifically, is meant to provide a more intense level of therapy than other settings, and that it would be flawed to try to synchronize the definition of group therapy across these settings that have different coverage requirements and patients with different acuity levels.

Response: We disagree with the notion that the change in the definition of group therapy to better align with other post-acute settings is ''misguided.'' Anecdotally, providers have stated that the acuity of SNF patients has increased over the years and that the level of care and therapy they require is comparable to that of IRF residents. Additionally, under RUG–IV, the majority of SNF therapy patients have been placed in the Ultra High therapy group, receiving at least 720 minutes of therapy a week. We do not believe that this level of therapy is very different from the intense level of therapy that is occurring in IRFs. We acknowledge that the higher acuity and need for an intense level of therapy does not apply to all SNF patients, but we expect the therapists and assistants who will be providing the group therapy will determine the appropriate intensity of therapy for each patient. Additionally, we continue to maintain that synchronization of the group therapy definition between settings will ease provider burden and help achieve CMS' goal of cross-setting alignment in this aspect.

Comment: Several commenters expressed concern that PDPM will inadvertently cause therapy students to lose out on opportunities for supervision and training. These commenters are concerned that maintaining compliance with the 25 percent combined limit on concurrent and group therapy may encourage therapists and assistants to forego supervising therapy students because doing so would add additional burden to their facilities. These commenters stated that this would affect the ability of students to get the valuable clinical training required to adequately treat geriatric patients in the SNF setting. One commenter explained that the current policy of considering a student clinician as an extension of the therapist or assistant who is training the student, as described in the FY 2012 final rule (76 FR 48511), (that is, the time the student spends with a patient is coded as if it were the supervising therapist or therapy assistant alone providing the therapy) should not be necessary under PDPM as it is under RUG–IV. This commenter stated that, because under the PDPM therapy minutes are no longer the primary driver for payment, this should not be a necessary aspect of the policy. One commenter recommended that CMS apply the 25 percent group and concurrent therapy limit at the facility level rather than individual level, and stated that doing this would not only maintain consistency of data comparison between RUG–IV and PDPM but also reduce the concerns with student supervision described above by creating a more flexible environment for treatment. Several commenters requested reiteration of CMS guidance regarding appropriate and effective use of student clinicians for group therapy.

Response: We do not agree with the comment that our policy under which the therapy student acts as an extension of the supervising therapist is no longer necessary under PDPM, as it is under RUG–IV, due to the discontinued use of therapy minutes as a primary driver of payment under PDPM. First, therapy minutes are still used under PDPM as part of calculating compliance with the cap on concurrent and group therapy. As such, maintaining this policy will ensure that therapy student time is reflected accurately and consistently with how it is reported under RUG–IV, to ensure an appropriate comparison between the two models. Additionally, we believe it is appropriate to maintain this policy under PDPM because it reflects the responsibility of the supervising therapist for the actions and treatments furnished by the student.

Further, we do not agree that PDPM will cause SNFs not to offer therapy students adequate supervision and training. Specifically, we do not agree that the combined 25 percent limit on group and concurrent therapy will create an extra burden that impedes therapists and therapy assistants from supervising students, and we believe that SNF therapists and therapy assistants will continue to be able to teach, train, and supervise therapy students in the same way under PDPM as they have in the past. As we have discussed previously (84 FR 17634), our data show that group therapy represents a very small proportion of therapy provided to SNF patients. Thus, the 25 percent limit on group and concurrent therapy should not adversely affect opportunities for student supervision and training. As stated in the FY 2019 SNF PPS final rule (83 FR 39242):

> . . . as mentioned above, our most recent (FY 2017) data show that individual therapy was provided 99.77 percent of the time, meaning that group and concurrent therapy combined was reported as having been provided 0.23 percent of the time. It concerns us that commenters have stated that they are providing so much concurrent therapy with students that the 25 percent cap would be too low for them, because this would suggest that either the comments were provided mistakenly or that facilities are falsely reporting concurrent therapy as individual therapy. While we agree with commenters that the opportunity to supervise student therapists in SNFs is valuable to the education of future therapists and assistants, our data indicate that a 25 percent combined cap on group and concurrent therapy should not deter facilities from taking more therapy students.

We do not agree with the suggestion to apply the 25 percent limit on group and concurrent therapy at a facility level. The notion that doing so would maintain consistency of data comparison between RUG–IV and PDPM is incorrect since we currently monitor data at the patient level under RUG–IV, not at the facility level. We also do not believe that we should apply the 25 percent limit at the facility level because, if we were to apply the 25 percent limit at a facility level, a large number of patients may receive 100 percent group or concurrent therapy and we do not believe that would be clinically appropriate. As we have stated previously, we believe that individual therapy is the preferred mode of therapy. The 25 percent limit on group and concurrent therapy underscores this. Anecdotally, we have been told by an industry group that they would advise their facilities to give as much group and concurrent therapy as possible based on the limit we set for group and concurrent therapy, so that if the limit were 50 percent, they would advise their facilities to give 50 percent group and concurrent therapy. This group informed us that they plan to advise their facilities to furnish 25 percent of all therapy as group and concurrent therapy. We note that we do not believe it would be appropriate to automatically provide the maximum amount of group and concurrent therapy

permitted under the percent cap set by Medicare without considering the individual clinical needs of each patient. As we stated previously, we expect therapists to determine the frequency, duration, and modality of therapy based on sound clinical reasoning and the individual needs of each patient. Further, as we stated above and in the FY 2020 SNF PPS proposed rule (84 FR 17635), we continue to believe that individual therapy is the preferred mode of therapy provision and should be considered the standard of care in therapy services provided to SNF residents. Regarding our guidance addressing the most appropriate use of student clinicians for group therapy, we have updated the MDS RAI manual in Chapter 3 Section O to include in it a revised explanation of how the time during which therapy students furnish either concurrent or group therapy should be captured on the MDS; however, we continue to believe the most appropriate ways to receive guidance on how to best incorporate students in the group and concurrent therapy process would come from the therapy associations and clinical departments of SNFs, as has been done in the past.

Comment: Several commenters requested that CMS discuss whether there will be a penalty for facilities that exceed the 25 percent concurrent and group therapy limit in the future. Commenters explained that the non-fatal warning is not a strong enough incentive for facilities to comply with the limit.

Response: We plan on monitoring the usage of group and concurrent therapy as well as looking at clinical outcomes. If the results of our monitoring efforts indicate substantial non-compliance with the 25 percent limit, we may consider taking additional action in future rulemaking. However, we expect that providers will pay close attention to the warning provided on their validation reports and be aware that we are monitoring their use of group and concurrent therapy as well.

After considering the comments above, for the reasons set forth in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing our revision to the definition of group therapy as proposed without modification. Effective October 1, 2019, under the SNF PPS, group therapy will be defined as a qualified rehabilitation therapist or therapy assistant treating two to six patients at the same time who are performing the same or similar activities.

2. Updating ICD–10 Code Mappings and Lists

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of PDPM, effective October 1, 2019. The PDPM utilizes ICD–10 codes in several ways, including to assign patients to clinical categories used for categorization in the PT, OT, and SLP components, as well as identifying certain comorbidities relevant for classification under the SLP and NTA components. The ICD–10 mappings and lists that would be used under PDPM, once implemented, are available on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*.

Each year, the ICD–10 Coordination and Maintenance Committee, a federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1, but has not yet done so.

We stated in the FY 2020 SNF PPS proposed rule (84 FR 17635) that as providers are required to follow the most up to date coding guidance issued by this committee in accordance with 45 CFR part 162, subpart J, it is essential that we be able to update our code mappings and lists consistent with the latest coding guidance. Therefore, to ensure that the ICD–10 mappings and lists used under PDPM reflect the most up to date codes possible, we proposed to update any ICD–10 code mappings and lists used under PDPM, as well as the SNF GROUPER software and other such products related to patient classification and billing, through a subregulatory process which would consist of posting updated code mappings and lists on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*. More specifically, we stated in the proposed rule that, beginning with the updates for FY 2020 (see discussion below), nonsubstantive changes to the ICD–10 codes included on the code mappings and lists under the PDPM would be applied through the subregulatory process described above, and substantive revisions to the ICD–10 codes on the code mappings and lists used under the PDPM would be proposed and finalized through notice and comment rulemaking.

As discussed in the proposed rule (84 FR 17635), nonsubstantive changes would be limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set, which Medicare providers are generally required to use. We stated that our intent in applying these nonsubstantive changes through the proposed subregulatory process would be to keep the same conditions in the PDPM clinical categories and comorbidities lists, but ensure that the codes used to identify those conditions are synchronized with the most current ICD–10 medical code data set. For example, to the extent that the ICD–10–CM Coordination and Maintenance Committee changes an ICD–10 code for a comorbid condition on our comorbidities lists into one or more codes that provide additional detail, we would update the SNF GROUPER software and ICD–10 mappings and lists on the CMS website to reflect the new codes through the above-referenced subregulatory process. By contrast, we stated that we would use notice and comment rulemaking to make substantive changes to the ICD–10 code mappings and lists under the PDPM. For the purposes of this policy, we stated that a substantive change would be defined simply as any change that does not fall within the definition of a nonsubstantive change—that is, changes that go beyond the intention of maintaining consistency with the most current ICD–10 medical code data set. For example, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy would be substantive changes. Taking the example above, we explained in the proposed rule that there may be situations in which the addition of one or more of these new codes to the list of comorbidities may not be appropriate. One such instance would be when the ICD–10 code for a particular condition is divided into two more detailed codes, one of which represents a condition that generally is predictive of the costs of care in a SNF and one of which is not. We stated that we would propose through notice and comment rulemaking to delete the code that does not reflect increased costs of care in a SNF from the list of comorbidities in the SNF GROUPER software because removing the code would constitute a substantive change. We proposed to indicate all changes to

codes in the GROUPER software by posting a complete ICD–10 mapping table, including new, discontinued, and modified codes, on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*. We also proposed to report the complete list of ICD–10 codes associated with the SNF PDPM clinical categories and SLP/NTA comorbidities in the SNF GROUPER documentation, which is also posted on the PDPM website. We stated that all changes would be included in these documents, with substantive changes being included only after being finalized through notice and comment rulemaking.

As discussed in the proposed rule (84 FR 17635 through 17636), we believe that the proposed subregulatory update process (by which nonsubstantive changes to the ICD–10 code mappings and lists used under PDPM as well as the SNF GROUPER software and other such products related to patient classification and billing would be posted on the CMS websites specified above), is the best way for us to convey information about changes to the ICD–10 medical code data set that affect the code mappings and lists used under the PDPM. We stated that we believe the proposed subregulatory process would help ensure providers have the most up-to-date information as soon as possible, in the clearest and most useful format, as opposed to publishing each nonsubstantive change to the ICD–10 codes in a rule after notice and comment rulemaking.

Additionally, we explained in the proposed rule (84 FR 17636) that the proposed subregulatory process is in alignment with similar policies in the SNF PPS and the IRF PPS settings. For example, the SNF PPS already uses a subregulatory process to make nonsubstantive updates to the list of Healthcare Common Procedure Coding System (HCPCS) codes that are used in determining the applicability of the consolidated billing (CB) provision of the SNF PPS to a given service, as discussed in section III.C.2 of this final rule. We post routine annual updates to the lists of codes that are included or excluded from CB on the SNF CB website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html*. The new codes identified in each update essentially describe the same overall set of services that are excluded from CB. No additional service categories are added by these routine updates; that is, these updates are necessary because of changes to the coding system, not because the basic service categories that are excluded from CB are themselves being redefined. We stated in the proposed rule that we believe the proposed subregulatory process to update ICD–10 codes associated with PDPM clinical categories and comorbidity lists is appropriate given that it is consistent with this subregulatory process already in use under the SNF PPS to make nonsubstantive coding updates.

Likewise, we explained in the proposed rule (84 FR 17636) that the IRF PPS also utilizes processes similar to that proposed here. In the FY 2007 IRF PPS final rule (71 FR 48360 through 48361), we implemented a similar subregulatory updating process for the IRF tier comorbidities list, and the FY 2018 IRF PPS final rule (82 FR 36267 through 36269) established a similar process for updating the ICD–10 code lists used for the IRF presumptive compliance methodology. Both the IRF tier comorbidities list and the IRF presumptive compliance methodology also use ICD–10 codes. Therefore, we stated that we believe the subregulatory process proposed in the proposed rule is appropriate because it is also consistent with processes used in another Medicare setting.

We proposed (84 FR 17636) that this subregulatory process for updating the ICD–10 codes used under the PDPM would take effect beginning with the updates for FY 2020. We further stated that the proposed ICD–10 code mappings and lists for use under the PDPM were available for download from the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*). We stated that these mappings and lists reflect the adoption of the ICD–10 Coordination and Maintenance Committee's draft changes to the ICD–10 medical code data sets, effective October 1, 2018. Furthermore, we explained in the proposed rule that the version of these mappings and lists that is finalized in conjunction with the FY 2020 SNF PPS final rule would constitute the baseline for any future updates to the mappings and lists using the proposed process described above.

Commenters submitted the following comments related to the proposed rule's discussion of Updating ICD–10 Code Mappings and Lists. A discussion of these comments, along with our responses, appears below.

Comment: The majority of commenters expressed support for the proposed subregulatory process for updating ICD–10 mappings. Several commenters noted that the proposed method would support the timely implementation of changes in coding, while ensuring additional consideration is given to substantive changes that amount to a change in policy. Only one commenter stated a preference for notice and comment rulemaking for all changes.

Response: We agree with the majority of commenters that the proposed subregulatory method is the best way to ensure the timely implementation of nonsubstantive changes in ICD coding under the PDPM. With regard to the comment that we utilize notice and comment rulemaking to implement all changes to ICD–10 code mappings and lists under the PDPM, we believe that this could represent a potential program vulnerability, as SNF providers would be prevented from utilizing valid ICD–10 codes under the SNF PPS pending the completion of the notice and comment rulemaking process and, moreover, could be compelled to utilize ICD–10 codes that are no longer valid due to our inability to ensure timely updates to our code mappings and lists when ICD–10 code revisions occur.

Comment: A commenter requested additional guidance on what constitutes a ''substantive'' change for the purposes of the proposed subregulatory process to update the ICD–10 code mappings and lists associated with the SNF PDPM.

Response: A ''substantive'' change would be any change to the mappings and lists that goes beyond the intention of maintaining consistency with the most current ICD–10 medical code data set. Any change that constitutes a change in policy, including changes to PDPM clinical category assignments or to the assignment of a code to the comorbidities list, would be considered a substantive change. For instance, consider a hypothetical code XYZ, which is mapped to a comorbid condition on our comorbidities list. In a revision to the ICD–10 codes, code XYZ is split into two separate codes, XYZ.1 and XYZ.2, providing additional detail. We would consider it a non-substantive change to update the mappings and lists to reflect the two new codes instead of the previous single code, and we would make this change to the mappings and lists through the proposed subregulatory process. On the other hand, if we believe the new code XYZ.2 is not predictive of SNF costs of care and wish to remove the new code XYZ.2 from the mappings and lists of PDPM comorbidities, this would be a substantive change, because it changes a policy: Conditions previously included on the comorbidities list under the old code XYZ would no longer be included on the comorbidities list if we chose to remove XYZ.2. Therefore, removing the new XYZ.2 code from the mappings and

lists would represent a substantive change. We would only make such a change through notice and comment rulemaking.

Comment: A commenter noted that the proposed rule does not clearly state whether non-substantive changes will be made according to the same schedule followed by the ICD–10 Coordination and Maintenance Committee, which updates ICD–10 medical code data sets in June of each year that then become effective in October 1 or April 1 of that year. The commenter stated that a predictable schedule for updates is necessary given the importance of ICD–10 codes and the associated mappings to the determination of patient classification and the calculation of per diem rates under PDPM. The commenter requested further clarification on when providers can expect non-substantive changes to be made according to the subregulatory process.

Response: The schedule for non-substantive CMS updates to the PDPM mappings and lists via the proposed subregulatory process will roughly follow the same schedule currently followed by the ICD–10 Coordination and Maintenance Committee in releasing updates to the ICD–10 medical code data sets in June. Once we receive the revised ICD–10 code lists from the committee, we will publish revised PDPM mappings and lists associated with the revised code lists shortly thereafter. Further, the revised PDPM mappings and lists would be effective at the same time as when the revised ICD–10 codes are effective. For example, if the revised codes are effective October 1 of a given year, than the revised PDPM mappings and lists based on these codes would also be effective October 1.

Comment: Several commenters made specific suggestions regarding how CMS should present changes made through the subregulatory process on the CMS website to ensure that stakeholders are aware of the changes. Commenters suggested that CMS should ensure the updates are communicated in a timely manner, easy to locate on the website, dated so providers are able to easily identify the most current files, and include a summary of what changes were made. Commenters also requested that updates include specific effective dates for the change, with such effective dates being reasonable for SNF staff to implement.

Response: We agree with these suggestions and note that we have established website maintenance and design practices that already incorporate the majority of the recommendations for presenting changes to the information uploaded on the website. The updates to the ICD–10 mappings and lists will be posted in a timely manner, easy to locate, dated, and accompanied by summaries of the changes and the specified effective dates.

Comment: Two commenters suggested that CMS send a monthly or quarterly newsletter announcing any changes made to the ICD–10 mappings and lists.

Response: We currently issue the Medicare Learning Network (MLN) newsletter and will issue an MLN article alerting providers and stakeholders to any update to the ICD–10 mappings and lists.

Comment: A commenter suggested that education and resources should be made available to all members of the interdisciplinary team, including therapy practitioners, to understand the implications of coding on patient categories and payment.

Response: We currently provide a number of educational materials on the PDPM website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*) including FAQs and fact sheets concerning PDPM patient classification and payment categories. We will update such materials on an ongoing basis to best serve the needs of providers.

Comment: Some commenters commented on an aspect of the PDPM established in the FY 2019 SNF PPS final rule (83 FR 39162), specifically, the use of ICD–10 codes in section I0020B to assign patients to clinical categories used for categorization in the PT, OT, and SLP components. Commenters noted a possible discrepancy between the American Health Information Management Association (AHIMA) guidance and MDS guidance with regard to how to code the ''principal diagnosis'' in I0020B. Commenters requested that CMS work with AHIMA or other professional coding organizations to ensure that coding instructions for the MDS are consistent with all relevant ICD–10 coding rules and guidelines.

Response: We appreciate these comments and will work to ensure that any guidance provided to SNFs on ICD–10 coding practice aligns with best practices in this field.

Comment: A commenter encouraged CMS to ensure that, for SNFs, the subregulatory process to update ICD–10 mappings and lists aligns with the process used in the context of the Inpatient Rehabilitation Facility (IRF) PPS, where the commenter understands providers globally have accepted the changes.

Response: We agree and believe the proposed subregulatory update process for SNFs aligns with the process used in the IRF PPS to update the tier comorbidities list and the code lists used for the IRF presumptive compliance methodology. As we noted in the proposed rule, the subregulatory update process used in the IRF PPS was one of the models we used to develop the proposed subregulatory process for updating ICD–10 code mappings and lists in the SNF PDPM.

Comment: A commenter noted that, in addition to annual implementation of new and revised ICD–10–CM codes, the conventions and instructional notes in the ICD–10–CM code set and the ICD–10–CM Official Guidelines for Coding and Reporting are also updated on October 1 of each year. The commenter stated that compliance with the current ICD–10–CM codes, conventions, instructions, and the Official Guidelines for Coding and Reporting is required for all healthcare settings under the Health Insurance Portability and Accountability Act (HIPAA). The commenter recommends that CMS ensure any appropriate updates to the ICD–10–CM codes associated with PDPM clinical categories and comorbidity lists that are necessitated by changes to the ICD–10–CM conventions, instructions, or guidelines are included in the proposed subregulatory process.

Response: We agree and will ensure that any appropriate updates to the ICD–10–CM codes associated with PDPM clinical categories and comorbidity lists that are necessitated by changes to the ICD–10–CM conventions, instructions, or guidelines are included in the proposed subregulatory update process.

Comment: Some commenters provided specific recommendations on revisions to the current mappings available on the CMS website, such as changes in code assignments to clinical categories and the comorbidities list, additional comorbidities, and other such changes.

Response: We appreciate the commenters' suggestions for changes in the current ICD–10 mappings and lists. However, because we consider these suggestions to be outside the scope of the current rulemaking, we are not addressing them in this final rule. We will certainly consider these suggestions as part of our future rulemaking efforts, or for inclusion in our updated mappings in case certain suggestions may be characterized as non-substantive in nature.

After consideration of the comments received, for the reasons discussed in this final rule and in the FY 2020 SNF PPS proposed rule, we are finalizing as proposed, without modification, the

process discussed above for updating the ICD–10 code mappings and lists associated with PDPM. As proposed, the subregulatory process for updating the ICD–10 codes used under the PDPM will take effect beginning with the updates for FY 2020. When the proposed rule was issued, the ICD–10 code mappings and lists available for download from the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM.html*) reflected the adoption of the ICD–10 Coordination and Maintenance Committee's draft changes to the ICD–10 medical code data sets, effective October 1, 2018, and we stated that these would constitute the baseline for any future updates to the mappings and lists using the update process finalized in this rule. Effective October 1, 2019, these baseline mappings and lists will be updated to incorporate, as appropriate under the process finalized in this rule, updates to the ICD–10 code sets issued by the ICD–10 Coordination and Maintenance Committee in June 2019 to be effective October 1, 2019. We plan to post these updated mappings and lists on our website prior to October 1, 2019 (and after issuance of this final rule) so that the public can access them prior to the effective date.

3. Revisions to the Regulations Text

We proposed to make certain revisions to the regulations text itself to reflect the revised assessment schedule under the PDPM, as finalized in the FY 2019 SNF PPS final rule (83 FR 39229). Specifically, we proposed to revise the prescribed PPS assessment schedule as set forth in § 413.343(b), to reflect the elimination, upon the conversion from RUG–IV to PDPM on October 1, 2019, of all scheduled assessments after the initial 5-day, Medicare-required assessment. We noted that even though this assessment is commonly referred to as the ''5-day'' assessment (reflecting its original 5-day assessment window), an additional 3 grace days have always been available beyond that window for its actual completion. Further, because those additional 3 grace days will be directly incorporated into the assessment window itself effective October 1, 2019 (as finalized in the FY 2019 SNF PPS final rule (83 FR 39231, 39232, and 39234)), thus resulting in an overall 8-day assessment window, we additionally proposed to include a conforming revision in § 413.343(b) that we stated was intended to clarify that the deadline for completing this assessment is no later than the 8th day of posthospital SNF care. In addition, because under the PDPM, there is only one scheduled patient assessment, we also proposed to replace the phrase ''patient assessments'' in § 413.343(b) with the phrase ''an initial patient assessment.'' Accordingly, we proposed to revise § 413.343(b) to state that the assessment schedule must include performance of an initial patient assessment no later than the 8th day of posthospital SNF care.

We further proposed to revise the existing language in § 413.343(b) that additionally requires the completion of ''such other assessments that are necessary to account for changes in patient care needs,'' to state ''such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.'' As we finalized in the FY 2019 SNF PPS final rule (83 FR 39230 through 39234), the optional Interim Payment Assessment (IPA) will serve as the instrument for conducting assessments under the PDPM that the SNF determines are necessary after the completion of the 5-day, Medicare-required assessment to address clinical changes throughout a SNF stay. We stated that we believe our proposed language is consistent with the expectation expressed in the FY 2019 SNF PPS final rule for SNFs ''to provide excellent skilled nursing and rehabilitative care and continually monitor and document patient status'' (83 FR 39233), and makes clear that the SNF's responsibility in this context would include recognizing those situations that warrant a decision to complete an IPA in order to account appropriately for a change in patient status. Finally, to ensure consistency, we also proposed to make a conforming revision to the regulations text in the introductory paragraph of § 409.30, so that it would use the same terminology of ''initial patient assessment'' as would appear in revised § 413.343(b). Specifically, in the introductory paragraph of § 409.30, we proposed to replace the phrase ''the 5-day assessment'' with ''the initial patient assessment.'' We also noted that the regulations text in the introductory paragraph of § 409.30 would continue to specify that the assessment reference date (ARD) for this assessment must occur no later than the 8th day of posthospital SNF care, consistent with the instructions set forth in sections 2.8 and 2.9 of the RAI Version 3.0 Manual.

Commenters submitted the following comments related to the proposed rule's discussion of the revisions to the regulations text. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters expressed concern that the term ''initial patient assessment'' is somewhat similar to (and, thus, might be confused with) the interim payment assessment, or IPA, and suggested a number of other names for the 5-day assessment as possible alternatives, such as the ''initial Medicare assessment.'' Some commenters noted confusion over the proposed rule's discussion of this 8-day timeframe (84 FR 17636) as representing the deadline for the assessment's ''completion.'' Others cited the proposed rule's discussion of the SNF's responsibility to continually monitor and document patient status and to recognize those situations that warrant a decision to complete an IPA in order to account appropriately for a change in status (84 FR 17636), and requested clarification regarding how this responsibility comports with the optional nature of the IPA. One of those commenters characterized the IPA as relating specifically to resetting the SNF's Part A per diem payment rate and suggested that the regulations text in proposed § 413.343(b)—which specifies performing such other IPAs as the SNF determines are necessary ''to account for changes in patient care needs''—is inappropriate in those instances where such changes would have no impact on payment. The commenter recommended deleting that phrase from the regulations text, noting that a Significant Change in Status Assessment (SCSA) is already required in those situations that meet the applicable SCSA criteria.

Response: Although we proposed in the FY 2020 SNF PPS proposed rule (84 FR 17636) to replace the phrase ''5-day assessment'' with ''initial patient assessment,'' to help distinguish that assessment more clearly from the IPA, we will henceforth refer to the 5-day assessment as the ''initial Medicare assessment.'' Further, we wish to resolve any confusion that the proposed rule's preamble language may have inadvertently created in referring to the 8th day of posthospital SNF care as the deadline for ''completing'' this assessment. As explained in the longstanding instructions in section 2.9 of the RAI Version 3.0 Manual, the initial Medicare assessment itself need not actually be *completed* by the 8th day; rather, the assessment reference date (ARD) for this assessment must be *set for* a date that is no later than the 8th day of posthospital SNF care (in other words, the facility cannot designate Day 9 or later as this assessment's ARD). In fact, it is the parameters for setting the ARD that the existing regulations text at 42 CFR

413.343(b) has always referenced when requiring a given assessment's ''performance'' in by a specified day. In order to convey that policy more directly and forestall additional confusion on this point, we are further revising the proposed regulations text at 42 CFR 413.343(b) to require the performance of an initial Medicare assessment ''with an assessment reference date that is set for no later than the 8th day of posthospital SNF care.'' To ensure consistency, we are also making a conforming revision in the introductory paragraph of the regulations text at 42 CFR 409.30, by specifying that the ARD for this assessment ''must be set for'' (rather than ''must occur'') no later than the 8th day of posthospital SNF care. As specified in section 2.9 of the RAI Version 3.0 Manual, the actual completion date (Item Z0500B) for this assessment is ''. . . within 14 days after the ARD (ARD + 14 days).'' Finally, regarding the request for clarification about the optional nature of the IPA, we note that while an SNF's decision to complete the IPA itself is indeed optional, the SNF's underlying responsibility to remain fully aware of (and respond appropriately to) any changes in its resident's condition is in no way discretionary. Moreover, the discussion of the IPA in the FY 2019 SNF PPS final rule (83 FR 39233) clearly envisions a role for this assessment that is not strictly limited to payment alone: ''We continue to believe that it is necessary for SNFs to continually monitor the clinical status of each and every patient in the facility regularly regardless of payment or assessment requirements *and we believe that there should be a mechanism in place that would allow facilities to do this*'' (emphasis added). At the same time, in making the IPA optional, we recognized ''. . . that providers may be best situated, as in the case of the Significant Change in Status Assessment, to determine when a change has occurred that should be reported through the IPA.'' (84 FR 39233) We believe this discussion clearly establishes the IPA as one of the vehicles that the SNF can utilize in the course of carrying out its ongoing patient monitoring responsibilities. Further, we believe that deleting the longstanding regulations text regarding changes in patient care needs—which dates all the way back to the inception of the SNF PPS itself, as originally issued in the May 12, 1998 SNF PPS interim final rule (63 FR 26311)—could be misinterpreted as actually precluding SNFs that may wish to use the IPA in this manner from doing so. Accordingly, we are not adopting the commenter's recommended revision to § 413.343(b).

After considering the comments received, for the reasons specified in this final rule and the FY 2020 SNF PPS proposed rule, we are finalizing the proposed changes to the regulation text in §§ 413.343 and 409.30, with the modifications discussed above.

E. Other Issues

1. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

a. Background

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Under the SNF QRP, the Secretary must reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566), and FY 2019 SNF PPS final rule (83 FR 39162 through 39272).

b. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, and other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

Comment: Several commenters expressed general support for CMS' proposed changes to the SNF QRP. One commenter expressed general support of CMS efforts to improve the Quality Reporting Program while another commenter recognized that the changes are part of a multi-year process to reform patient assessment and quality reporting across multiple levels of care. Another commenter expressed appreciation for CMS transparency and responsiveness to stakeholder input during the development and testing of the proposed SNF QRP measures, measure refinement, and proposed Standardized Patient Assessment Data Elements (SPADEs) which they believe are much improved from earlier draft versions and reflect many of the concerns and recommendations we have previously offered. One commenter was concerned about specialty populations and suggested that CMS make appropriate modifications to the application of the QRP to special populations programs and via distinct reimbursement to state-recognized special populations programs to avoid unintended consequences for specialty populations such as those living with HIV/AIDS.

Response: We thank the commenters for their support and suggestions. While we consider general comments regarding specialty populations to be out of the scope of this final rule, we will take into consideration the impact of specialty populations in our future work.

c. Quality Measures Currently Adopted for the FY 2021 SNF QRP

The SNF QRP currently has 11 measures for the FY 2021 SNF QRP, which are set out in Table 12.

TABLE 12—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2021 SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan.	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post—Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

While we did not solicit comments on currently adopted measures (with the exception of the Discharge to Community Measure discussed in section III.E.1.d.(3) of this rule and the policies regarding public display of Drug Regimen Review Conducted With Follow-Up for Identified Issues-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure data in section III.E.1.i. of this rule), we received several comments.

Comments: One commenter expressed concerns with the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure, believing that the measure does not identify where clinically significant recommendations originate, there is no measure of what is considered ''good'' when comparing rates at different facilities, and that facilities that place a high value on regular drug regimen review conducted by a consultant pharmacist deserve to be recognized for their efforts to improve patient safety and adherence to medication regimens. Another commenter does not support the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) measure, preferring outcome-based measures based on measures currently used in Nursing Home Compare. The commenter suggested a number of alternative measures for interim use in the SNF QRP until more measures are developed. This commenter also expressed concerns with the use of the four functional outcome measures in the SNF QRP encouraging CMS to identify a timeline for NQF endorsement. One commenter recommended that CMS adopt a standard process for evaluating whether a measure should be retained in the SNF QRP or removed or retired from the SNF QRP.

Response: We appreciate the comments on our implemented measures, the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) and the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) and note that we did not propose changes to these measures, so comments are outside the scope of this rule. In Table 12, we have provided a list of measures that are currently adopted in the SNF QRP. For the eight factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to § 413.360(b)(3) of our regulations.

d. Adoption of Two New Quality Measures and Updated Specifications for a Third Quality Measure Beginning With the FY 2022 SNF QRP

In the FY 2020 SNF PPS proposed rule (84 FR 17637 through 17643), we proposed to adopt two process measures for the SNF QRP that, as required by section 1888(e)(6)(B)(i)(II) of the Act, would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain titled ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual when the individual transitions from a post-acute care (PAC) provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.'' Given the length of this domain title, hereafter, we will refer to this quality measure domain as ''Transfer of Health Information.''

The two measures we proposed to adopt were: (1) Transfer of Health Information to the Provider—Post-Acute Care (PAC); and (2) Transfer of Health Information to the Patient—Post-Acute Care (PAC). Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability.

In addition to the two measure proposals, we proposed to update the specifications for the Discharge to Community—PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure.

IV. (1) Transfer of Health Information to the Provider—Post-Acute Care (PAC) Measure

The Transfer of Health Information to the Provider—Post-Acute Care (PAC) Measure that we proposed to adopt beginning with the FY2022 SNF QRP is a process-based measure that assesses whether or not a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current PAC setting.

(a) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and nine

percent who were discharged to SNFs.[1] The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS). Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to a home health agency (HHA), 3 percent were discharged to an IRF, and 1 percent were discharged to an LTCH.[2] Of the Medicare FFS beneficiaries with a SNF stay in FY 2017, an estimated 21 percent were discharged or transferred to an acute care hospital, 11 percent discharged home with home health services, and two percent discharged or transferred to another PAC setting (for example, an IRF, a hospice, or another SNF).[3]

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange network using an electronic health/medical record, and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[4] [5] [6] [7] [8] [9] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[10] [11] [12] [13] [14] [15] [16] [17] [18] [19] Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission [20] defines as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.[21] When care transitions are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[22] [23] [24] [25] [26]

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.[27] [28] The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between $25 billion and $45 billion in wasteful spending in 2011.[29] The communication of health information and patient care preferences is critical to ensuring safe and effective

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[2] Ibid.

[3] RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

[4] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: a systematic review,'' *Annals of Internal Medicine,* 2013, Vol. 158(5), pp. 397–403.

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transitions from one health care setting to another.[30] [31]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[32] [33] [34] Individuals in PAC settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[35] [36] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[37] A 2014 Office of Inspector General report found that almost one-tenth of Medicare beneficiaries experienced an ADE, such as delirium, bleeding, fall or injury, or constipation, during their stay in a SNF in 2011. Of these, two-thirds were classified as preventable.[38] Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[39] [40]

Patients in PAC settings are often taking multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Furthermore, inter-facility communication barriers delay resolving medication discrepancies during transitions of care.[41] Medication discrepancies are common,[42] and found to occur in 86 percent of all transitions, increasing the likelihood of ADEs.[43] [44] [45] Up to 90 percent of patients experience at least one medication discrepancy in the transition from hospital to home care, and discrepancies occur within all therapeutic classes of medications.[46] [47]

Transfer of a medication list between providers is necessary for medication reconciliation interventions, which have been shown to be a cost-effective way to avoid ADEs by reducing errors,[48] [49] [50] especially when medications are reviewed by a pharmacist using electronic medical records.[51]

(b) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[52] January 27,

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2017,[53] and August 3, 2017 [54] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure's reliability, components of face validity, and feasibility of being implemented across PAC settings. Overall, the TEP was supportive of the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4-June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT Medication–Profile-Transferred–Public-Comment-Summary-Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

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[54] Ibid.

(c) Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(d) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 Measures Under Consideration (MUC) List. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange, and recommended that the medication information transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx.*

As part of the measure development and selection process, we also identified one NQF-endorsed quality measure similar to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014, and was also adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter.

The proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) measure addresses the transfer of information whereas the NQF-endorsed measure #0419 assesses the documentation of medications, but not the transfer of such information. This is important as the proposed measure assesses for the transfer of medication information for the proposed measure calculation. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419 does not.

After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments. Section 1899B(e)(2)(A) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF). However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For the reasons discussed previously, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The proposed Transfer of Health Information to the Provider—Post-Acute Care (PAC) quality measure is calculated as the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at the time of discharge. The proposed measure denominator is the total number of SNF resident stays, ending in discharge to a ''subsequent provider,'' which is defined as a short-term general acute-care hospital, a skilled nursing facility (SNF), intermediate care (intellectual and developmental disabilities providers), home under care of an organized home health service organization or hospice, hospice in an institutional facility, an inpatient rehabilitation facility (IRF), an LTCH, a Medicaid nursing facility, an inpatient psychiatric facility, or a critical access hospital (CAH). These health care providers were selected for inclusion in the denominator because they are identified as subsequent providers on the discharge destination item that is currently included on the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at the time of discharge. For additional technical information about this proposed measure, we refer readers to the document titled, ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. The data source for the proposed quality measure is the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we proposed for this measure, we refer readers to section III.E.1.h.(3) of this final rule.

Commenters submitted the following comments related to the proposed rule's discussion of the SNF QRP Quality Measure Proposals beginning with the FY 2022 SNF QRP. A discussion of these comments, along with our responses, appears below. We also address comments on the proposed Transfer of Health Information to the Patient—Post-Acute Care measure (discussed further in a subsequent section of this final rule) in this section because commenters frequently addressed both Transfer of Health Information measures together.

Comment: The majority of commenters supported the adoption of both of the Transfer of Health Information measures. These commenters stated that the measures will help improve care coordination, patient safety, and care transitions.

Response: We thank commenters for their support of the Transfer of Health Information measures.

Comment: One commenter suggested that other providers, such as outpatient physical therapists, should be included in the definition of a subsequent provider for the Transfer of Health Information to the Provider—Post-Acute Care measure.

Response: We appreciate the suggestion to expand the Transfer of Health Information to the Provider—Post-Acute Care measure outcome to assess the transfer of health information to other providers such as outpatient physical therapists. We recognize that sharing medication information with outpatient providers is important, and will take into consideration additional providers in future measure modifications. Through our measure development and pilot testing we learned that outpatient providers cannot always be readily identified by the PAC provider. For this process measure, which serves as a building block for improving the transfer of medication information, we specified providers who will be involved in the care of the patient and medication management after discharge and can be readily identified through the discharge location item on the MDS. The clear delineation of the recipient of the medication list in the measure specifications will improve measure reliability and validity.

Comment: One commenter recommended that the Transfer of Health Information to the Provider—Post-Acute Care measure be expanded to include the transfer of information that would help prevent infections and facilitate appropriate infection prevention and control interventions during care transitions in addition to the medication information in the finalized measures.

Response: The Transfer of Health Information to the Provider—Post-Acute Care measure focuses on the transfer of a reconciled medication list. The measure was designed after input from TEPs, public comment, and other stakeholders that suggested the quality measures focus on the transfer of the most critical pieces of information to support patient safety and care coordination. However, we acknowledge that the transfer of many other forms of health information is important, and while the focus of this measure is on a reconciled medication list, we hope to expand our measures in the future.

Comment: Some commenters raised concerns about both of the Transfer of Health Information measures not being endorsed by the National Quality Forum (NQF). Some commenters recommended that CMS receive NQF approval before adoption.

Response: We agree that the NQF endorsement process is an important part of measure development. As discussed in the FY 2020 SNF PPS proposed rule (84 FR 17639 through 17640), we believe that the measures better address the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, than any endorsed measures. While section 1899B(e)(2)(A) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF), when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We plan to submit the measure for NQF endorsement consideration as soon as feasible.

Comment: Several commenters believe that the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures will add burden. One commenter stated that both measures will add burden with no added value and did not support the measures for that reason. Another commenter noted that there will be additional burden to collect and report data for these two measures in part because most PAC providers do not have access to EHRs or health information technology systems that facilitate their ability to electronically share this information.

Response: We are very mindful of burden that may occur from the collection and reporting of these measures, as supported by the CMS

Meaningful Measures and Patients over Paperwork initiatives. The timely and complete transfer of information focuses on the medication list, as suggested by our TEP, public comment, and SMEs. We would like to emphasize that both measures are comprised of one item only, and further, the activities associated with the measures align with existing requirements related to transferring information at the time of a discharge in order to safeguard patients. Additionally, TEP feedback and pilot test found that burden of reporting will not be significant. We believe that these measures will likely drive improvements in the transfer of medication information between providers and with patients, families, and caregivers.

Comment: A commenter stated there will be no additional data collection time or overall burden to SNFs as the Transfer of Health Information measures will use data already captured in the MDS.

Response: We agree that the Transfer of Health Information measures will not add additional burden in data collection over time as the data captured by these measures aligns with the standards of care for the discharge or transfer of a SNF resident and are a part of common practice.

Comment: In comments related to both Transfer of Health Information measures, some commenters raised concerns about documenting the transfer of a medication list in the event of an audit, noting that providers are simply required to attest to the transfer process taking place. One commenter stated that there are many ways to operationalize and document this process in the medical record; however, CMS has not indicated whether it would favor certain methods over others. A few commenters also noted that the form of the current reconciled medication list is not specified, nor is the method or route that the medication list is provided (that is, verbal, paper copy), which presents its own documentation challenges in ensuring adequate supporting evidence is available in the event of an audit. For these reasons, some commenters requested that CMS provide additional clarity regarding its documentation expectations and to consider the least burdensome ways for providers to comply while meeting the needs of a potential audit. One commenter also questioned whether the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures require that the facility prove receipt of the transferred information by the other provider or patient. Lastly, another commenter questioned if there are any potential penalties related to documentation that may be associated with the measures as part of QRP program.

Response: Both measures simply require a SNF to document that the transfer of medication information took place. The Transfer of Health Information measures serve as a check to ensure that a reconciled medication list is provided as the patient changes care settings. We would like to note that it is up to the provider to decide if they have transferred a medication list that may include the following information: Known medication and other allergies, known drug sensitivities and reactions; each medication, including the name, strength, dose, route of medication administration, and/or the reason for holding a medication or when a medication should resume. Defining the completeness of that medication list is left to the discretion of the providers and patient who are coordinating this care. We interpret the comments on audits to be referring to data validation. While we do not have a data validation program in place at this time, we are exploring such a program akin to that of the hospital inpatient quality reporting program. For all measures and data collected for the SNF QRP, we monitor and evaluate our data to assess for coding patterns, errors, reliability, and soundness of the data. Through data monitoring, we are able to assess if measure outcomes are consistent with the information that is collected.

With respect to the comment asking about whether there are any penalties associated with the proposed Transfer of Health Information measures, our policy for the SNF QRP is that, as detailed in 42 CFR 413.360(b)(2), SNFs must submit 100 percent of the required data elements on at least 80 percent of the MDS assessments submitted to be in compliance with SNF QRP requirements for a program year. SNFs are penalized if they do not meet this threshold.

Comment: In comments related to both Transfer of Health Information measures, some commenters commented on requiring hospitals to provide SNFs with important information at discharge. One commenter recommended that the Transfer of Health Information Measures be applied to acute care hospitals to ensure two-way, or bi-directional transfer of information and to support interoperability. A few commenters encouraged CMS to finalize revisions to ''Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' (CMS–3317–P), which would require hospitals to transfer patient information, including diagnosis and other clinical information, to the patient's next setting in a timely manner.

Response: We agree that the bi-directional transfer of health information between hospitals and PAC providers is important and will support efforts to improve interoperability.

Further, we believe that these measures will bring greater attention to the importance of the transfer of health information across all settings, increasing the seamless exchange of information across the care continuum. The Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies proposed rule (CMS–3317–P) has not been finalized. CMS has issued an extension notice for the publication of the final rule, which extends the timeline for publication of the final rule until November 3, 2019 (please see (*https://www.federalregister.gov/documents/2018/11/02/2018-23922/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals*).

Comment: A few commenters noted concerns that the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures are not indicative of provider quality and questioned the ability of the measures to improve patient outcomes. One commenter did not support the measures for this reason. One commenter noted that the measures assess whether a medication list was transferred and not whether that medication list was accurate and received by the subsequent provider.

Response: The Transfer of Health Information to the Provider–Post-Acute Care and Transfer of Health Information to the Patient–Post-Acute Care measures are process measures designed to address and improve an important aspect of care quality. Lack of timely transfer of medication information at transitions has been demonstrated to lead to increased risk of adverse events, medication errors, and hospitalizations. Because this measure would encourage the transfer of medication information, it would be expected to have a positive impact on these type of patient outcomes. Process measures hold a lot of value as they delineate negative and/or positive aspects of the health care process. This measure will capture the quality of the process of medication information transfer and help improve those processes. Process measures, such as these, are building blocks toward improved coordinated care and discharge planning, providing information that will improve shared

decision making and coordination. When developing future measures, we will take into consideration suggestions about measures that assess the accuracy of the medication list and whether it was received by the subsequent provider.

Comment: A few commenters suggested that CMS work to identify interoperability solutions to facilitate coordinated care, improve outcomes and overall quality comparisons related to both Transfer of Health Information measures. One commenter added that this would decrease opportunities for errors by providing clinicians and patients secure access to the most up-to-date medication-related information. One commenter also suggests that if CMS is required by the IMPACT Act to adopt these measures, that they do so as an interim step, within a defined timeframe, while interoperability solutions are explored and tested. A few commenters stated that while the rule acknowledges that information may be transferred verbally, on paper or electronically, CMS has not provided funding to nursing facilities to facilitate deployment of EMRs. These commenters suggested that meaningful use incentives be extended to SNFs and other post-acute care providers. One commenter stated that the use of existing clinical and interoperability standards should be considered in the development of these and future measures and that using standardized quality measures and standardized data will help enable interoperability and access to longitudinal information to facilitate coordinated care, improved outcomes, and overall quality comparisons and suggested that CMS leverage ongoing efforts to adopt data standards and implementation guides for certified EHRs (such as the USCDI). One commenter cites numerous CMS requirements and states that they are not sufficiently aligned for purposes of electronic exchange and, as a result, create significant provider burden as providers attempt to navigate and comply with these various requirements. The commenter recommends that CMS seek greater alignment between its various data collection requirements included in both finalized and proposed rules.

Response: We agree with the comments on the importance of interoperability solutions to support health information transfer. CMS and ONC are focused on improving interoperability and the timely sharing of information between providers, patients, families and caregivers. We believe that PAC provider health information exchange supports the goals of high quality, personalized, and efficient healthcare, care coordination and person-centered care, and supports real-time, data driven, clinical decision making.

To further support interoperability, we recently released the Data Element Library (DEL), a new public resource aimed at advancing interoperable health information exchange by enabling users to view assessment questions and response options about demographics, medical problems, and other types of health evaluations and their associated health IT standards. All data elements adopted for use in the Quality Reporting programs (QRPs), and not limited to data collected under the IMPACT Act, will be included in the DEL. In the initial version of the DEL (*https://del.cms.gov/*), assessment questions and response options are mapped to LOINC and SNOMED, where feasible. We also recognize the importance of leveraging existing standards, obtaining input from standards setting organizations, and alignment across federal interoperability efforts. We acknowledge that meaningful use incentives have not been extended to SNFs and other PAC providers and we will share these comments with the appropriate CMS staff and other governmental agencies to ensure they are taken into account as we continue to encourage adoption of health information technology. The Transfer of Health Information measures may encourage the electronic transfer of medication information at transitions. These measures and related efforts may help accelerate interoperability solutions.

The Transfer of Health Information measures assess the process of medication transfer, which can occur through both electronic and non-electronic means. We would like to clarify that these measures are an interim step in improving coordinated care, and we also believe that other interoperable solutions should be explored. Finalizing these Transfer of Health Information measures will be a first step in measuring the transfer of this medication-related information.

Comment: One commenter suggested that we develop a future outcome measure related to the transfer of medication information.

Response: We appreciate the suggestion that we develop an outcome measure related to the transfer of medication information, and agree that an outcome would be the next step when modifying the Transfer of Health Information measures. We will take this comment into consideration as we commence future measure development activities.

Comment: In comments related to both the Transfer of Health Information to the Provider and Transfer of Health Information to the Patient measures, one commenter requested the definition of a reconciled medication list and quoted from an older version of measure specifications where a medication profile had been defined.

Response: We appreciate these comments. We can confirm that as we tested these measures and gathered consensus input by TEPs and public comments, the definition of what is a reconciled medication list has been modified to decrease burden and to align to common clinical practice. Defining the completeness of that reconciled medication list is left to the discretion of the providers and patient who are coordinating this care.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure under section 1899B(c)(1)(E) of the Act beginning with the FY 2022 SNF QRP as proposed.

V. (2) Transfer of Health Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2022 SNF QRP

We proposed to adopt the Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure, a measure that satisfies the IMPACT Act domain of Transfer of Health Information, with data collection for discharges beginning October 1, 2020. This process-based measure assesses whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization or a hospice.

(a) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.[55] Of the Medicare FFS beneficiaries with a SNF stay in fiscal year 2017, an estimated 11 percent were discharged home with home health services, 41 percent were discharged home with self-care, and 0.2

[55] Tian, W. ''An all-payer view of hospital discharge to postacute care,'' May 2016. Available at *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

percent were discharged with home hospice services.[56]

The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a patient safety risk, often life-threatening.[57] [58] [59] [60] [61] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[62] [63] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[64] [65] [66] The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse effects. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[67] [68]

Finally, the transfer of a patient's discharge medication information to the patient, family, or caregiver is common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[69] [70] Most PAC EHR systems generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.[71]

(b) Stakeholder and Technical Expert Panel (TEP) Input

The proposed measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS MMS Blueprint.

Our measure development contractors constituted a TEP which met on September 27, 2016,[72] January 27, 2017,[73] and August 3, 2017 [74] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the

[56] RTI International analysis of Medicare claims data for index stays in SNF 2017. (RTI program reference: IB55).

[57] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: a systematic review,'' Annals of Internal Medicine, 2013, Vol. 158(5), pp. 397–403.

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importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT—Medication Profile Transferred Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

(c) Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated an 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report titled ''Transfer of Health Information 2018 Pilot Test Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

(d) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure in the SNF QRP section of the 2018 MUC list. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_PAC-LTC.aspx*.

Section 1899B(e)(2)(A) of the Act, requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF-endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF-endorsed as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure would be based on the proportion of resident stays with a discharge assessment indicating that a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge.

The proposed measure denominator is the total number of SNF resident stays ending in discharge to a private home/apartment, a board and care home, assisted living, a group home, transitional living or home under care of an organized home health service organization or a hospice. These locations were selected for inclusion in the denominator because they are identified as home locations on the discharge destination item that is currently included on the MDS. The proposed measure numerator is the number of SNF resident stays with an MDS discharge assessment indicating a current reconciled medication list was provided to the resident, family, or caregiver at the time of discharge. For technical information about this proposed measure we refer readers to the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*. Data for the proposed quality measure would be calculated using data from the MDS assessment instrument for SNF residents.

For more information about the data submission requirements we proposed for this measure, we refer readers to section III.E.1.h.(3) of this final rule.

Commenters submitted the following comments related to the proposed rule's discussion of the SNF QRP Quality Measure Proposals Beginning with the FY 2022 SNF QRP. A discussion of these comments, along with our responses, appears below. Comments that applied to both Transfer of Health Information measures are discussed in section III.E.1.d.(1) of this final rule.

Comment: One commenter suggested that CMS use the field's experience with transferring information to patients and reporting on the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure to disseminate best practices about how to best convey the medication list and suggested this include formats and informational elements helpful to patients and families.

Response: We have interpreted ''the field'' to mean PAC providers. Facilities and clinicians should use clinical judgement to guide their practices around transferring information to patients and how to best convey the medication list, including identifying the best formats and informational elements. This may be determined by the patient's individualized needs in response to their medical condition. CMS does not determine clinical best practices standards and facilities are advised to refer to other sources, such as professional guidelines.

Comment: A couple of comments suggested that the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure require transfer of the medication list to both the patient and family or caregiver. One of these commenters also stated that the measure should assess whether the patient, family or caregiver understands the medication list and has had a chance to ask questions about it.

Response: We agree there are times when it is appropriate for the SNF to provide the medication list to the patient and family and this decision should be based on clinical judgement. However, because it is not always necessary or appropriate to provide the medication list to both the patient and

family, we are not requiring this for the measure.

Comment: One comment suggested that CMS adopt standards around the Transfer of Health Information to Patient measure that ensures a consultant pharmacist is involved in patient-centered medication counseling.

Response: We understand that it is important for patient safety and outcomes that patients, their family and caregivers have good understanding of medications and how to take them and the role that pharmacists fulfill in this process. However, we believe that PAC providers should rely on their facility policies or standards of practice to determine who will provide medication counseling to patients.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure under section 1899B(c)(1)(E) of the Act beginning with the FY 2022 SNF QRP as proposed.

VI. (3) Update to the Discharge to Community—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Measure

In the FY 2020 SNF PPS proposed rule (84 FR 17643) we proposed to update the specifications for the Discharge to Community—PAC SNF QRP measure to exclude baseline nursing facility (NF) residents from the measure. This measure reports a SNF's risk-standardized rate for Medicare FFS residents who are discharged to the community following a SNF stay, do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. We adopted this measure in the FY 2017 SNF PPS final rule (81 FR 52021 through 52029).

In the FY 2017 SNF PPS final rule (81 FR 52025), we addressed public comments recommending exclusion of SNF residents who were baseline NF residents, as these residents lived in a NF prior to their SNF stay and may not be expected to return to the community following their SNF stay. In the FY 2018 SNF PPS final rule (82 FR 36596), we addressed public comments expressing support for a potential future modification of the measure that would exclude baseline NF residents; commenters stated that the exclusion would result in the measure more accurately portraying quality of care provided by SNFs, while controlling for factors outside of SNF control.

We assessed the impact of excluding baseline NF residents from the measure using CY 2015 and CY 2016 data, and found that this exclusion impacted both patient- and facility-level discharge to community rates. We defined baseline NF residents as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and qualifying hospitalization for measure inclusion. Baseline NF residents represented 10.4 percent of the measure population after all measure exclusions were applied. Observed resident-level discharge to community rates were significantly lower for baseline NF residents (2.37 percent) compared with non-NF residents (53.32 percent). The national observed resident-level discharge to community rate was 48.01 percent when baseline NF residents were included in the measure, increasing to 53.32 percent when they were excluded from the measure. After excluding baseline NF residents, 38.5 percent of SNFs had an increase in their risk-standardized discharge to community rate that exceeded the increase in the national observed resident-level discharge to community rate.

Based on public comments received and our impact analysis, we proposed to exclude baseline NF residents from the Discharge to Community–PAC SNF QRP measure beginning with the FY 2020 SNF QRP, with baseline NF residents defined as SNF residents who had a long-term NF stay in the 180 days preceding their hospitalization and SNF stay, with no intervening community discharge between the NF stay and hospitalization.

For additional technical information regarding the Discharge to Community—PAC SNF QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Resident Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported the proposed exclusion of baseline NF residents from the Discharge to Community—PAC SNF QRP measure. Commenters referred to their recommendation of this exclusion in prior years and appreciated CMS' willingness to consider and implement stakeholder feedback. One commenter recommended also excluding individuals without viable means to return to the community, such as those who are homeless, dependent on shelters, or unable to find a safe discharge option. One commenter suggested that CMS instead consider other quality measures for NF residents, such as functional status measures, to determine whether residents receive the appropriate standard of care they need during a long-term NF stay.

Response: We thank the commenters for their support of the proposed exclusion of baseline nursing facility residents from this measure, and for recommending additional exclusions and measures for consideration for baseline NF residents. We will consider the commenters' suggestions and would also note that exclusions and risk adjustment require the presence of reliable and valid data sources.

Comment: MedPAC did not support the proposed exclusion of baseline NF residents from the Discharge to Community-PAC SNF QRP measure. They stated that assessing safe discharge to ''home'' without post-discharge readmissions or death was also important for the baseline NF resident population and that excluding these residents would hold nursing homes harmless for their readmissions and death. MedPAC suggested that CMS instead expand their definition of ''return to the community'' to include baseline nursing home residents returning to the nursing home where they live, as this represents their home or community. MedPAC was also concerned that providers that mostly treat long-term care residents could have most stays excluded from the measure, and consumers using these rates for provider selection may not know that the measure would reflect only a small share of the provider's stays. Finally, MedPAC stated that providers should be held accountable for the quality of care they provide for as much of their Medicare patient population as feasible.

Response: We agree that providers should be accountable for quality of care for as much of their Medicare population as feasible; we endeavor to do this as much as possible, only specifying exclusions we believe are necessary for measure validity. We also believe that monitoring quality of care and outcomes is important for all PAC patients, including baseline NF residents who return to a NF after their

PAC stay. We publicly report several long-stay resident quality measures on Nursing Home Compare including measures of hospitalization and emergency department visits.

Community is traditionally understood as representing non-institutional settings by policy makers, providers, and other stakeholders. Including long-term care NF in the definition of community would confuse this long-standing concept of community and would misalign with CMS' definition of community in patient assessment instruments. CMS conceptualized this measure using the traditional definition of ''community'' and specified the measure as a discharge to community measure, rather than a discharge to baseline residence measure.

Baseline NF residents represent an inherently different patient population with not only a significantly lower likelihood of discharge to community settings, but also a higher likelihood of post-discharge readmissions and death compared with PAC patients who did not live in a NF at baseline. The inherent differences in patient characteristics and PAC processes and goals of care for baseline NF residents and non-NF residents are significant enough that we do not believe risk adjustment using a NF flag would provide adequate control. While we acknowledge that a return to nursing home for baseline NF residents represents a return to their home, this outcome does not align with our measure concept. Thus, we have chosen to exclude baseline NF residents from the measure. While we agree that the proposed exclusion could affect providers differentially since the mix of skilled and long-term care residents differs across nursing homes, we believe it is necessary for measure validity. We also appreciate the concern that consumers using the measures may not know that the measure does not reflect outcomes for baseline NF residents. We will consider strategies to convey this information to consumers.

Comment: One commenter requested that CMS provide the definition of ''long-term'' NF stay in the proposed measure exclusion, requesting further clarification in the measure specifications.

Response: We have further clarified the definition of long-term NF stay in the ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* A long-term NF stay is identified by the presence of a non-SNF PPS MDS assessment in the 180 days preceding the qualifying prior acute care admission and index SNF stay.

After consideration of the public comments, we are finalizing our proposal to exclude baseline NF residents from the Discharge to Community—PAC SNF QRP measure. This measure is now NQF-endorsed.

e. SNF QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We sought input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and concepts under consideration listed in the Table 13 for future years in the SNF QRP.

TABLE 13—FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADES) UNDER CONSIDERATION FOR THE SNF QRP

Assessment-Based Quality Measures and Measure Concepts:
Functional maintenance outcomes.
Opioid use and frequency.
Exchange of electronic health information and interoperability.
Claims-Based:
Healthcare-Associated Infections in Skilled Nursing Facility (SNF)—claims-based.
Standardized Patient Assessment Data Elements (SPADEs):
Cognitive complexity, such as executive function and memory.
Dementia.
Bladder and bowel continence including appliance use and episodes of incontinence.
Care preferences, advance care directives, and goals of care.
Caregiver Status.
Veteran Status.
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation.

In the FY 2020 SNF PPS proposed rule, we included a Request for Information (RFI) related to assessment and claims-based quality measures and standardized patient assessment data elements. We received various comments on this RFI, and appreciate the input provided by commenters.

Several commenters offered general support for the future measures, measure concepts, and SPADEs under consideration, however a few commenters questioned the detail on intent and process for selecting them.

- Assessment-Based Quality Measures and Measure Concepts

A few commenters offered support for the addition of assessment-based quality measures related to functional maintenance outcomes. With respect to quality measures related to opioid use and frequency, one commenter offered general support and another commenter suggested caution in developing opioid related quality measures to ensure that they do not result unintended consequences that leave patients without access to critical treatments for pain management. A few commenters offered general support for exchange of electronic health information and interoperability. One commenter suggested that CMS enhance its efforts to develop standards and measures for data exchange and sharing across all care settings including post-acute care, to explore approaches to incentivize the adoption of EHRs across the care continuum, and to develop future measures and SPADEs that use data that are available within EHRs used by PAC providers.

- Claims-Based

The claims-based quality measure, Healthcare-Associated Infections in Skilled Nursing Facility (SNF) received several comments of support, a few suggesting subcategorization to distinguish SNF-acquired infections and

non-SNF-acquired infections such as infections acquired in the hospital or community.

• Standardized Patient Assessment Data Elements (SPADEs)

One commenter offered support for the SPADE categories, stating that each of these SPADE categories represent elements that will provide a fuller picture of the patients in the SNF setting and could be used for creating and risk adjusting quality measures.

Several commenters supported SPADEs related to cognitive complexity such as executive function and memory, dementia, and caregiver status. One commenter noted that regularly assessing cognitive function and mental status presents opportunities for better care and quality of life, and that regular assessment of caregivers will also result in better care for the beneficiary and better quality of life for both individuals. Another commenter suggested that CMS should further consider the prevalence and clinical and economic burden of agitation in Alzheimer's disease when evaluating future SPADEs for dementia, suggesting that treatment of symptoms of agitation in patients with Alzheimer's disease reduces caregiver burden and the cost of care for the patient symptoms of agitation in patients with Alzheimer's disease. One commenter encouraged CMS to continue to place emphasis on the importance of innovative payment approaches to ensuring the financial stability of organizations delivering care related to Alzheimer's and dementia.

One commenter suggested that it is critical to consider the patient's needs and experience when measuring the quality of such care and supported the development and testing of patient experience measures to ensure reliability as well as validity of the measures. This commenter suggested development of a standardized tool as part of the SNF QRP to truly measure patient and/or caregiver experiences in the SNF setting, initially through a voluntary data collection phase.

One commenter supported SPADEs focused on bowel and bladder continence including appliance use and episodes of incontinence. Another commenter requested that CMS evaluate existing data MDS elements before adding additional data elements in to SPADEs in the areas of Dementia and Bladder and Bowel Continence.

For the collection of SPADE related to education, sex and gender identity, and sexual orientation, one commenter agreed that gender identity and sexual orientation are important and relevant to understanding patient care delivery needs and outcomes, and believes more information is needed to understand what data points would be collected. Another commenter proposed that CMS consider adding some measure of trauma history citing that a history of trauma can result in increased care needs and that in light of SNFs providing trauma-informed care, more SNFs will be assessing and addressing trauma and this should be captured in the measures.

One commenter endorsed adding Veteran status as a SPADE, as it may encourage more patient-centered care practices and system-wide focus on older Veterans' post-acute healthcare needs and may also encourage more research/analysis of Veteran status as a health determinant in PAC settings, particularly for investigators outside of VA for whom this information may be more difficult to access.

Finally, there were suggestions for SPADE development for other specific clinical areas such as behavioral and bariatric care.

f. Standardized Patient Assessment Data Reporting Beginning With the FY 2022 SNF QRP

Section 1888(e)(6)(B)(i)(III) of the Act requires that, for fiscal years 2019 and each subsequent year, SNFs must report standardized patient [75] assessment data (SPADE) required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including SNFs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit SPADEs under applicable reporting provisions (which, for SNFs, is the SNF QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

In the FY 2018 SNF PPS proposed rule (82 FR 21059 through 21076), we proposed to adopt SPADEs that would satisfy the first five categories. In the FY 2018 SNF PPS final rule, commenters expressed support for our adoption of SPADEs in general, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs. However, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 36598 through 36600). In addition, we noted our intention to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid, and appropriate for their intended use (82 FR 36599).

We did, however, finalize the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported by SNFs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and (2) Medical conditions and comorbidities: The data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by SNFs for the calculation of quality measures.

Since we issued the FY 2018 SNF PPS final rule, SNFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the SPADEs, as

[75] In the FY 2018 SNF PPS final rule, we used the term ''standardized resident assessment data'' to refer to standardized assessment data elements collected from SNF residents. However, in this final rule and going forward, we will use the term ''standardized patient assessment data'' to refer to the collect of SPADEs from SNF residents.

described more fully below, and believe that this testing supports the use of the SPADEs in our PAC assessment instruments. Therefore, we have proposed to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We proposed that SNFs would be required to report these SPADEs beginning with the FY 2022 SNF QRP. If finalized, SNFs would be required to report these data with respect to SNF admissions and discharges that occur between October 1, 2020 and December 31, 2020 for the FY 2022 SNF QRP. Beginning with the FY 2023 SNF QRP, we proposed that SNFs must report data with respect to admissions and discharges that occur during the subsequent calendar year (for example, CY 2021 for the FY 2023 SNF QRP, CY 2022 for the FY 2024 SNF QRP).

We also proposed that SNFs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to admission will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

In selecting the proposed SPADEs below, we considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADEs. In selecting the SPADEs below, we also took into consideration the following factors with respect to each data element:

(1) Overall clinical relevance;

(2) Interoperable exchange to facilitate care coordination during transitions in care;

(3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and

(4) Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed below, we additionally drew on input from several sources, including TEPs held by our data element contractor, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element contractor (hereafter ''National Beta Test'').

The National Beta Test collected data from 3,121 patients and residents across 143 PAC providers (26 LTCHs, 60 SNFs, 22 IRFs, and 35 HHAs) from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The 3,121 patients and residents with an admission assessment included 507 in LTCHs, 1,167 in SNFs, 794 in IRFs, and 653 in HHAs. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test are available in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described above. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

Comment: One commenter expressed support for the addition of SPADEs to the SNF-Resident Assessment Instrument (RAI), noting that many of them are already collected and reported on today. A second commenter noted support for the use of existing MDS items as SPADEs, noting that it will not increase provider burden. Another commenter recognized that data standardization will help facilitate appropriate payment reforms and appropriate quality measures.

Response: We thank the commenters for their support for the proposed SPADEs. We wish to clarify that we proposed the addition of the SPADEs to the MDS for SNFs, which is one component of the RAI. We agree with the commenters that many of the SPADEs are already collected and reported currently through the MDS, and that data standardization will help facilitate appropriate payment reforms and quality measures.

Comment: One commenter noted appreciation for CMS' transparency and responsiveness to stakeholders and noted that the SPADEs are much improved from earlier draft versions and reflect many of the concerns and recommendations CMS had previously offered. The commenter stated that the SPADEs appear to reflect a reasonable compromise between the need to collect meaningful standardized resident assessment data across the continuum of care to improve care, and the need to minimize provider administrative burden.

Response: We appreciate the commenter's recognition of our stakeholder engagement activities.

Comment: One commenter noted support for the goals of the IMPACT Act, but expressed concern about the scope and timing of proposed changes, including the SPADEs. The same commenter went on to urge CMS to share with the public a data use strategy and analysis plan for the SPADEs so that providers better understand how CMS will assess the potential usability of the SPADEs to support changes to payment and quality programs.

Response: We thank the commenter for their support of the goals of the IMPACT Act and appreciate their concern about the proposed changes. Since we issued the FY 2018 SNF PPS final rule, SNFs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act and prepare for additional changes. We have provided regular updates to stakeholders and gathered feedback through Special Open Door Forums and other events as described in our proposal. CMS will continue to communicate and collaborate with stakeholders by soliciting input on how the SPADEs will be used in the SNF QRP through future rulemaking.

We are in the process of creating research identifiable files of data collected in the National Beta Test. We anticipate that these files will be available through a data use agreement sometime in 2019. We also note that additional volumes of the National Beta Test report will be available in late 2019. This report contains supplemental analyses of the SPADEs that may be of interest to stakeholders.

Comment: Some commenters stated support but noted reservations. One commenter described the SPADEs as an appropriate start, but noted that the SPADEs cannot stand alone, and must be built upon in order to be useful for risk adjustment and quality measurement. Similarly, another commenter urged CMS to continue working with clinicians and researchers to ensure that the SPADEs are collecting valid, reliable, and useful data, and to continue to refine and explore new data elements for standardization. Yet another commenter urged CMS to be cautious in its implementation of some of the SPADEs, specifically those associated with social determinants of health (SDOH).

Response: We agree with the commenter's statement that the SPADEs are an appropriate start for standardization, but we disagree that they cannot stand alone. While we intend to evaluate SPADE data as they are submitted and explore additional opportunities for standardization, we also believe that the SPADEs as proposed represent an important core set of information about clinical status and patient characteristics and they will be useful for quality measurement. We would welcome continued input, recommendations, and feedback from stakeholders—including clinicians and researchers—about refinement and new development of SPADEs. Input can be shared with CMS through our PAC Quality Initiatives email address: *PACQualityInitiative@cms.hhs.gov*. We acknowledge the commenter's request that we be cautious implementing some SPADEs, particularly those associated with SDOH. We believe that our SPADE development process has been transparent and engaged stakeholders, as described in our proposals. However, we will monitor the implementation of the SPADEs in order to identify any issues that might arise.

Comment: Two commenters recommended that CMS seek greater alignment in its various data collection activities across settings. One commenter recommended alignment of SPADEs with the U.S. Core Data set for Interoperability (USCDI) once there is final rulemaking for ONC's Interoperability, Information Blocking and ONC Health IT Certification Program regulation. Although the USCDI only have current applicability in an acute care setting, the commenter pointed out that alignment, where possible (that is Cognitive Measures, Treatment Continuity, SDOH, Pain, Hearing, Speech, and Vision), would be advantageous to the quality and continuity of a patient's care. A second commenter also recommended alignment of SPADEs with the USCDI, but also mentioned the Requirements for Participation for Long Term Care Facilities (RoPs) and the Hospital Discharge Planning proposed rule as alternative guidelines with which to align the SPADEs. For data elements that are unlikely to change between settings, this commenter also urged CMS to require settings that are already collecting these data elements to send them to the next setting (that is, from acute care to PAC settings).

Response: We appreciate the commenters' recommendation for the potential for greater alignment to reduce burden and improve continuity of information as patients move between health care provider types. We are proposing SPADEs to satisfy the requirements of the IMPACT Act, which focuses on the four PAC provider types. At this time, alignment of patient assessment requirements with acute care and long-term care facilities is out of scope for these proposals. We will take the commenters' recommendations into consideration with future data element development work.

Comment: A commenter expressed concerns about the level of evidence to support the SPADEs shared by CMS from the National Beta Test. The commenter described several concerns about the scope and implementation of the National Beta Test, including the representativeness of SNFs included in the sample, the share of total SNF patients included in the National Beta Test, the reported exclusion of patients with communication and cognitive impairments, and the exclusion of non-English speaking patients, and described how these concerns compromise their confidence in the findings of the National Beta Test. The commenter also remarked on the lack of information about clinical characteristics that has been shared with stakeholders, limiting their ability to draw conclusions about the data, and requested that CMS release the data from the National Beta Test to be analyzed by third parties.

Response: In a supplementary document to the proposed rule (the document titled ''Proposed Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*), we described key findings from the National Beta Test related to the proposed SPADEs. We also referred readers to an initial volume of the National Beta Test report that details the methodology of the field test (''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*). Additional volumes of the National Beta Test report will be available in late 2019. In addition, we are committed to making data available for researchers and the public to analyze, and to doing so in a way that protects the privacy of patients and providers who participated in the National Beta Test. We are in the process of creating research identifiable files that we anticipate will be available through a data use agreement sometime in 2019.

To address the commenter's specific concerns, we note that the National Beta Test was designed to generate valid and robust national SPADE performance estimates for each of the four PAC provider types, which required acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of clinical characteristics. To meet these requirements, the National Beta Test was carefully designed so that data could be collected from a wide range of environments, allowing for thorough evaluation of candidate SPADE performance in all PAC settings. The approach included a stratified random sample, to maximize generalizability, and subsequent analyses included extensive checks on the sampling design.

The National Beta Test did not exclude non-communicative patients/residents; rather, it had two distinct samples, one of which focused on patients/residents who were able to communicate, and one of which focused on patient/residents who were not able to communicate. The assessment of non-communicative patients/residents differed primarily in that observational assessments were substituted for some interview assessments. Non-English speaking patients were excluded from the National Beta Test due to feasibility constraints during the field test. Including limited English proficiency patients/residents in the sample would have required the Beta test facilities to engage or involve translators during the test assessments. We anticipated that this would have added undue complexity to what facilities/agencies were being requested to do, and would have undermined the ability of facility/agency staff to complete the requested number of assessments during the study period. Moreover, there is strong existing evidence for the feasibility of all patient/resident interview SPADEs included in this proposed rule (BIMS section III.E.1.g.(1) in this final rule), Pain Interference (section III.E.1.g.(4) in this final rule), PHQ (section III.E.1.g.(2) in this final rule) when administered in other languages, either through standard PAC workflow (for example, as tested and currently collected in the MDS 3.0) and/or through rigorous translation and testing (for example, PHQ). For all these reasons, we determined that the performance of translated versions of these patient/resident interview

SPADEs did not need to be further evaluated. In addition, because their exclusion did not threaten our ability to achieve acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of PAC patient/resident clinical characteristics, the exclusion of limited English proficiency patients/residents was not considered a limitation to interpretation of the National Beta Test results.

Comment: Some commenters expressed concerns for the scope of the standardized patient assessment data proposals. These commenters were concerned that the proposed standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that were proposed to be simultaneously added to the MDS within a short timeframe.

Response: We acknowledge the additional burden that the SPADEs will impose on SNF providers and residents. Our development and selection process for the SPADEs we are adopting in this final rule prioritized data elements that are essential to comprehensive patient care. In selecting the SPADEs that we are adopting, we took into consideration clinical relevance, ability to capture medical complexity, data element performance, and expert and stakeholder input. We maintain that there will be significant benefit associated with each of the SPADEs to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers. During the SPADE development process, we were cognizant of the changes that providers will need to implement these additions to the MDS. We note that CMS has modified many current MDS data elements to reduce the impact of SPADEs on overall burden. This effort resulted in the total addition of only 59.5 items across the PPS admission and PPS discharge assessments. In addition, changes to the SNF QRP were coordinated across CMS' quality, payment, and policy teams so that collection of SPADES will begin after the October 1, 2019 implementation of the Patient Driven Payment Model. The PDPM streamlines the PPS assessments schedule eliminating the need for the 14-day, 30-day, 60-day and 90-day assessments. When burden is evaluated in these broader terms we believe providers will find the burden of the SPADES to be negligible.

Comment: Two commenters expressed concern that this additional burden was not justified because, in their view, there was limited or no evidence for the SPADEs to improve patient care.

Response: The IMPACT Act requires that we foster interoperable data exchange between PAC providers, including SNFs, by establishing a core set of data elements. We contend that supporting care transitions through improved data exchange will improve patient care.

Comment: One commenter stated that time burden (as in, ''time-to-complete'') estimates are underestimated. This commenter stated that because testing conditions focused on cognitively intact, English-speaking patients with no speech or language deficits, the estimates of impact to providers' time and resources is inadequate.

Response: We disagree with the commenter that the National Beta Test time-to-complete estimates are underestimates. We wish to clarify that the National Beta Test did exclude patients/residents who were not able to communicate in English but did not categorically exclude patients with cognitive impairment or patients with speech or language deficits. Therefore, we believe that time-to-complete estimates from the National Beta Test capture the full range of SNF residents who are able to communicate, including those with speech and language deficits.

Comment: To reduce administrative burden, some commenters' recommended changes to when and how SPADEs would be collected. One commenter was concerned that asking patients or their care partners to repeat questions throughout the admission could create a perception of poor communication and ineffectiveness that could result in an undesirable patient experience. This commenter urged CMS to reduce the number of additional standardized patient assessment data elements to ensure questions and categories do not create an undue administrative and patient burden. Other recommendations included collecting data only at admission when answers are unlikely to change between admission and discharge, adopting a staged implementation or only a subset of the proposed data elements, and that CMS explore options for obtaining these data via claims or voluntary reporting only.

Response: We appreciate the commenters' recommendations. We acknowledge that several SPADEs being finalized in this rule require the patient to be asked questions directly. We believe that direct patient assessment and patient-reported outcomes on these topics have benefits for providers and patients. These data elements support patient-centered care by soliciting the patient's perspective, and better information on a patient's status should improve the care the patient receives.

To support data exchange between settings, and to support quality measurement, section 1899B(b)(1)(A) of the Act requires that the SPADEs be collected with respect to both admission and discharge. In the FY 2020 SNF PPS proposed rule (84 FR 17644), we proposed that SNFs that submit four SPADEs with respect to admission will be deemed to have submitted those SPADEs with respect to both admission and discharge because we asserted that it is unlikely that the assessment of those SPADEs at admission would differ from the assessment of the same SPADEs at discharge. We note that a patient's ability to hear or ability to see are more likely to change between admission and discharge than, for example, a patient's self-report of his or her race, ethnicity, preferred language, or need for interpreter services, (although it is possible that any of these data elements may change). The Hearing and Vision SPADEs are also different from the other SPADEs (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) because evaluation of sensory status is a fundamental part of the ongoing nursing assessment conducted for SNF patients. Therefore, significant changes that occur in a patient's hearing or vision impairment during the SNF stay would be captured as part of the clinical record, even if they are not assessed by a SPADE. After consideration of public comments discussed in sections III.E.1.g.(5) and (6) of this final rule, we will deem SNFs that submit the Hearing, Vision, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs with respect to admission to have submitted with respect to both admission and discharge.

Regarding the number of SPADEs proposed, we note that these items span many substantive clinical areas and patient characteristics, and are comprised of a mix of patient interview and non-interview assessments. We contend that we have been highly selective when identifying SPADEs, and that our selections reflect a balanced approach to assessor and patient burden versus need for assessment data to support care planning, foster interoperability, and inform future quality measures. We will take into consideration the recommendation to obtain patient data from claims data in future work.

Comment: A commenter encouraged CMS to create and make transparent a

data use strategy and analysis plan for the SPADEs so PAC providers, including SNFs, better understand how the agency will further assess the adequacy and usability of the SPADEs. This commenter noted appreciation for CMS' efforts to provide opportunities for stakeholder communication and input, but also urged CMS to develop additional lines of communication with stakeholders, such as a multi-disciplinary stakeholder workgroup representing all PAC settings to advise on strategic and operational implications of implementation and a data analytics advisory group to assist CMS in establishing a framework for SPADE analysis and ongoing assessment. Another commenter believed that the SPADEs would provide a more accurate reflection on the resident's SNF resource use and could inform refinements to case-mix methodology. This commenter stated that CMS should include the potential impact of the SPADEs on case-mix payment methodology in the final rule.

Response: We appreciate the commenter's recommendation. It is our intention, as delineated by the IMPACT Act, to use the SPADE data to inform care planning, the common standards and definitions to facilitate interoperability, and to allow for comparing assessment data for standardized measures. In order to maintain open lines of communication with our stakeholders, we have used the public comment periods, TEPs, Subject Matter Expert working groups, stakeholder meetings, data forums, MLNs, open door forums, help desks, in-person trainings, webinars with communication with the public, ''We Want to Hear From You'' sessions, and have had stakeholders serve as consultants on our measure work. If there are any other opportunities for communication and comment, we will publish those opportunities. We will continue to communicate with stakeholders about how the SPADEs will be used in quality programs, as those plans are established, by soliciting input during the development process and establishing use of the SPADEs in quality programs through future rulemaking.

Comment: One commenter recommended that CMS focus on providing funding and administrative support to allow improvements and standardization to the electronic medical record to allow effective interoperability across all post-acute sites.

Response: We appreciate the commenter's recommendation. At this time, funding for electronic medical record adoption and support is not authorized for PAC providers.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

g. Standardized Patient Assessment Data by Category

VII. (1) Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in PAC patient and resident populations.[76] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[77] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[78] [79] [80] and promising treatments for severe traumatic brain injury are currently being tested.[81] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[82] [83] [84] [85] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[86]

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized patient assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable standardized patient assessment data elements assessing cognitive function and mental status are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

The data elements related to cognitive function and mental status were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21063). In response to our proposals, a few commenters noted that the proposed data elements did not capture some dimensions of cognitive function and mental status, such as functional cognition, communication, attention, concentration, and agitation. One commenter also suggested that other cognitive assessments should be

[76] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[77] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[78] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–211.

[79] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[80] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[81] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[82] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[83] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[84] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[85] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[86] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

considered for standardization. Another commenter stated support for the standardized assessment of cognitive function and mental status, because it could support appropriate use of skilled therapy for beneficiaries with degenerative conditions, such as dementia, and appropriate use of medications for behavioral and psychological symptoms of dementia.

We invited comments on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

Commenters submitted the following comments related to the proposed rule's discussion of the cognitive function and mental status data elements.

Comment: A few commenters were supportive of the proposal to adopt the BIMS, CAM, and PHQ–2 to 9 as SPADEs on the topic of cognitive function and mental status. One commenter agreed that standardizing cognitive assessments will allow providers to identify changes in status, support clinical decision-making, and improve care continuity and interventions.

Response: We thank the commenters for their support. We selected the Cognitive Function and Mental Status data elements for proposal as standardized data in part because of the attributes that the commenters noted.

Comment: A few commenters noted limitations of these SPADEs to fully assess all areas of cognition and mental status, particularly mild to moderate cognitive impairment, and performance deficits that may be related to cognitive impairment. A few commenters urged CMS to continue exploring assessment tools on the topic of cognition and to include a more comprehensive assessment of cognitive function for use in PAC settings, noting that highly vulnerable patients with a mild cognitive impairment cannot be readily identified through the current SPADEs.

Response: We acknowledge the limitations of the SPADEs to fully assess all areas of cognition and mental status. We have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. In our past work, we evaluated the potential of several different cognition assessment for use as standardized data elements in PAC settings. We ultimately decided on the data elements in our proposal as a starting point, and we welcome continued input, recommendations, and feedback from stakeholders about additional data elements for standardization, which can be shared with CMS through our PAC Quality Initiatives email address: *PACQualityInitiative@cms.hhs.gov*.

Comment: Regarding future use of these data elements, one commenter recommended that CMS monitor the use of the cognition and mental status SPADEs as risk adjustors and make appropriate adjustments to methodology as needed.

Response: We intend to monitor data submitted via the proposed SPADEs and will consider the use of SPADEs as risk adjustors in the future. We will also continue to review recommendation and feedback from stakeholders regarding candidate data for standardization that would provide meaningful data for PAC providers and patients.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

• Brief Interview for Mental Status (BIMS)

In the FY 2020 SNF PPS proposed rule (84 FR 17645 through 17646), we proposed that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS Proposed Rule (82 FR 21060 through 21061), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[87] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[88]

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: the MDS used by SNFs and the IRF–PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The data elements that comprise the BIMS were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21060 through 21061). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the BIMS as standardized patient assessment data elements. Other commenters were critical of the BIMS, noting its limitations for assessing mild cognitive impairment and functional cognition. Another stated that the BIMS should be administered with respect to discharge, as well as admission to capture changes during the stay. One expressed concern that the BIMS cannot

[87] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[88] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

be completed by patients and residents who are unable to communicate.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled ''Final Specifications for SNF Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements and the TEP supported the assessment of patient or resident cognitive status at both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums (SODFs) and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters also expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment (MCI). A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient's condition and will take this feedback into consideration in the development of future standardized patient assessment data elements. However, taking together the importance of assessing for cognitive status, stakeholder input, and strong test results, we proposed that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the BIMS as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the BIMS data elements.

Comment: Several commenters support the use of the BIMS to assess cognitive function and mental status.

Response: We thank the commenters for their support of the BIMS data element.

Comment: One commenter supported the collection of BIMS at both admission and discharge and believes it will result in more complete data and better care.

Response: We thank the commenter for their support of collecting the BIMS data element at admission and discharge.

Comment: Several commenters stated that the BIMS fails to detect mild cognitive impairment or functional cognition, differentiate cognitive impairment from a language impairment, link impairment to functional limitation, or identify issues with problem solving and executive function. One commenter recommended use of the Development of Outpatient Therapy Payment Alternatives (DOTPA) items for PAC as well as a screener targeting functional cognition.

Response: We recognize that the BIMS assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements that may be proposed in the future would be intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment that the commenter describes.

We evaluated the suitability of the DOTPA, as well as other screening tools that targeted functional cognition, by engaging our TEP, through ''alpha'' feasibility testing, and through soliciting input from stakeholders. At the second meeting of TEP in March 2017, members questioned the use of data elements that rely on assessor observation and judgment, such as DOTPA CARE tool items, and favored other assessments of cognition that required patient interview or patient actions. The TEP also discussed performance-based assessment of functional cognition. These are assessments that require patients to respond by completing a simulated task, such as ordering from a menu, or reading medication instructions and simulating the taking of medications, as required by the Performance Assessment of Self-Care Skills (PASS) items.

In Alpha 2 feasibility testing, which was conducted between April and July 2017, we included a subset of items from the DOTPA as well as the PASS. Findings of that test identified several limitations of the DOTPA items for use as SPADEs, such as relatively long to administer (5 to 7 minutes), especially in the LTCH setting. Assessors also indicated that these items had low relevance for SNF and LTCH patients. In addition, interrater reliability was highly variable among the DOTPA items, both overall and across settings, with some items showing very low agreement (as low as 0.34) and others showing excellent agreement (as high as 0.81). Similarly, findings of the Alpha 2 feasibility test identified several limitations of the PASS for use as SPADEs. The PASS was relatively time-intensive to administer (also 5 to 7 minutes), many patients in HHAs and IRFs needed assistance completing the PASS tasks, and missing data were prevalent. Unlike the DOTPA items, interrater reliability was consistently high overall for PASS (ranging from 0.78 to 0.92), but the high reliability was not deemed to outweigh fundamental feasibility concerns related to administration challenges. A summary report for the Alpha 2 feasibility testing titled ''Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing'' is available at

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Document.pdf.

Feedback was obtained on the DOTPA and other assessments of functional cognition through a call for input that was open from April 26, 2017 to June 26, 2017. While we received support for the DOTPA, PASS, and other assessments of functional cognition, commenters also raised concerns about the reliability of the DOTPA, given that it is based on staff evaluation, and the feasibility of the PASS, given that the simulated medication task requires props, such as a medication bottle with printed label and pill box, which may not be accessible in all settings. A summary report for the April 26 to June 26, 2017 public comment period titled ''Public Comment Summary Report 2'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Public-Comment-Summary-Report_Standardized-Patient-Assessment-Data-Element-Work_PC2_Jan-2018.pdf*.

Based on the input from our TEP, results of alpha feasibility testing, and input from stakeholders, we decided to propose the BIMS for standardization at this time due to the body of research literature supporting its feasibility and validity, its relative brevity, and its existing use in the MDS and IRF–PAI.

Comment: One commenter stated that the BIMS is a screening tool for cognition, and not necessarily an assessment item for confirming a diagnosis.

Response: As stated previously, the BIMS was developed to be a brief, objective screening tool, with a focus on learning and memory. It is designed to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. We recognize that the BIMS assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements that may be proposed in the future would be intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment that the commenter describes.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the BIMS as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

- Confusion Assessment Method (CAM)

In the FY 2020 SNF PPS proposed rule (84 FR 17646 through 17647), we proposed that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21061), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[89] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: A four-item version of the CAM is used in the MDS in SNFs and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We proposed the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The data elements that comprise the CAM were first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21061). In that proposed rule, we stated that the proposal was informed by input we received on the CAM through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination and, therefore, contribute to quality improvement. We also stated that those commenters had noted the CAM is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the use of the CAM as standardized patient assessment data elements, with one noting that it distinguishes delirium or reversible confusion from other types of cognitive impairments to share across settings for care coordination.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the CAM data elements, the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/*

[89] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' *J of Hospital Med* 8(9): 500–505.

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for delirium, stakeholder input, and strong test results, we proposed that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the CAM as standardized patient assessment data elements for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the CAM data elements.

Comment: Several commenters support the use of the CAM to assess cognitive function and mental status.

Response: We thank the commenters for their support of the CAM data element.

Comment: One commenter believed the CAM would be difficult to administer and raised concerns about the training that staff would receive in order to ensure that administration is consistent and valid.

Response: We appreciate the commenter's recommendation to provide clear training for administering the CAM. We note that the CAM is already collected on the MDS. We will take this recommendation into consideration in our review of the current training information for the MDS.

Comment: One commenter stated that the CAM is a screening tool for cognition, and not necessarily an assessment item for confirming a diagnosis.

Response: We agree with the commenter that the CAM assessment alone, is not sufficient for confirming a diagnosis of delirium. We also recognize that the CAM assesses components of cognition and does not, alone, provide a comprehensive assessment of potential cognitive impairment. However, we would also like to clarify that any SPADE or set of data elements is intended as a minimum assessment and would not limit the ability of providers to conduct more comprehensive assessment of cognition to identify the complexities or potential impacts of cognitive impairment, such as delirium.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the CAM as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

VIII. (2) Patient Health Questionnaire–2 to 9 (PHQ–2 to 9)

In the FY 2020 SNF PPS proposed rule (84 FR 17647 through 17648), we proposed that the Patient Health Questionnaire–2 to 9 (PHQ–2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ–2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ–9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ–2 to 9, refers to an embedded a skip pattern that transitions residents with a threshold level of symptoms in the PHQ–2 to the longer assessment of the PHQ–9. The skip pattern is described further below.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ–2 to 9 is based on the PHQ–9 mood interview. The PHQ–2 consists of questions about only the first two symptoms addressed in the PHQ–9: Depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ–2 has performed well as a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.[90] [91] If a patient demonstrates signs of depressed mood and anhedonia under the PHQ–2, then the patient is administered the lengthier PHQ–9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview assessment for residents who fail to report the cardinal symptoms of depression. The design of the PHQ–2 to 9 reduces the burden that would be associated with the full PHQ–9, while ensuring that patients with indications of depressive symptoms based on the PHQ–2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ–2) and the MDS for SNFs (PHQ–9). We proposed altering the administration instructions for the existing data elements to adopt the PHQ–2 to 9 gateway logic, meaning that administration of the full PHQ–9 is contingent on resident responses to questions about the cardinal symptoms of depression. For more information on the PHQ–2 to 9, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The PHQ–2 data elements were first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21062 through 21063). In that proposed rule we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ–2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First

[90] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). ''Validity of the Patient Health Questionnaire 2 (PHQ–2) in identifying major depression in older people.'' *J of the A Geriatrics Society,* 55(4): 596–602.

[91] Löwe, B., Kroenke, K., & Gräfe, K. (2005). ''Detecting and monitoring depression with a two-item questionnaire (PHQ–2).'' *J of Psychosomatic Research,* 58(2): 163–171.

Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* That proposed rule was also informed by public input through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions of the PHQ depression screener: The PHQ–2; the PHQ–9; and the PHQ–2 to 9 with the skip pattern design. Many commenters provided feedback on using the PHQ–2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC provider types was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ–9, which exhibits higher specificity,[92] for patients and residents who showed signs and symptoms of depression on the PHQ–2. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal to use the PHQ–2 in the FY 2018 SNF PPS proposed rule, a few commenters supported screening residents for depression with the PHQ–2. One commenter opposed the replacement of the PHQ–9 on the MDS with PHQ–2 because of the clinical significance of depression on quality of care and resident outcomes in the SNF population. Another expressed concern about the use of multi-step ''gateway'' questions, because use of the PHQ–2 and PHQ–9 may result in data not being standardized across settings and providers gathering data unrelated to the appropriateness of care.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the PHQ–2 to 9 was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the PHQ–2 to 9 to be feasible and reliable for use with PAC patients and residents. More information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the PHQ–2 to 9. The TEP was supportive of the PHQ–2 to 9 data element set as a screener for signs and symptoms of depression. The TEP's discussion noted that symptoms evaluated by the full PHQ–9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ–2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ–2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for depression, stakeholder input, and strong test results, we proposed that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the PHQ–2 to 9 data elements as standardized patient assessment data elements for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the PHQ–2 to 9 data elements.

Comment: Several commenters support the use of the PHQ–2 to 9 to assess cognitive function and mental status.

Response: We thank the commenters for their support of the PHQ–2 to 9.

Comment: One commenter stated that the PHQ–2 to 9 is a screening tool for depression, and not necessarily an assessment item for confirming a diagnosis.

Response: We agree with the commenter than the PHQ–2 to 9 alone is not sufficient for confirming a diagnosis of depression. Rather, the PHQ–2 to 9 is a screening tool that identifies residents who should receive further evaluation for depression. We would also like to clarify that any SPADE or set of data elements is intended as a minimum assessment and would not limit the ability of providers to conduct a more comprehensive assessment of depression to identify the complexities or potential impacts of depression.

Comment: One commenter noted that experts in geriatric psychiatry have identified care transitions as a prime period for intervening in suicide risk among older adults. This commenter was concerned that there would be no universal screening for suicide risk in patients discharged from SNFs unless the patient meets the required threshold on the PHQ–2 assessment and suggested that CMS consider adding the suicide ideation item from the PHQ–9 to the PHQ–2 at points of transition (for example discharge and transition to the community or between settings) as a step toward universal screening of suicide risk.

Response: We appreciate the commenter's concern for a universal screening for suicide risk. The PHQ–2 screens for the cardinal symptoms of depression, but does not ask about being bothered ''by thoughts that you would

[92] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–353. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

be better off dead, or hurting yourself in some way.'' [93] We will take the commenter's recommendation into consideration in future item development work. We note that despite not being adopted as a SPADE, individual providers have the ability to include this particular question or any screening or assessment tools that they believe would benefit their ability to provide high-quality care to their residents.

Comment: Lastly, one commenter expressed confusion about how depression relates to cognitive function.

Response: Section 1899B(b)(1)(B)(ii) of the Act specifies that the category of ''cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia.'' This category includes both cognitive function and mental status. The PHQ–2 to 9 data elements do not pertain to cognitive function, but do pertain to mental status. After careful consideration of the public comments we received, we are finalizing our proposal to adopt the PHQ–2 to 9 data elements as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

IX. (3) Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

A TEP convened by our data element contractor provided input on all of the proposed data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, this TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21073) public comment period. A comment across all special services, treatments, and interventions data elements requested that the additional reporting burden of the special services, treatments, and interventions data elements be addressed in payment calculations. Another comment submitted for several special services, treatments, and interventions data elements requested additional time be allowed before the providers are required to submit these data. One commenter expressed concern about increased reporting burden of the data elements proposed in FY 2018 because they would require an additional look-back time frame. Several commenters supported the inclusion of nutritional data elements as standardized data elements noting their importance in capturing information on care coordination and safe care transitions. One commenter noted the limitations of the nutritional data elements, namely that they do not capture information on swallowing or the clinical rationale for feeding/nutrition needs.

Information on data element performance in the National Beta Test, which collected data between November 2017 and August 2018, is reported within each data element proposal below. Clinical staff who participated in the National Beta Test supported these data elements because of their importance in conveying patient or resident significant health care needs, complexity, and progress. However, clinical staff also noted that, despite the simple ''check box'' format of these data element, they sometimes needed to consult multiple information sources to determine a patient's or resident's treatments.

We invited comments on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

Commenters submitted the following comments related to the proposed rule's discussion of the special services, treatments, and interventions data elements.

Comment: Some commenters were supportive of collecting these data elements, one noting that collection will help to better inform CMS and SNF providers on the severity and needs of patients in this setting.

Response: We thank the commenters for their support of these items. We selected the Special Services, Treatments, and Interventions data elements for proposal as standardized data in part because of the attributes noted.

Comment: One commenter expressed concern about the relevance of the Special Services, Treatments, and Interventions data elements to patients in SNFs. This and other commenters also noted concern around burden of completion of these data elements, in particular, the documentation burden taking away from patient care in the SNF settings.

Response: We acknowledge the commenters' concern for burden on completion of these data elements. We

[93] The Patient Health Questionnaire–9 (PHQ–9) states: ''Over the last 2 weeks, have you been bothered by any of the following problems?'' The ninth response option state: ''Thoughts that you would be better off dead, or of hurting yourself in some way.''

note that many of the SPADEs in this category are already collected on the MDS and the additional burden introduced by the sub-elements is minimal. To the extent that assessment and reporting may detract from time spent in direct patient care, we assert that SNFs already have processes in place to provide special services, treatments, and interventions for patients upon admission, during their stay, and at the time of discharge. We are asking that this available information be recorded on the Part A Discharge assessment.

Comment: One commenter was concerned about the reliability of the Special Services, Treatments, and Interventions data elements, noting that the results of the National Beta Test indicated that these data elements had a low interrater reliability kappa statistic, relative to other data elements in the test.

Response: In the category of Special Services, Treatments, and Interventions, for SPADEs where kappas could be calculated, 1 data element and 2 sub-elements demonstrated overall reliabilities in the moderate range (0.41–0.60) and only 1 sub-element demonstrated an overall reliability in the slight/poor range (0.00–0.20). These overall reliabilities were as follows: 0.60 for the Therapeutic Diet data element, 0.55 for the ''Continuous'' sub-element of Oxygen Therapy, 0.46 for the ''Other'' sub-element of IV Medications, and 0.13 for the ''Anticoagulant'' sub-element of IV Medications. However, the overall reliabilities for all other Special Services, Treatments, and Interventions data elements and sub-elements where kappas could be calculated were substantial/good or excellent/almost perfect. When looking at percent agreement—an alternative measure of interrater agreement—values of overall percent agreement for all Special Services, Treatments, and Interventions SPADEs and sub-elements ranged from 80 to 100 percent.

Comment: One commenter expressed concern that the Special Services, Treatments, and Interventions data elements assess the presence or absence of something rather than the clinical rationale or patient outcomes. This commenter stressed the importance of bringing this assessment to the ''next level'' in order to determine impact of these treatments on patients' outcomes.

Response: We agree with the commenter's concern that recording the presence or absence of certain treatments is only a first step in characterizing the complexity that is often the cause of a patient's receipt of special services, treatments, and interventions. We would like to clarify that all the SPADEs we proposed are intended as a minimum assessment and do not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

(a) Cancer Treatment: Chemotherapy (IV, Oral, Other)

In the FY 2020 SNF PPS proposed rule (84 FR 17649 through 17650), we proposed that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, and can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally, or more commonly, given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

The Chemotherapy (IV, Oral, Other) data element consists of a principal data element (Chemotherapy) and three response option sub-elements: IV chemotherapy, which is generally resource-intensive; Oral chemotherapy, which is less invasive and generally requires less intensive administration protocols; and a third category, Other, provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to chemotherapy delivery by other routes (for example, intraventricular or intrathecal). If the assessor indicates that the resident is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (for example, IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. We proposed to expand the existing Chemotherapy data element in the MDS to include sub-elements for IV, Oral, and Other. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Chemotherapy data element was first proposed as a standardized patient assessment data element in the FY 2018 SNF PPS proposed rule (82 FR 21063 through 21064). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. We also stated that those commenters had noted that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that

collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Chemotherapy (IV, Oral, Other) as standardized patient assessment data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for chemotherapy, stakeholder input, and strong test results, we proposed that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Chemotherapy (IV, Oral, Other) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Chemotherapy data element.

Comment: One commenter agreed that it is important to know if a patient is receiving chemotherapy for cancer and the method of administration, but also expressed concern about the lack of an association with a patient outcome. This commenter noted that implications of chemotherapy for patients needing speech-language pathology services include chemotherapy-related cognitive impairment, dysphagia, and speech and voice related deficits.

Response: We appreciate the commenter's concern. We agree with the commenter that chemotherapy can create related treatment needs for patients, such as the examples noted by the commenter. We believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

Comment: One commenter noted concern around burden of completion of the Chemotherapy data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Chemotherapy data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for administrative burden. We agree that assessment of Chemotherapy received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(b) Cancer Treatment: Radiation

In the FY 2020 SNF PPS proposed rule (84 FR 17650 through 17651), we proposed that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The

Radiation data element is currently in use in the MDS in SNFs. For more information on the Radiation data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Radiation data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21064 through 21065). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, expressed support for the Radiation data element, noting its importance and clinical usefulness for patients and residents in PAC settings, due to the side effects and consequences of radiation treatment on patients and residents that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Radiation as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for radiation, stakeholder input, and strong test results, we proposed that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Radiation data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Radiation data element.

Comment: One commenter expressed concern that the Radiation data element assesses whether a patient is receiving radiation for cancer treatment, but does not identify the rationale for and outcomes association with radiation. The commenter noted that implications of radiation for patients needing speech-language pathology services include reduced head and neck range of motion due to radiation or severe fibrosis, scar bands, and reconstructive surgery complications and that these can impact both communication and swallowing abilities.

Response: We appreciate the commenter's concern. We agree with the commenter that radiation can create related treatment needs for patients, such as the examples noted by the commenter. We believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Radiation data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(c) Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

In the FY 2020 SNF PPS proposed rule (84 FR 17651 through 17652), we proposed that the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065), oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for

example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here captures patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three response option sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as > =14 hours per day); Intermittent; or High-concentration oxygen delivery system. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the resident is receiving oxygen therapy on the principal oxygen therapy data element, the assessor then would indicate the type of oxygen the patient receives (for example, Continuous, Intermittent, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS in SNFs (''Oxygen Therapy''), previously used in the OASIS (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40 percent''). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Oxygen Therapy (Continuous, Intermittent) data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the adoption of Oxygen Therapy (Continuous, Intermittent) as a standardized patient assessment data element. Another commenter recommended that an option for high-concentration oxygen be added. In response to public comments, we added a third sub-element for ''High-Concentration Oxygen Delivery System'' to the Oxygen Therapy data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing oxygen therapy, stakeholder input, and strong test results, we proposed that the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Oxygen Therapy (Continuous, Intermittent, High-concentration Oxygen Delivery System) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Oxygen Therapy data element.

Comment: One commenter noted concern around burden of completing the Oxygen Therapy data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Oxygen Therapy data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for burden on clinical staff. The primary data element, Oxygen Therapy, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of oxygen support received by a patient—that is, Continuous, Intermittent, High-concentration Oxygen Delivery System—can be reasonably expected to be included in the medical record with the indication for oxygen therapy overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of Oxygen Therapy received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(d) Respiratory Treatment: Suctioning (Scheduled, As Needed)

In the FY 2020 SNF PPS proposed rule (84 FR 17652 through 17653), we proposed that the Suctioning (Scheduled, As needed) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients and residents with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of a principal data element, and two sub-elements: Scheduled; and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour; As needed means suctioning only when indicated. If the assessor indicates that the resident is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (for example, Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __hours]''). We proposed to expand the existing Suctioning data element on the MDS to include sub-elements for Scheduled and As Needed. For more information on the Suctioning data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Suctioning data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21065 through 21066). In that proposed rule, we stated that the proposal was informed by input we received on the Suctioning data element currently included in the MDS in SNFs through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for this data element. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also stated that those commenters had suggested that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Suctioning (Scheduled, As needed) as a standardized patient assessment data element. One commenter objected to

''scheduled'' suctioning as a response option due to a clinical practice guideline recommendation that suctioning should only be performed when clinically indicated and not on a scheduled basis.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Suctioning data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for suctioning, stakeholder input, and strong test results, we proposed that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Suctioning (Scheduled, As needed) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Suctioning data element.

Comment: One commenter requested that this data element also assess the frequency of suctioning, as it can impact resource utilization and potential medication changes in the plan of care.

Response: We appreciate that the response options for this data element may not fully capture impacts to resource utilization and care plans. The Suctioning data element includes sub-elements to identify if suctioning is performed on a ''Scheduled'' or ''As Needed'' basis, but it does not directly assess the frequency of suctioning by, for example, asking an assessor to specify how often suctioning is scheduled. This data element differentiates between patients who only occasionally need suctioning, and patients for whom assessment of suctioning needs is a frequent and routine part of the care (that is, where suctioning is performed on a schedule according to physician instructions). In our work to identify standardized data elements, we strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers, and we believe that modifying the Suctioning data element to assess frequency of suction would collect an overly-detailed and potentially burdensome level of clinical information about a patient that is not necessary to support quality measures, care planning, or care transitions. Therefore, we will not be modifying the Suctioning data element to assess the frequency of suctioning. However, we would like to clarify that any standardized patient assessment data element is intended as a minimum assessment and does not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

Comment: One commenter noted concern around burden of completion of the Suctioning data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Suctioning data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for burden on clinical staff. The primary data element, Suctioning, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of suctioning support received by a patient, that is, Scheduled or As Needed, can be reasonably expected to be included in the medical record with the indication for suctioning overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of Suctioning received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(e) Respiratory Treatment: Tracheostomy Care

In the FY 2020 SNF PPS proposed rule (84 FR 17653 through 17654), we proposed that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS in SNFs (''Tracheostomy care''). For more information on the Tracheostomy Care data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Tracheostomy Care data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21066 through 21067). In that proposed rule, we stated that the proposal was informed by input we received on the Tracheostomy Care data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016, supported this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, we received a few comments in support of the adoption of Tracheostomy Care as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for tracheostomy care, stakeholder input, and strong test results, we proposed that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Tracheostomy Care data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Tracheostomy Care data element.

Comment: One commenter noted the importance of determining if a patient had a tracheostomy as it helps with risk adjustment and identifying increased resource utilization, but recommended that the SPADE be expanded to ask about the size of the tracheostomy and whether the tracheostomy has a cuff or is fenestrated.

Response: Risk adjustment determinations is an issue that we continue to evaluate in all of our QRP programs. We will note this issue for further analysis in our future work to

determine how the SPADEs will be used. With regard to the commenter's request to expand the Tracheostomy Care SPADE to include more detail about the type of tracheostomy, we do not believe that this level of clinical detail is needed to fulfill the purposes of the SPADEs, which are to support care coordination, care planning, and future quality measures. We believe the broad indication that a patient is receiving Tracheostomy Care will be sufficient for the purposes of standardization and quality measurement, and that additional detail would generate unnecessary burden.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Tracheostomy Care data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(f) Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

In the FY 2020 SNF PPS proposed rule (84 FR 17654 through 17655), we proposed that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BiPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two response option sub-elements: BiPAP and CPAP. If the assessor indicates that the resident is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (for example, BiPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (''Non-invasive Ventilator (BiPAP, CPAP)''), and the MDS for the SNF setting (''Non-invasive Mechanical Ventilator (BiPAP/CPAP)''). We proposed to expand the existing BiPAP/CPAP data element on the MDS, retaining and relabeling the BiPAP/CPAP data element to be Non-invasive Mechanical Ventilator (BiPAP, CPAP), and adding two sub-elements for BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Non-invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data elements in the FY 2018 SNF PPS proposed rule (82 FR 21067). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 on a single data element, BiPAP/CPAP, that captures equivalent clinical information but uses a different label than the data element currently used in the MDS in SNFs and LCDS in LTCHs, expressed support for this data element, noting the feasibility of these items in PAC, and the relevance of this data element for facilitating care coordination and supporting care transitions. In addition, we also stated that some commenters supported separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Non-Invasive Mechanical Ventilator (BiPAP, CPAP) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements

(SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for non-invasive mechanical ventilation, stakeholder input, and strong test results, we proposed that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Non-Invasive Mechanical Ventilator data element.

Comment: One commenter noted concern around burden of completion of the Non-Invasive Mechanical Ventilator data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Non-Invasive Mechanical Ventilator data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern on additional administrative burden. The primary data element, Non-Invasive Mechanical Ventilator, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of ventilator received by a patient—that is, CPAP or BiPAP—can be reasonably expected to be included in the medical record with the indication for ventilator overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of non-mechanical ventilator services received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(g) Respiratory Treatment: Invasive Mechanical Ventilator

In the FY 2020 SNF PPS proposed rule (84 FR 17655 through 17656), we proposed that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia, and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[94]

The proposed data element, Invasive Mechanical Ventilator, consists of a single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. The MDS currently assesses invasive mechanical ventilation with the Ventilator or Respirator data element. We proposed to rename this data element in the MDS to be Invasive Mechanical Ventilator. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The Invasive Mechanical Ventilator data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21067 through 21068). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning''). Input submitted from August 12 to September 12, 2016 expressed support for this data element, highlighting the importance of this information in supporting care coordination and care transitions. We also stated that some commenters had expressed concern about the appropriateness for standardization given: The prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' we received is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, a few commenters supported the adoption of Invasive Mechanical Ventilator as a standardized patient assessment data element. One commenter stated that a

[94] Wunsch, H., Linde-Zwirble, W.T., Angus, D.C., Hartman, M.E., Milbrandt, E.B., & Kahn, J.M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' *Critical Care Med* 38(10): 1947–1953.

data element to indicate ''weaning'' is important because it indicates higher resource utilization.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for invasive mechanical ventilation, stakeholder input, and strong test results, we proposed that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Invasive Mechanical Ventilator data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for the support of the Invasive Mechanical Ventilator data element.

Comment: One commenter was disappointed to see that this data element only assesses whether or not a patient is on a mechanical ventilator. The commenter urged CMS to consider collecting data to track functional outcomes related to progress towards independence in communication and swallowing.

Response: We have attempted to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. We believe that assessing the use of an invasive mechanical ventilator will be a useful point of information to inform care planning and further assessment, such as related to functional outcomes, as the commenter suggests, but we do not believe it is necessary to track functional outcomes related to progress towards independence in communication and swallowing as part of the SPADEs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(h) Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

In the FY 2020 SNF PPS proposed rule (84 FR 17656 through 17657), we proposed that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069), when we proposed a similar data element related to IV medications, IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter. IV medications are administered via intravenous push, single, intermittent, or continuous infusion through a catheter placed into the vein. Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medications data element (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when the bioavailability of the oral form of the medication would be inadequate to kill the pathogen or an oral form of the medication does not exist. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we proposed consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the FY 2018 SNF PPS proposed rule. We added the Vasoactive Medications sub-element

to our proposal in order to harmonize the proposed IV Mediciations element with the data currently collected in the LCDS.

If the assessor indicates that the resident is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (for example, Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. We proposed to expand the existing IV Medications data element in the MDS to include sub-elements for Antibiotics, Anticoagulants, Vasoactive Medications, and Other. For more information on the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

An IV Medications data element was first proposed as SPADEs in the FY 2018 SNF PPS proposed rule (82 FR 21068 through 21069). In that proposed rule, we stated that the proposal was informed by input we received on Vasoactive Medications through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element with one noting the importance of this data element in supporting care transitions. We also stated that those commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing for IV medications, stakeholder input, and strong test results, we proposed that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comment related to the proposed rule's discussion of the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element.

Comment: One commenter noted concern around burden of completion of the IV Medication data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that IV Medication data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for administrative burden. The primary data element, IV Medications, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of IV Medications received by a patient can be reasonably expected to be included in the medical record with the indication for IV medications overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS

additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of IV medications received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(i) Transfusions

In the FY 2020 SNF PPS proposed rule (84 FR 17657 through 17658), we proposed that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21069), transfusion refers to introducing blood or blood products into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element consists of the single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs (''Transfusions'') and a data element tested in the PAC PRD (''Blood Transfusions'') was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Transfusions as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for transfusions, stakeholder input, and strong test results, we proposed that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Transfusions data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Transfusions data element.

Comment: One commenter applauded CMS for including the Transfusion data element noting that it will provide information on care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs and will contribute to higher quality and coordinated care for patients who rely on these life-saving treatments.

Response: We thank the commenter for the support. We selected the Transfusions data element for proposal as standardized data in part because of the attributes that the commenters noted.

Comment: One commenter was concerned that SNFs will not have the resources needed to provide patients with access to blood transfusions and requested that CMS consider whether payments to SNFs are adequate to cover the cost of this resource intensive, specialized service.

Response: At this time, this item will not be used for any payment purposes, and thus we are not able to comment on cost of this service. We wish to clarify that the Transfusion SPADE collects information on the complexity of the patient and resources the patient requires. This SPADE is not intended to measure the ability of a SNF to provide in-house transfusions, only to capture the services a given resident may be receiving. We are not evaluating the costs that SNFs incur when providing blood transfusions. Further, for patients who require services related to blood transfusions, information collected by this data element is a part of common clinical workflow, and thus, we believe that burden on resource intensity would not be affected by the standardization of this data element.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfusions data element as standardized patient assessment data

beginning with the FY 2022 SNF QRP as proposed.

(j) Dialysis (Hemodialysis, Peritoneal Dialysis)

In the FY 2020 SNF PPS proposed rule (84 FR 17658 through 17659), we proposed that the Dialysis (Hemodialysis, Peritoneal dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility for treatment. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis and Peritoneal dialysis. If the assessor indicates that the resident is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis or Peritoneal dialysis). Dialysis data elements are currently included on the MDS in SNFs and the LCDS in LTCHs and assess the overall use of dialysis. We proposed to expand the existing Dialysis data element in the MDS to include sub-elements for Hemodialysis and Peritoneal dialysis.

As the result of public feedback described below, we proposed a data element that includes the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal dialysis). For more information on the Dialysis data elements, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Dialysis data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070). In that proposed rule, we stated that the proposal was informed by input we received on a singular Hemodialysis data element through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. We proposed the version of the Dialysis element that includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of Dialysis (Hemodialysis, Peritoneal dialysis) as a standardized patient assessment data element.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although they did not specifically discuss the Dialysis data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-*

Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

Taking together the importance of assessing for dialysis, stakeholder input, and strong test results, we proposed that the Dialysis (Hemodialysis, Peritoneal dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Dialysis (Hemodialysis, Peritoneal dialysis) data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter noted concern around burden of completion of the Dialysis data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that the Dialysis data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for additional administrative burden. The primary data element, Dialysis, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of dialysis received by a patient—that is, Hemodialysis or Peritoneal Dialysis—can be reasonably expected to be included in the medical record with the indication for dialysis overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of dialysis services received by patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(k) Intravenous (IV) Access (Peripheral IV, Midline, Central line)

In the FY 2020 SNF PPS proposed rule (84 FR 17659 through 17660), we proposed that the IV Access (Peripheral IV, Midline, Central line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071), patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed data element, IV Access (Peripheral IV, Midline, Central line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments. For more information on the IV Access (Peripheral IV, Midline, Central line) data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The IV Access data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21070 through 21071). In that proposed rule, we stated that the proposal was informed by input we received on one of the PAC PRD data elements, Central Line Management, a type of IV access, through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters noted feasibility and importance of facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with expert input, described below, we created an overarching IV Access data element with sub-elements for other types of IV access in addition to central lines (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of the IV Access (Peripheral IV, Midline, Central line, Other) as a standardized patient assessment data element, with one commenter encouraging clear guidance in the Resident Assessment Instrument User Manual to distinguish between coding instructions for this data element and those for other data elements on IV treatments.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-*

Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the IV Access data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for IV access, stakeholder input, and strong test results, we proposed that the IV access (Peripheral IV, Midline, Central line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the IV Access (Peripheral IV, Midline, Central line) data element.

Comment: One commenter noted concern around burden of completion of the IV Access data element, in particular the additional administrative burden because this data element adds sub-elements to an existing MDS item. However, the commenter also stated their belief that IV Access data element would provide a more accurate reflection of residents' resource needs that could inform case-mix payment methodology.

Response: We appreciate the commenter's concern for additional administrative burden. The primary data element, IV Access, is already included in the MDS. Our clinical advisors and stakeholders have stated that the type of IV access received by a patient can be reasonably expected to be either plainly apparent or included in the medical record at the same place as the indication for IV access overall. We contend that the addition of sub-elements to the existing MDS data element will not require the assessor to undertake an entirely new search within the medical record for this information. Rather, the additional information required by the sub-elements will be documented within or adjacent to information on the primary data element. Therefore, the additional burden of data collection related to the sub-elements is minimal, requiring only that the assessor document in the MDS additional information that should be readily available in a patient's medical record with the documentation of the primary data element. We agree that assessment of IV access for patients in the SNF setting would provide important information for care planning and resource use in SNFs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the IV Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(l) Nutritional Approach: Parenteral/IV Feeding

In the FY 2020 SNF PPS proposed rule (84 FR 17660 through 17661), we proposed that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and the maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as air embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS in SNFs, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and OASIS. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Parenteral/IV Feeding data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21071 through 21072). In that proposed rule, we stated that the proposal was informed by input we received on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD) through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-*

Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of the Parenteral/IV Feeding as a standardized patient assessment data element, with one requesting ''universal'' guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for parenteral/IV feeding, stakeholder input, and strong test results, we proposed that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the SNF QRP.

A commenter submitted the following comment related to the proposed rule's discussion of the Parenteral/IV Feeding data element.

Comment: One commenter was supportive of collecting this data element but noted that it should not be a substitute for capturing information related to swallowing which reflects additional patient complexity and resource use.

Response: We thank the commenter for their support and appreciate the concerns raised. We agree that the Parenteral/IV Feeding SPADE should not be used as a substitute for an assessment of a patient's swallowing function. The proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We agree that information related to swallowing can capture patient complexity, but we also note that Parenteral/IV Feeding data element captures a different construct. That is, the Parenteral/IV Feeding data element captures a patient's need to receive calories and nutrients intravenously, while an assessment of swallowing would capture a patient's functional ability to safely consume food orally for digestion in their gastrointestinal tract.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Parenteral/IV Feeding data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(m) Nutritional Approach: Feeding Tube

In the FY 2020 SNF PPS proposed rule (84 FR 17661 through 17662), we proposed that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and, therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[95] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF–PAI for IRFs (''Tube/Parenteral Feeding''), assesses use of both feeding tubes and parenteral nutrition. For more information on the Feeding Tube data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Feeding Tube data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21072). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website.

[95] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

Input submitted from August 12 to September 12, 2016 on an Enteral Nutrition data element (the Enteral Nutrition data item is the same as the data element we proposed, but is used in the OASIS under a different name) supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of the Feeding Tube as a standardized patient assessment data element. Another commenter recommended that the term ''enteral feeding'' be used instead of ''feeding tube.''

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for feeding tubes, stakeholder input, and strong test results, we proposed that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Feeding Tube data element as standardized patient assessment data for use in the SNF QRP.

A commenter submitted the following comment related to the proposed rule's discussion of the Feeding Tube data element.

Comment: One commenter noted that in addition to identifying if the patient is on a feeding tube or not, it would be important to assess the patient's progression towards oral feeding within this data element, as this impacts the tube feeding regimen.

Response: We agree that the progression to oral feeding is important for care planning and transfer, but we do not believe that standardizing the collection of this information would be useful for risk adjustment or the development of quality measures, which were considerations in the selection of the SPADEs. At this time, we are finalizing a singular Feeding Tube SPADE, which assesses the nutritional approach only and does not capture the patient's prognosis with regard to oral feeding. We wish to clarify that the proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We will take this recommendation into consideration in future work on standardized data elements.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Feeding Tube data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(n) Nutritional Approach: Mechanically Altered Diet

In the FY 2020 SNF PPS proposed rule (84 FR 17662 through 17663), we proposed that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[96]

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients and residents on mechanically altered diets also require additional nursing supports, such as individual feeding or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is

[96] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

therefore important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element is currently included on the MDS for SNFs. A related data element (''Modified food consistency/supervision'') is currently included on the IRF–PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' For more information on the Mechanically Altered Diet data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Mechanically Altered Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21072 through 21073).

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported the adoption of the Mechanically Altered Diet as a standardized patient assessment data element, with one requesting ''universal'' guidance for coding, which would be clearly defined and more broadly applicable to patients and residents in all PAC settings.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Mechanically Altered Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for mechanically altered diet, stakeholder input, and strong test results, we proposed that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Mechanically Altered Diet data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for their support of the Mechanically Altered Diet data element.

Comment: One commenter was concerned that this data element does not capture clinical complexity and does not provide any insight into resource allocation because it only measures whether the patient needs a mechanically altered diet and not, for example, the extent of help a patient needs in consuming his or her meal.

Response: We believe that assessing patients' needs for mechanically altered diets captures one piece of information about clinical complexity and resource allocation. That is, patients with this special nutritional requirement may require additional nutritional planning services, special meals, and staff to ensure that meals are prepared and served in the way the patient needs. Additional factors that would affect resource allocation, such as those noted by the commenter, are not captured by this data element. We have decided not to alter the SPADE as proposed in order to balance the scope and level of detail of the data elements against the potential burden placed on providers who must complete the assessment. We will take this suggestion into consideration in future refinement of the clinical SPADEs.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Mechanically Altered Diet data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(o) Nutritional Approach: Therapeutic Diet

In the FY 2020 SNF PPS proposed rule (84 FR 17663), we proposed that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21073), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient's or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients and residents in PAC provides insight on the clinical complexity of these patients and residents and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet

is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. This data element is currently in use in the MDS in SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Therapeutic Diet data element was first proposed as standardized patient assessment data in the FY 2018 SNF PPS proposed rule (82 FR 21073). In response to our proposal in the FY 2018 SNF PPS proposed rule, commenters supported the adoption of the Therapeutic Diet as a standardized patient assessment data element. Some commenters stated that the coding instructions should be clear and more broadly applicable to patients and residents in all PAC settings. Other commenters suggested that the definition of Therapeutic Diet should be aligned with the Academy of Nutrition and Dietetics' definition, with one stating that ''medically altered diet'' should be added to the nutritional data elements.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the proposed standardized patient assessment data elements. Although the TEP did not specifically discuss the Therapeutic Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for therapeutic diet, stakeholder input, and strong test results, we proposed that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic data element as standardized patient assessment data for use in the SNF QRP.

A commenter submitted the following comment related to the proposed rule's discussion of the Therapeutic Diet data element.

Comment: One commenter was supportive of collecting this data element.

Response: We thank the commenter for their support of the Therapeutic Diet data element.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Therapeutic Diet data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(p) High-Risk Drug Classes: Use and Indication

In the FY 2020 SNF PPS proposed rule (84 FR 17663 through 17665), we proposed that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[97] Moreover, changes in a patient's condition, medications, and transitions between care settings put patients and residents at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[98]

ADEs are known to occur across different types of healthcare settings. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[99] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[100] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[101] In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge

[97] U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI–06–09–00090. November 2010.

[98] Boockvar KS, Liu S, Goldstein N, Nebeker J, Siu A, Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. Qual Saf Health Care. 2009;18(1):32–6.

[99] Gandhi TK, Seger AC, Overhage JM, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6.doi:10.1097/PTS.0b013e3181dcae06.

[100] Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med.* 2005; 118(3):251±8. Epub 2005/03/05. *https://doi.org/10.1016/j.amjmed.2004.09.018* PMID: 15745723.

[101] Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. Kidney Int. 2009; 76:1192–1198. [PubMed: 19759525].

from a hospital.[102] [103] [104] ADEs are more common among older adults, who make up most patients receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.[105]

Understanding the types of medication a patient is taking and the reason for its use are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.[106] We proposed one High-Risk Drug Class data element with six sub-elements. The response options that correspond to the six medication classes are: Anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular: Bleeding risk is associated with anticoagulants and antiplatelets; [107] [108] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics; [109] misuse is associated with opioids; [110] fractures and strokes are associated with antipsychotics; [111] [112] and various adverse events, such as central nervous systems effects and gastrointestinal intolerance, are associated with antimicrobials,[113] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[114] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.[115]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a resident is taking any medications within the six drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is required to indicate if the resident is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the resident is taking anticoagulant medication, the assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. Similar data elements on some high-risk medications are already included in the MDS. We proposed to modify and expand existing data elements in the MDS to include additional high-risk drug classes and indications for all drug classes. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data element contractor. At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications.[116] A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited public input on data elements related to medication reconciliation during a public input

[102] Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31–36.

[103] Rozich J, Roger, R. Medication safety: One organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[104] Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm.* 2004;61(16):1689–1695.

[105] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

[106] Ibid.

[107] Shoeb M, Fang MC. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239–013–0899–7.

[108] Melkonian M, Jarzebowski W, Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: A systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

[109] Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[110] Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32 (4):725–735.

[111] Rigler SK, Shireman TI, Cook-Wiens GJ, Ellerbeck EF, Whittle JC, Mehr DR, Mahnken JD. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366].

[112] Wang S, Linkletter C, Dore D et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

[113] Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[114] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2019; 00:1–21. DOI: 10.1111/jgs.15767.

[115] Li Y, Salmasian H, Harpaz R, Chase H, Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011: 768–76.

[116] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

period from April 26 to June 26, 2017. Several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stated that the items seemed feasible and clinically useful. A few commenters were critical of the choice of 10 drug classes posted during that comment period, arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May–June 2017 Public Comment Summary Report'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. The TEP acknowledged the challenges of assessing medication safety, but were supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes and using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete this SPADE would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

Taking together the importance of assessing high-risk drugs and for whether or not indications are noted for high-risk drugs, stakeholder input, and strong test results, we proposed that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the High-Risk Drug Classes: Use and Indication data.

Comment: Several commenters supported the High-Risk Drug Class data element.

Response: We thank the commenters for their support of the High-Risk Drug Class data element.

Comment: One commenter requested detailed instructions and examples in the RAI Manual and a period established for ongoing feedback after data collection begins. Another commenter questioned whether ''high-risk drugs'' is the appropriate label for these medications and questioned whether the training and instruction manuals will cover all labeled indications within a drug class such as antipsychotics.

Response: We are committed to providing comprehensive training to providers for any new data elements, including standardized data elements, in order to foster common definitions, thereby ensuring the fidelity of the assessment. Resources available to SNFs will include the MDS RAI Manual, annual in-person trainings on the MDS, and CMS' ''helpdesk'' web resources.

We contend that the label of ''high-risk drugs'' is appropriate for this SPADE. We have selected drug classes that are commonly used by older adults and are related to adverse drug events which are clinically significant, preventable, and measurable. Anticoagulants, antibiotics, and diabetic agents have been implicated in an estimated 46.9 percent (95 percent CI, 44.2 percent–49.7 percent) of emergency department visits for adverse drug events.[117] Among older adults (aged ≥65 years), three drug classes (anticoagulants, diabetic agents, and opioid analgesics) have been implicated in an estimated 59.9 percent (95 percent CI, 56.8 percent–62.9 percent) of emergency department visits for adverse drug events.[118] Further, antipsychotic medications have been identified as a drug class for which there is a need for increased outreach and educational efforts to reduce use among older adults.

The commenter also inquired whether the training and instruction manuals will cover all labeled indications within a drug class such as antipsychotics. We wish to clarify that the assessor will be

[117] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. JAMA 2016;316(2):2115–2125.

[118] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. JAMA 2016;316(2):2115–2125.

recording whether or not a patient is taking any medication within the named drug classes (for example, antipsychotics), then, if indications are known for all medications within the drug class. Training and instruction manuals, as well as the instructional text in the SPADE itself, will specify that medications be recorded according to their pharmacological classification, not by how they are used.

Comment: One commenter noted that an adverse drug event may be a causal factor for admission to a PAC setting rather than an adverse drug event occurring while in a PAC setting. Further, the commenter urged CMS to avoid considering facilities with many patients taking a high-risk drug as negligent. Another cautioned that the quality of care of facilities should not be compared based on the mere presence of more high-risk drugs, which may be due to medical necessity.

Response: We appreciate the commenters' concern that the mere presence of medications in these drug classes should not be interpreted as a measure of quality; that is, we agree that having many patients at a facility taking high-risk drugs is not in and of itself an indicator of negligence or poor quality. We believe that medications in these classes can be safe, effective, and necessary for some patients/residents receiving care from PAC providers. We believe that each SNF serves a unique patient population with varying percentages of patients for whom high-risk medications are medically necessary, and therefore agree with the commenter that quality of care of PAC providers cannot be compared based on the presence of high-risk drugs alone.

Comment: One commenter encouraged CMS to collect more than the use of, and indication for, the drug. Another commenter suggested that the proposed antiplatelets item be combined with the existing anticoagulant MDS item and the proposed hypoglycemic medications item be added to the existing insulin injections MDS item.

Response: We appreciate the commenters' recommendations. We believe that gathering information on the use of and presence of an indication for these classes of medications is sufficient for a standardized data element, although we will take the recommendation to collect more information about medication under consideration in future work evaluating and refining the SPADEs. We decline the recommendation to combine antiplatelet and anticoagulants because of the different clinical considerations and associations related to each of these drug classes. We also believe that it would be inappropriate to combine the hypoglycemic drug class with the insulin injections item, as the High-Risk Drugs: Use and Indication SPADE pertains to all medications, not only those taken by injection.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(4) Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

In this section, we discuss our proposals for data elements related to the medical condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.[119] We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.[120] [121] [122]

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. The SPADEs will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

We invited comment that apply specifically to the standardized patient assessment data for the category of medical conditions and co-morbidities. We did not receive any comments on the category of medical conditions and co-morbidities.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

(a) Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities)

In acknowledgement of the opioid crisis, we specifically sought comment on whether or not we should add these pain items in light of those concerns. Commenters were asked to address to what extent collection of the data below through patient queries might encourage providers to prescribe opioids.

[119] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[120] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[121] Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[122] Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: Results of an interprofessional consensus summit. Pain Med Malden Mass. 2013;14(7):971–981. doi:10.1111/pme.12107.

In the FY 2020 SNF PPS proposed rule (84 FR 17666 through 17668), we proposed that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical condition and comorbidity data under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.[123] In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.[124] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[125] Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step towards appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.[126] Further, the focus on pain *interference,* as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in the FY 2020 SNF PPS proposed rule (84 FR 17663 to 17665) we proposed a SPADE that assess for the use of, as well as importantly the indication for the use of, high-risk drugs, including opioids. Further, in the FY 2017 SNF PPS final rule (81 FR 52039) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) SNF QRP measure which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s), which includes issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADE related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly,[127] [128] [129] an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[130] [131] [132]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example, the standardized assessment of both opioids and pain interference would support providers in successfully tapering the dosage regimens in patients/residents who arrive in the PAC setting with long-term opioid use off of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[133] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis [134] which includes ''Better Pain Management.''

The Pain Interference data elements consist of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain affects a resident's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a resident's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a resident's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument. We proposed to expand and modify the existing Pain data elements in the MDS to include the Pain Effect on Sleep; Pain Interference with Therapy Activities; and Pain Interference with Day to Day Activities data elements. For more information on the Pain

[123] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (US); 2011. *http://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[124] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[125] National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.* Washington DC: National Academies of Sciences, Engineering, and Medicine.; 2017.

[126] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

[127] Chau, D.L., Walker, V., Pai, L., & Cho, L.M. (2008). Opiates and elderly: Use and side effects. *Clinical interventions in aging, 3*(2), 273–8.

[128] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[129] Solomon, D.H., Rassen, J.A., Glynn, R.J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S. (2010). *Archives Internal Medicine,* 170(22):1979–1986.

[130] Byrd L. Managing chronic pain in older adults: Along-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging.* 2013;21(12):34–40.

[131] Kligler, B., Bair, M.J., Banerjea, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine, 33*(Suppl 1): 16. *https://doi.org/10.1007/s11606-018-4323-z.*

[132] Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. An*nals of Internal Medicine, 166*(7):493–505.

[133] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. *https://paltc.org/opioids%20in%20nursing%20homes.*

[134] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

Interference data elements, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We held a public input period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference—Therapy Activities; Pain Interference—Other Activities) in a second call for public input, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May-June 2017 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the standardized patient assessment data elements. The TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the Pain data elements and was encouraged by the fact that this portion of the assessment goes beyond merely measuring the presence of pain. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for the effect of pain on function, stakeholder input, and strong test results, we proposed that the three Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to our proposal to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities).

Comment: Several commenters expressed support for the Pain Interference SPADEs, noting that these SPADEs will provide a useful and more accurate assessment of a patient's ability to function, and that understanding the impact of pain on therapy and other activities, including sleep, can improve the quality of care, which in turn will support providers in their ability to provide effective pain management services.

Response: We thank the commenters for their support of the Pain Interference data elements.

Comment: One commenter noted that the proposed Pain Interference SPADEs document pain frequency but stated that it is important to identify both pain frequency and pain intensity. Another commenter noted that the Pain Interference questions do not address frequency of pain interference.

Response: We wish to clarify the Pain Interference SPADEs are interview data elements that ask the patient the frequency with which pain interferes with sleep, therapy, or non-therapy activities. These data elements therefore combine the concepts of frequency and intensity, with the measure of intensity being interference with the named activities. Self-reported measures of pain intensity are often criticized for being infeasible to standardize. In these data elements, interference with activities is an alternative to asking about intensity.

Comment: A commenter expressed concerns about the suitability of the Pain Interference SPADEs for use in patients with cognitive and communication deficits and urged CMS to consider the use of non-verbal means to allow patients to respond to SPADEs related to pain. Another commenter questioned how pain interference would be captured for residents who refused or were unable to complete the pain interview.

Response: We appreciate the commenter's concern surrounding pain assessment with patients with cognitive and communication deficits. The Pain Interference SPADEs require that a patient be able to communicate, whether verbally, in writing, or using another method. Assessors may use non-verbal means to administer the questions (for example, providing the questions and response in writing for a patient with severe hearing impairment). Patients who are unable to communicate by any means, would not be required to complete the Pain Interference SPADEs. In addition, evidence suggests that pain presence can be reliably assessed in non-communicative patients through structural observational protocols. To that end, we tested observational pain presence elements in the National Beta Test, but have chosen not to propose those data elements as SPADEs at this time out of consideration of the scale of additions and changes that would be required of PAC providers. We will take the commenter's concern into consideration as the SPADEs are monitored and refined in the future.

Comment: A commenter expressed concerns about how CMS might use these data elements, noting particular concern that collection of these SPADEs may inappropriately translate into an assessment of quality, and that data collection on this topic could create incentives that directly or indirectly interfere with treatment decisions.

Response: We appreciate the commenter's concern related to wanting to understand how we will use the SPADEs. Any additional uses of these SPADEs for the assessment of quality will be adopted through the rulemaking process. We intend to communicate and collaborate with stakeholders about how the SPADEs will be used in the SNF QRP, as those plans are developed, by soliciting input through future rulemaking.

Comment: One commenter noted that there are currently seven MDS questions in the Resident Pain Assessment and that the current proposal adds three additional interview questions, but it is unclear if the existing pain questions will be replaced. This commenter requested that CMS balance the need for additional documentation requirements with the impact on the clinician's ability to focus on patient care.

Response: We acknowledge the commenter's concern about the number of additional data elements being added to the MDS as part of the Pain Interview. The MDS currently contains two questions under the heading Pain Effect on Function (J0500) on the topics of pain interference with sleep and pain interference with day-to-day activities. The current items have Yes/No response options. The proposed SPADEs will make two changes to these items. First, we added a data element on pain interference with therapy activities. Second, we proposed response options that reflect the frequency of pain interference on a 5-point scale, ranging from ''Rarely or not at all'' to ''Almost constantly.'' Other items on the MDS will remain unchanged. By adapting existing data elements from the MDS and integrating new SPADEs into existing skip patterns, we believe we have minimized additional documentation requirements while still ensuring that we have the appropriate data to foster interoperability, support care planning, and inform quality measurement.

Comment: One commenter appreciated CMS' request to provide feedback on the relation between pain assessment via the proposed Pain Interference SPADEs and the provider's willingness to prescribe opioids. This commenter believes CMS should monitor the correlation between the incidence of prescribing opioids and interview items and ensure expectations are aligned about what level of pain is acceptable and tolerable to the patient, through shared decision-making and education across the care delivery continuum, which includes the patients, their families, the patient care delivery teams, as well as regulators and surveyors.

Response: We intend to monitor the data submitted via the proposed SPADEs and will consider this use in the future.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(5) Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients and residents will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients and residents continue to have their vision and hearing needs met when they leave the facility.

In alignment with our Meaningful Measures Initiative, we expect accurate

and individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promote effective prevention and treatment of chronic disease; strengthen person and family engagement as partners in their care; and promote effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will: Enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

Comments on the category of impairments were also submitted by stakeholders during the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21076) public comment period. A commenter stated hearing, vision, and communication assessments should be administered at the beginning of assessment process, to provide evidence about any sensory deficits that may affect the patient's or resident's ability to participate in the assessment and to allow the assessor to offer an assistive device. Another commenter supported the decision to assess hearing and vision with respect to admission and not discharge, and to use existing MDS items for hearing and vision, thereby not creating additional burden.

We invited comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments. Commenters submitted the following comments related to the proposed rule's discussion of Impairments.

Comment: One commenter was concerned that screening for impairments would lead to an expectation that SNFs would need to take on the burden and cost of pursuing treatment for these impairments on short-stay SNF patients. This commenter suggested a provision be added to the final rule to clarify that a SNF is not responsible for pursuing treatments and services beyond the scope of care and services normally provided by the SNF.

Response: We appreciate the commenter's concern. The adoption of SPADEs related to hearing and vision impairment are intended to collect data related to patient acuity and to ensure that clinically important information is assessed in a standardized way across settings, to support interoperability and care transitions. The adoption of the Hearing and Vision SPADEs does not affect the expectations that CMS has for SNF providers to provide a standard of care to residents that conforms to the CoPs. Under 42 CFR 483.21(b)(1), the facility must provide the treatment and services set out in the resident's care plan. The facility, however, may transfer or discharge a resident under 42 CFR 483.15(c)(1)(i)(A) if his or her needs cannot be met at that facility.

Final decisions on the SPADEs are given below, following more detailed comments on each SPADE proposal.

(a) Hearing

In the FY 2020 SNF PPS proposed rule (84 FR 17668 through 17669), we proposed that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, social functioning, and emotional health.[135] [136] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[137] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[138] [139] [140] higher rates of incident cognitive impairment and cognitive decline,[141] and less time in occupational therapy.[142] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Hearing data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21074 through 21075). In that proposed rule, we stated that the proposal was informed by input we received on the PAC PRD form of the data element (''Ability to Hear'') through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported Hearing as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions

[135] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[136] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[137] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[138] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: A review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[139] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[140] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[141] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[142] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

about use of a hearing device by the resident should be more clearly defined. Commenters were supportive of adopting the Hearing data element for standardized cross-setting use, noting that it would help address the needs of patient and residents with disabilities and that failing to identify impairments during the initial assessment can result in inaccurate diagnoses of impaired language or cognition and can validate other information obtained from patient assessment.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for hearing, stakeholder input, and strong test results, we proposed that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Hearing data element.

Comment: Three commenters supported the collection of information on hearing impairment. One of these commenters also suggested that CMS consider how hearing impairment impacts a patient's ability to respond to the assessment tool in general.

Response: We thank the commenters for their support of the Hearing data element.

Comment: One commenter recommended adding ''unable to assess'' as a response option, which the commenter believed would be the appropriate choice if a patient has a diagnosis that may limit a hearing assessment.

Response: We appreciate the commenter's recommendation. The assessment of hearing is completed based on observing the patient during assessment, patient interactions with others, reviewing medical record documentation, and consulting with patient's family and other staff, in addition to interviewing the patient. Therefore, the assessment can be completed when the patient is unable to effectively answer questions related to an assessment of their hearing.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Hearing data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(b) Vision

In the FY 2020 SNF PPS proposed rule (84 FR 17669 through 17671), we proposed that the Vision data element meets the definition of SPADE with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076), evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and residents and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[143] [144] [145] [146] [147] [148] [149] Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the SNF setting for care planning and defining resource use.

The proposed data element consists of the single Vision data element (Ability To See in Adequate Light) that consists of one question with five response categories. The Vision data element that we proposed for standardization was tested as part of the development of the

[143] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: Who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[144] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: The Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[145] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[146] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[147] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[148] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[149] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

MDS in SNFs and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS. For more information on the Vision data element, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

The Vision data element was first proposed as a SPADE in the FY 2018 SNF PPS proposed rule (82 FR 21075 through 21076). In that proposed rule, we stated that the proposal was informed by input we received on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. Although the data element in public comment differed from the proposed data element, input submitted from August 12 to September 12, 2016 supported assessing vision in PAC settings and the useful information a vision data element would provide. We also stated that commenters had noted that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element in SNFs over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In response to our proposal in the FY 2018 SNF PPS proposed rule, some commenters supported Vision as a standardized patient assessment data element to facilitate care coordination. One stated that coding instructions for use of a vision device by the resident should be more clearly defined. Commenters recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. One commenter supported having a SPADE for vision across PAC settings, but stated it captures only basic information for risk adjustment, and more detailed information would need to be collected to use it as an outcome measure.

Subsequent to receiving comments on the FY 2018 SNF PPS rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our on-going SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on Standardized Patient Assessment Data Elements (SPADEs) Received After November 27, 2018 Stakeholder Meeting'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

Taking together the importance of assessing for vision, stakeholder input, and strong test results, we proposed that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the SNF QRP.

Commenters submitted the following comments related to the proposed rule's discussion of the Vision data element.

Comment: A few commenters supported the collection of information on vision impairment. One of these commenters additionally recommended that a doctor of optometry should play a lead role in conducting vision assessments, and that vision assessments done by other clinicians should also obtain the patient's own assessment of his or her vision, such as used by the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factors Surveillance System survey, which asks patients ''Do you have serious difficulty seeing, even when wearing glasses?'' This commenter expressed concerns about the proposed SPADE being subjective and risks of mis-categorizing patients.

Response: We thank the commenters for their support. We also appreciate the commenter's recommendation about how to assess for vision impairment. We do not require that a certain type of clinician complete assessments; the SPADEs have been developed so that any clinician who is trained in the administration of the assessment will be able to administer it correctly. The proposed item relies on the assessor's evaluation of the patient's vision, which has the advantage of reducing burden placed on the patient. We will take the recommendation to use patient-reported vision impairment assessment into consideration in the development of future assessments.

Comment: A commenter also urged CMS to require vision assessment at

discharge, noting that vision impairment could be related to challenges in medication management and compliance with written follow-up instructions for care.

Response: We appreciate the commenter's feedback. We agree that adequate vision—or the accommodations and assistive technology needed to compensate for vision impairment—is important to patient safety in the community, in part for the reasons the commenter mentions. In the FY 2020 SNF PPS proposed rule (84 FR 17644), we proposed that SNFs that submit the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge, as there is a low likelihood that the assessment of this SPADEs at admission would differ from the assessment at discharge. Vision assessment, collected via the Vision SPADE with respect to admission, will provide information that will support the patient's care while in the SNF. We also contend that significant clinical changes to a patient's vision will be documented in the medical record as part of routine clinical practice, and would therefore be known to the provider at the time of discharge. Awareness of the patient's vision impairment would likely require accommodations with regard to written follow up instructions and medication management plan, but the information on visual impairment at discharge would be available in the medical record even though it would not be collected as part of the Vision SPADE.

Out of consideration for the burden of data collection, and based on our understanding of visual impairments being monitored by providers throughout a patient's episode of care, SNFs that submit the Vision SPADE with respect to admission will be deemed to have submitted with respect to both admission and discharge. We note that during the discharge planning process, it is incumbent on SNF providers to make reasonable assurances that the patient's needs will be met in the next care setting, including in the home.

Comment: One commenter recommended adding ''unable to assess'' as a response option, which the commenter believed would be the appropriate choice if a patient has a diagnosis that may limit a vision assessment.

Response: We appreciate the commenter's recommendation. However, the assessment of vision is completed based on consulting with patient's family and other staff, observing the patient, including asking the patient to read text or examine pictures or numbers, in addition to interviewing the patient about their vision abilities. These other sources/methods can be used to complete the assessment of vision when the patient is unable to effectively answer questions related to an assessment of their vision.

Comment: One commenter noted that assessment through the vision data element is just an initial step towards a care coordination system that recognizes the impact that eye health has on overall health outcomes. This commenter noted that a critical next step would be to ensure that patients get to the physician who can address their eye health needs.

Response: We appreciate the commenter's recommendation and we agree that screening for vision impairment is an initial step towards ensuring patients receive the care they need. We expect SNF providers to provide a standard of care to residents that conforms to the CoPs, and we defer to the clinical judgement of the resident's care team to determine when further assessment of vision or eye-related issues is warranted.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Vision data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(6) New Category: Social Determinants of Health

(a) Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare based on those measures, after taking into account studies conducted by ASPE on social risk factors (described below) and other information, and based on an individual's health status and other factors. Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every three years, based on the factors referred to subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described above in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we proposed to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act. We proposed to collect and access data about social determinants of health (SDOH) in order to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail below. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We proposed to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section III.E.1.g.(6) of this final rule.

We also proposed to use the resident assessment instrument minimum data set (MDS), the current version being MDS 3.0, described as a PAC assessment instrument under section 1899B(a)(2)(B) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC health care providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in section III.E.1.h.(4) of this final rule. Subparagraphs (A) and (B) of section 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed below, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We

acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering, and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature review. Based on the information collected, the 2016 NASEM panel report titled, ''Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors,'' concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These factors are discussed at length in chapter 2 of the NASEM report, titled ''Social Risk Factors.'' [150] Consequently NASEM framed the results of its report in terms of ''social risk factors'' rather than ''socioeconomic status'' or ''sociodemographic status.'' The full text of the ''Social Risk Factors'' NASEM report is available for reading on the website at *https://www.nap.edu/read/21858/chapter/1*.

Each of the data elements we proposed to collect and access under our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[151]

ASPE issued its first Report to Congress, titled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' under section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.[152] Using NASEM's social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) Dual enrollment in Medicare and Medicaid as a marker for low income, (2) residence in a low-income area, (3) Black race, (4) Hispanic ethnicity, and; (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been collected, the collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports*.

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under sections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, CMS' ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information relating to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible. The three components of this strategy are to: (1) Measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed above, ASPE's study, and considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we proposed to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section III.E.1.g.(6) of this final rule, under

[150] National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors*. Chapter 2. Washington, DC: The National Academies Press.

[151] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health*. (February 2019).

[152] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

section 2(d)(2) of the IMPACT Act, would be independent of our proposal below (in section III.E.1.g.(6) of this final rule) and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed above, we proposed under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section III.E.1.g.(6)(b)(i) of this final rule; (2) Ethnicity, as described in section III.E.1.g.(6)(b)(i) of this final rule; (3) Preferred Language, as described in section III.E.1.g.(6)(b)(ii) of this final rule; (4) Interpreter Services as described in section III.E.1.g.(6)(b)(ii) of this final rule; (5) Health Literacy, as described in section III.E.1.g.(6)(b)(iii) of this final rule; (6) Transportation, as described in section III.E.1.g.(6)(b)(iv) of this final rule; and (5) Social Isolation, as described in section III.E.1.g.(6)(b)(v) of this final rule. These data elements are discussed in more detail below in section III.E.1.g.(6)(b) of this final rule. A detailed discussion of the comments we received, along with our responses, is included in each section.

(b) Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. Below we proposed to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined above under section 2(d)(2)(B) of the IMPACT Act, we also proposed to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We proposed to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we proposed under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of residents and patients, and to inform our understanding of resident and patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional social determinants of health, we proposed to assess some of the factors relevant for patients and residents receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients and residents with identified needs with transportation programs, certified interpreters, or social support programs.

We proposed to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health category: Race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations and state agencies and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled ''Listening Session on Social Determinants of Health Data Elements: Summary of Findings,'' includes a list of participating stakeholders and their affiliations, and is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We solicited comment on these proposals.

Comment: One commenter supported the incorporation of SDOH to promote access and assure high-quality care for all beneficiaries, but encouraged CMS to be mindful of meaningful collection and the potential for data overload as well as the ability to leverage existing data sources from across care settings. Since SDOH have impacts far beyond the post-acute care (PAC) setting, the commenter cautioned data collection that cannot be readily gathered, shared, or replicated beyond the PAC setting.

The commenter encouraged CMS to consider leveraging data points from primary care visits and pointed out that the ability to have a hospital's or physician's EHR also collect, capture, and exchange segments of this information is powerful. The commenter recommended that CMS take a holistic view of SDOH across the care continuum so that all care settings

may gather, collect or leverage this data efficiently and impactfully.

Response: We agree that collecting SDOH data elements can be useful in identifying and address health disparities and agree with the feedback that we should be mindful of meaningful collection of SDOH data collection efforts so that data elements that are selected are useful. The proposed SDOH SPADEs are aligned with SDOH identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report, which was commissioned by Office of the Assistant Secretary for Planning and Evaluation (ASPE). Regarding the commenter's suggestion that we consider how it can align existing and future SDOH data elements to minimize burden on providers, we agree that it is important to minimize duplication efforts and will take this under advisement for future consideration.

Comment: One commenter supported and applauded CMS' recognition of the impact of social determinants of health (SDOH), as well as its efforts to implement a data collection process for social risk factors. However, the commenter is concerned that CMS proposed to implement untested data elements and recommended CMS should first develop a thoughtful data analysis plan, as it has done in other provider settings that uses a proxy for SDOH to help inform next steps in data collection at the patient level.

Response: We want to note that each of the data elements proposed is currently in use and was developed with significant testing as part of our analysis plan before proposing. Additionally, as provided in the FY 2020 SNF PPS proposed rule (84 FR 17620), the proposed SPADE was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors.

Comment: One commenter is pleased to see the proposal for a new category of SPADEs that would collect data on SDOH. In addition to potentially adding to the provider's knowledge of the individual, when aggregated, this information will allow for greater understanding of the needs of vulnerable populations as well as permit the creation of tools to assess provider performance on quality metrics among different populations. One commenter recommended that CMS may also want to consider adding level of education to the data collected regarding social determinants of health.

Response: We will consider this feedback as we continue to improve and refine the SPADEs.

Comment: One commenter supported CMS' continuing emphasis on SDOH and recognized that well-executed SDOH approaches have wide-ranging effects on government payment systems, and are interconnected to the development of QRP reporting requirements. The commenter noted that any change to payment methodologies should account for these factors to maintain access to care in an equitable manner. Another commenter supports CMS' proposal to adopt the seven data elements as SPADEs under the proposed SDOH.

Response: We agree that SDOH impact patient outcomes and healthcare costs. We will share your feedback with those who provide oversight for the SNF prospective payment system.

Comment: Commenters were generally in favor of the concept of collecting SDOH data elements and provided that if implemented appropriately the data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. However, some of the commenters suggested that CMS not finalize the proposed policy until it can address important issues around the potential future uses of these elements and the requirements around data collection for certain elements. The commenters provided that CMS did not state explicitly in the rule whether it anticipates the SDOH SPADEs will be used in adjusting measures and believe that the IMPACT Act's requirements make it likely the SPADEs will be considered for use in future adjustments. The commenters urged CMS to be circumspect and transparent in its approaches to incorporating the data elements proposed in payment and quality adjustments, such as by collecting stakeholder feedback before implementing any adjustments.

Response: We thank the commenters for recognizing that collecting SDOH data elements can be useful in identifying and addressing health disparities. As provided in the FY 2020 SNF PPS proposed rule (84 FR 17672), accessing standardized data relating to the SDOH data elements on a national level is necessary to permit us to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Additionally, these data will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs, and improve the quality of care for all beneficiaries. We will continue to work with stakeholders to promote transparency and support providers who serve vulnerable populations, promote high quality care, and refine and further implement SDOH SPADE to meet the IMPACT Act requirements. We appreciate the comment on collecting stakeholder feedback before implementing any adjustments to measures based on the SDOH SPADE. Collection of this data will help us in identifying potential disparities, conducting analyses, and assessing whether any adjustments are needed. Any future policy development based on this data would be done transparently, and involve solicitation of stakeholder feedback through the notice and comment rulemaking process as appropriate.

Comment: One commenter supported the proposal to collect information on the seven proposed SDOH SPADE data elements. However, the commenter suggested that it is important to include metrics to determine if a resident is low-income in the SNF QRP SPADEs. The commenter referenced the ASPE report to Congress in 2016 that noted Medicare beneficiaries with social risk factors have worse outcomes on many quality measures; therefore, the commenter urged CMS to incorporate risk adjustment for sociodemographic and socioeconomic status into the appropriate SNF QRP and SNF VBP performance measures. The commenter also recommended that CMS closely monitor the effects of its quality improvement initiatives on low-income communities to ensure that resources are not being driven away from these communities to more affluent communities solely on the basis of comparatively higher quality scores and consider new initiatives that provide incentives specifically targeted at reducing identified disparities.

Response: We appreciate the commenter's support. We understand the commenters concern that CMS ensure that the new SDOH data elements not negatively impact the resources of low-income communities and would note that at this time we did not propose using SDOH SPADEs for risk adjustment as part of this rulemaking. We will consider the commenter's feedback in future policy making, including in regard to risk adjustment, and as we monitor the effects of our quality improvement initiatives.

Comment: Several commenters recommended that CMS include

disability status as a SDOH that contributes to overall patient access to care, health status, outcomes, and many other determinants of health since it is already included in some Medicare risk adjustment. The commenters stated that ASPE's report to Congress entitled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs'' reported that disability is an independent predictor of poor mental and physical health outcomes, and that individuals with disabilities may receive lower-quality preventive care.

Response: We appreciate the comments and suggestions provided by the commenters, and we agree that it is important to understand the needs of patients with disabilities. While disability is not being currently assessed through the SPADE, it is comprehensively assessed as part of existing protocols around care plans and health goals. However, as we continue to evaluate SDOH SPADEs, we will keep commenters' feedback in mind and may consider these suggestions in future rulemaking.

Comment: One commenter supported the use of the seven proposed SDOH data elements and suggested that CMS explore assessing if a patient has a family or caregiver and whether they are competent. They suggested this should be assessed since the health and capability of the family caregiver for someone with advanced illness can have a significant impact on their health and medical interventions.

Response: Thank you for the comment. We had to balance the importance of new SDOH data elements with the potential burden of adding more SDOH data elements to the assessment, beyond the seven that were selected. We will consider this feedback as we continue to improve and refine the SPADEs.

(i) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[153] [154] [155] [156] [157] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[158] For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower rates of having a usual source of care and receiving immunizations such as the flu vaccine.[159] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[160] However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.[161]

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF–PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[162] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino, and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54*.

We proposed to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we proposed two separate data elements: one for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards, a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, ''What is your race?'' We proposed to include fourteen response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, ''Are you of Hispanic, Latino/a, or Spanish origin?'' We proposed to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano/a; (3) Puerto Rican; (4) Cuban; and, (5) Another Hispanic, Latino, or Spanish Origin. We are including the addition of ''of'' to the Ethnicity data

[153] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[154] Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). Annual Review of Public Health. 37:375–394.

[155] 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

[156] Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). Unequal treatment: Confronting racial and ethnic disparities in health care. Washington, DC, National Academy Press.

[157] Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. *J of Aging and Health.* 30(9):1406–1426.

[158] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/research/findings/nhqrdr/index.html*.

[159] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[160] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse*.aspx?lvl=4&lvlid=19.

[161] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/*.

[162] ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)''. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available from: *https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf*.

element to read, ''Are you of Hispanic, Latino/a, or Spanish origin?''

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the current race/ethnicity data element included in MDS, LCDS, IRF–PAI and, OASIS.[163] [164] [165] [166] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[167] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[168] By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the US population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt the Race and Ethnicity data elements described above as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we proposed to replace the current Race/Ethnicity data element with the proposed Race and Ethnicity data elements on the MDS. We also proposed that SNFs that submit the Race and Ethnicity data elements with respect to admission will be considered to have submitted with respect to discharge as well, because it is unlikely that the results of these assessment findings will change between the start and end of the SNF stay, making the information submitted with respect to a resident's admission the same with respect to a resident's discharge.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Race and Ethnicity SPADEs. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters noted that the response options for race do not align with those used in other government data, such as the U.S. Census or the Office of Management and Budget (OMB). The commenters also stated these responses are not consistent with the recommendations made in the 2009 Institute of Medicine (IOM) report. The commenters pointed out that IOM report recommended using broader OMB race categories and granular ethnicities chosen from a national standard set that can be ''rolled up'' into the broader categories. The commenters stated that it is unclear how CMS chose the 14 response options under the race data element and the five options under the ethnicity element and worried that these response options would add to the confusion that already may exist for patients about what terms like ''race'' and ''ethnicity'' mean for the purposes of health care data collection. The commenters also noted that CMS should confer directly with experts in the issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized. One commenter also suggested that in lieu of data collection on Race/Ethnicity, collection of cultural information such as End of Life decisions, cultural holidays, celebrations or ceremonies, and other cultural norms is much more valuable for patient care outcomes and care delivery.

Response: The proposed Race and Ethnicity categories align with and are rolled up into the 1997 OMB minimum data standards and conforming with the 2011 HHS Data Standards as described in the implementation guidance titled ''U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status'' at *https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status*. As stated in the proposed rule, the 14 race categories and the 5 ethnicity categories conform with the 2011 HHS Data Standards for person-level data collection, which were developed in fulfillment of section 4302 of the Affordable Care Act that required the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability

[163] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. J Public Health Manag Pract. 22 Suppl 1: S33–42.

[164] Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: Do you have REGAL data? Qual Manag Health Care. 21(3):176–87.

[165] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[166] ''Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).'' **Federal Register** 82: 39 (March 1, 2017) p. 12242.

[167] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/*.

[168] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

status. Through the HHS Data Council, which is the principal, senior internal Departmental forum and advisory body to the Secretary on health and human services data policy and coordinates HHS data collection and analysis activities, the Section 4302 Standards Workgroup was formed. The Workgroup included representatives from HHS, the OMB, and the Census Bureau. The Workgroup examined current federal data collection standards, adequacy of prior testing, and quality of the data produced in prior surveys; consulted with statistical agencies and programs; reviewed OMB data collection standards and the Institute of Medicine (IOM) Report Race, Ethnicity, and Language Data Collection: Standardization for Health Care Quality Improvement; sought input from national experts; and built on its members' experience with collecting and analyzing demographic data. As a result of this Workgroup, a set of data collection standards were developed, and then published for public comment. This set of data collection standards is referred to as the 2011 HHS Data Standards.[169] The categories of race and ethnicity under the 2011 HHS Data Standards allow for more detailed information to be collected and the additional categories under the 2011 HHS Data Standards can be aggregated into the OMB minimum standards set of categories.

As noted in the FY 2020 SNF PPS proposed rule (84 FR 17672 through 17675), CMS conferred with experts by conducting a listening session regarding the proposed SDOH data elements regarding the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Data Standards to better reflect state and local diversity.

Collecting Race/Ethnicity is important for evaluating the impact that SDOHs have on health outcomes. Because of this, CMS will collect Race/Ethnicity instead of replacing these data element with the collection of cultural information such as End of Life decisions, cultural holidays, celebrations or ceremonies, and other cultural norms.

Comment: A commenter supported the opportunities to better account for SDOH in the diagnosis and treatment of patients but was concerned by the specificity of several of the seven proposed element for data collection for example, collection of race by Japanese, Chinese, Korean, etc. The commenter's concern was with the added burden in collecting the level of specificity outlined, and they requested that CMS provide more detailed guidance in the final rule regarding how this information should be collected and shared in compliance with HIPAA. Further, the commenter requested that the agency outlines its expectations for how this newly collected information will be used by Medicare for payment and public reporting.

Response: For the Race and Ethnicity SPADE data element, this data should be completed based on the response of the patient, which is considered the gold standard of assessing race and ethnicity. It is important ask the patient to select the category or categories that most closely correspond to their race and ethnicity. Respondents should be offered the option of selecting one or more race and ethnicity categories. Observer identification or medical record documentation may not be used.

Finally, as provided in the FY 2020 SNF PPS proposed rule (84 FR 17671through 17672), accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Any potential future use of the data for payment and public reporting purposes would be done through rulemaking.

SDOH Data elements should be treated the same as other information currently collected on the assessment tool. As to any specific HIPAA question, we appreciate the commenter's commitment to compliance with the HIPAA requirements, but note that the Office for Civil Rights (OCR) is tasked with implementing and enforcing HIPAA, not CMS. Commenters should consult appropriate counsel in instances in which they are unsure of their HIPAA status, or the permissibility of a disclosure under the HIPAA Privacy Rule. In doing so, commenters may wish to consult 45 CFR 164.103 (definition of ''required by law'') and 164.512(a) (allowing ''required by law'' disclosures).

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Race data element as SPADE as proposed, and the Ethnicity data element as SPADE with the addition of one technical change discussed above, beginning with the FY 2022 SNF QRP.

(ii) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).[170] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[171] [172] [173] Communication with individuals with LEP is an important component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing high quality care. Understanding the communication assistance needs of residents and patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of residents and patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs

[169] HHS Data Standards. Available at *https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status.*

[170] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[171] Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. *J Hosp Med.* 2010 May–Jun;5(5):276–82. doi: 10.1002/jhm.658.

[172] Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. *J Gen Intern Med.* 2017 Jun;32(6):632–639. doi: 10.1007/s11606–017–3999–9.

[173] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

should be assessed as a standard part of health care delivery and quality improvement strategies.[174]

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-reviewed research. The current preferred language data element in LCDS and MDS asks, ''What is your preferred language?'' Because the preferred language data element is open-ended, the patient or resident is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, ''Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.'' In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, ''Do you want or need an interpreter to communicate with a doctor or health care staff?'' and includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's or resident's preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing resident and patient needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54*.

Research consistently recommends collecting information about an individual's preferred spoken language and evaluating those responses for purposes of determining language access needs in health care.[175] However, using ''preferred spoken language'' as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient or resident. Therefore we proposed to retain the Preferred Language and Interpreter Services data elements currently in use on the MDS.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt the Preferred Language and Interpreter Services data elements currently used on the MDS, and describe above, as SPADEs with respect to the Social Determinants of Health category.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of Preferred Language and Interpreter Services SPADEs. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters noted that, if finalized, SNFs only would need to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient's preferred language and need for an interpreter also are unlikely to change between admission and discharge; thus, the commenter urged CMS to deem SNFs that submit data with respect to admission for these SDOH SPADEs to have submitted with respect to both admission and discharge.

Response: We thank the commenters for the comment. With regard to the submission of the Preferred Language and the Interpreter Services SPADE, we agree with the commenters that it is unlikely that the assessment of Preferred Language and Interpreter Services at admission would differ from assessment at discharge. As discussed in previous response for Vision and Hearing, we believe that the submission of preferred language and the need for an interpreter is similar to the submission of Race, Ethnicity, Hearing, and Vision SPADEs.

In response to commenters' feedback, we are finalizing that SNFs that submit the Preferred Language and Interpreter Services SPADES with respect to admission will be deemed to have submitted with respect to both admission and discharge.

Based on the comments received, and for the reasons discussed, we are finalizing that the Preferred Language and Interpreter Services SPADEs be collected with the modification that we will deem SNFs that submit these two SPADEs with respect to admission to have submitted with respect to discharge as well.

[174] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[175] Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7—April 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf*.

(iii) Health Literacy

The Department of Health and Human Services defines health literacy as ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' [176] Similar to language barriers, low health literacy can interfere with communication between the provider and resident or patient and the ability for residents and patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.[177]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[178] Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM noted that health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.[179] Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and residents and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF–PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, ''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'' Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability, (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S–TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[180] [181] The S–TOFHLA is a more complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.[182] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[183] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we proposed to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of SNF residents to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients and residents understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided at an appropriate literacy level based on individualized assessment of health literacy.[184] Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice, we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.[185] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt the SILS question, described above for the Health Literacy data element, as SPADE under the Social Determinants of Health Category. We proposed to add the Health Literacy data element to the MDS.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Health Literacy data element. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters noted that, if finalized, SNFs should only need

[176] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

[177] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[178] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health*. (February 2019).

[179] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*. Washington, DC: 2016.

[180] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[181] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[182] University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available at *https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html*.

[183] Nurss, J.R., Parker, R.M., Williams, M.V., & Baker, D.W., David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: *http://www.peppercornbooks.com/catalog/information.php?info_id=5*.

[184] Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

[185] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

to submit data on the race and ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. The commenters believe that a patient's health literacy is unlikely to change between admission and discharge; thus, the commenter suggested that CMS require collection of all SDOH SPADEs, including Health Literacy, with respect to admission only.

Response: We thank the commenters for their comments. We disagree with the commenters that it is unlikely patient status for health literacy will change from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, some patients may develop health issues, such as cognitive decline, during their stay that could impact their response to health literacy thus changing their status at discharged. Although not directly evaluated for health literacy, clinical conditions that impact a patient's health literacy status would be captured in the clinical record, even if they are not assessed by a SPADE. Therefore, we proposed to collect this SPADEs with respect to both admission and discharge.

Comment: One commenter did not support the proposal to add health literacy data element because the question focuses on whether an individual may (or may not) have a literacy deficit, but fails to identify the many reasons why a literacy deficit may exist, which the commenter notes would be more valuable to patient care delivery and patient care outcomes. The commenter also requested more clarification on the connection between the frequencies in which an individual needs assistance with reading in lieu of the reasons why an individual has a literacy deficit.

Response: As provided in the proposed rule (84 FR 17675 through 17676), low health literacy can interfere with communication between the provider and patient and the ability for patients or their caregivers to understand and follow treatment plans, including medication management. Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. While we agree that exploring the reasons for low health literacy are important, we proposed the Health Literacy SPADE while balancing the need to avoid excessive burden on patients and health care providers, and we believe that a Health Literacy SPADE that identifies reasons why a literacy deficit exists creates additional burden on both the patients and the providers. The SILS Health Literacy data element we proposed performed well when tested, and it minimizes concerns related to burden by requiring one, instead of multiple, questions on health literacy.[186] [187]

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Health Literacy data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(iv) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[188] Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient or resident would be given the option to select all responses that apply. We proposed to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[189]

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.[190] This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[191] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for SNF residents and patients to facilitate appropriate discharge planning and care coordination across PAC settings. As such, we proposed to adopt the Transportation data element from

[186] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[187] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[188] Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. *J Community Health.* 38(5): 976–993.

[189] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.www.aha.org/transportation.*

[190] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.*

[191] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

PRAPARE. More information about development of the PRAPARE tool is available on the website at *https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare*.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt the Transportation data element described above as SPADE with respect to the Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the MDS.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Transportation data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supported the proposal to add the Transportation data element to the MDS because they agreed that this information is valuable to discharge planning and understanding the outcomes of post discharge from an inpatient stay. The commenter provided that transportation has been a long-standing barrier to health care and quality of life for the elderly and that an increase in financial or community resources would improve a patient's capacity to comply with their discharge plan of care or their ability to stay engaged in social activities.

Response: We thank the commenter.

Comment: One commenter requested that CMS consider the limited resources in the community to assist patients in meeting their transportation needs and requested that CMS consider using this data to facilitate the increase in access to transportation services for the elderly patients living in the community.

Response: Thank you for the comment and we will consider this feedback as we continue to improve and refine the SPADES.

Comment: The commenters believe that a patient's access to transportation is unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of all SDOH SPADEs, including Transportation, with respect to admission only.

Response: We disagree with the commenters that stated that access to transportation will always be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, as previously discussed, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact his or her access to transportation and impact how the patient responds to the access to transportation SPADE data element. Therefore, we believe that the response to this SDOH data element is likely to change from admission to discharge for some patients and we proposed to collect this SPADE data element with respect to both admission and discharge. As outlined in the FY 2020 SNF QRP proposed rule, multiple studies have demonstrated that access to transportation has an impact on the health of patients (84 FR 17676 through 17677). Therefore, it is important for providers to be able to identify a patient's needs when the patient is admitted and when the patient is discharged in order to better inform the patient's care decisions made during and after the stay, including understanding the patient's unique risk factors and treatment preferences. Because of this, we are keeping our proposal to require SNFs to submit the Transportation data element at both admission and discharge.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transportation data element as standardized patient assessment data beginning with the FY 2022 SNF QRP as proposed.

(v) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote area. [192] [193] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[194] [195] [196] Post-acute care providers are well-suited to design and implement programs to increase social engagement of patients and residents, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation in SNFs and across PAC settings would facilitate the identification of residents and patients who are socially isolated and who may benefit from engagement efforts.

We proposed to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress and asks, ''How often do you feel lonely or isolated from those around you?'' The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[197] The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at *https://innovation.cms.gov/*

[192] Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. J of Aging and Health. 18(3): 359–384.

[193] Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). Leading Age. Available at *https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1*.

[194] Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. BMJ Open. 7(5): e013778.

[195] Ong, A.D., Uchino, B.N., and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. *Gerontology*. 62:443–449.

[196] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. *Public Health*. 152:157–171.

[197] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

Files/worksheets/ahcm-screeningtool.pdf.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how social isolation and loneliness impact health outcomes in adults 50 years and older. We believe that adding a Social Isolation data element would be an important component of better understanding resident and patient complexity and the care goals of residents and patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled ''Proposed Specifications for SNF QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

In an effort to standardize the submission of social isolation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we proposed to adopt the Social Isolation data element described above as SPADE with respect to the proposed Social Determinants of Health category. We proposed to add the Social Isolation data element to the MDS.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion the Social Isolation data element. A discussion of these comments, along with our responses, appears below.

Comment: One commenter did not support the proposal to add the social isolation data element. The commenter provided that the MDS currently collects data on mood using the Resident Mood Interview and that the current data items in the Resident Mood Interview are sufficient to adequately assess the resident's mood without adding additional documentation requirements. The commenter also believed that the existing interview is the beginning of a larger conversion that often occurs between the resident and the interviewer. Additional insight is also needed to understand the purpose of collecting this information in addition to the existing mood questions. The commenter requested that CMS consider that there are life events that may occur in which it may be appropriate for an individual to feel lonely or isolated.

Response: As provided in the MDS, the intent of Resident Mood Interview items is to ''address mood distress, a serious condition that is underdiagnosed and undertreated in the nursing home and is associated with significant morbidity. It is particularly important to identify signs and symptoms of mood distress among nursing home residents because these signs and symptoms can be treatable''. However, the intent of the social isolation data element is not to assess how the individual feels, but whether the individual feels connected to those around them and can affect their mood. To collect and analyze information about social isolation in SNFs and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts. We appreciate the suggestion from the commenter that CMS should consider that there are life events that may occur in which it may be appropriate for an individual to feel lonely or isolated and will take the suggestion under consideration.

Comment: One commenter supported the addition of SDOH to the SPADEs, recognizing how these elements impact care use, cost and outcomes for Medicare beneficiaries. The commenter believed that an accurate understanding of the impact of SDOH is imperative and suggest adding clarifiers to the SDOH measures for transportation and social isolation. Adding a qualifying statement such as ''in your normal home environment'' to each of the two data elements would help patients to consider their normal daily living experiences rather than their acute experiences of the hospital and post-acute care stays when answering these questions.

Response: We thank the commenter and we will consider this feedback as we continue to improve and refine the SPADES.

Comment: A commenter supported the addition of SDOH to the SPADEs and noted that gathering these data will inform their understanding of resident and patient complexity and risk factors that may affect utilization of care, care outcomes and associated costs, and facilitate better alignment of payments with the added challenges posed by SDOHs. However, the commenter recommended adding a qualifier to the proposed SDOH measure for Social Isolation to ensure the patient's response reflects his/her home environment.

Response: As we continue to evaluate SDOH SPADEs, we will keep this in mind and will evaluate the addition of this qualifier.

Comment: The commenters believe that a patient's response to social isolation is unlikely to change between admission and discharge; thus, the commenter urged CMS to require collection of all SDOH SPADEs, including Social Isolation, with respect to admission only.

Response: We disagree with the commenters that stated that the response to the Social Isolation data element will be the same from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs as discussed previously, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, a patient could lose a family member or caregiver between admission and discharge, which could impact their response to the Social Isolation data element. Therefore, we proposed to collect this SPADE data element with respect to both admission and discharge. As outlined in the FY 2020 SNF PPS proposed rule, multiple studies have demonstrated that social isolation has an impact on the health of patients (84 FR 17677 through 17678). Therefore, we believe it is important for providers to be able to identify a patient's needs when the patient is admitted and when the patient is discharged in order to better inform the patient's care decisions made during and after the stay, including understanding the patient's unique risk factors and treatment preferences. Because of this, we are requiring that the Social Isolation data element be assessed at both admission and discharge.

Based on the comments received, and for the reasons discussed, we are finalizing our proposals for Social Isolation as proposed.

After consideration of the public comments, we are finalizing our proposals to collect SDOH data for the purposes under section 2(d)(2)(B) of the IMPACT Act and section 1899B(b)(1)(B)(vi) of the Act as follows. We are finalizing our proposals for Race, Ethnicity, Health Literacy,

Transportation, and Social Isolation as proposed. In response to stakeholder comments, we are revising our proposed policies and finalizing that SNFs that submit the Preferred Language and Interpreter Services data elements SPADEs with respect to admission will be deemed to have submitted with respect to both admission and discharge.

h. Form, Manner, and Timing of Data Submission Under the SNF QRP

(1) Background

We refer readers to the regulatory text at § 413.360(b) for information regarding the current policies for reporting SNF QRP data.

(2) Update to the CMS System for Reporting Quality Measures and Standardized Patient Assessment Data and Associated Procedural Proposals

SNFs are currently required to submit MDS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. We will be migrating to a new internet Quality Improvement and Evaluation System (iQIES) that will enable real-time upgrades over the next few years, and we proposed to designate that system as the data submission system for the SNF QRP once it becomes available. In the proposed rule, we anticipated the migration would occur no later than October 1, 2021. CMS can no longer commit to this date based on the current development timeline therefore, this migration will occur when technically feasible.

We proposed to revise our regulatory text at § 413.360(a) by replacing ''Certification and Survey Provider Enhanced Reports (CASPER)'' with ''CMS designated data submission''. We proposed to revise our regulatory text at § 413.360(d)(1) by replacing the reference to the ''Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP)'' with ''CMS designated data submission'' and § 413.360(d)(4) by replacing the reference to ''QIES ASAP'' with ''CMS designated data submission'' effective October 1, 2019. We are correcting our proposal to revise § 413.360(d)(4) to remove the term ''system'' from ''CMS designated data submission system''. In addition we proposed to notify the public of any future changes to the CMS designated system using subregulatory mechanisms, such as website postings, listserv messaging, and webinars.

We invited public comments on this proposal.

Commenters submitted the following comments related to the proposed rule's discussion of the Form, Manner, and Timing of Data Submission under QRP. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters noted support for the revisions to the regulatory text to reflect the migration to the new iQIES system for MDS data submission. One commenter further supported the proposal to notify the public of any future changes to the CMS designated system using subregulatory mechanisms. Another commenter suggested that CMS increase the number of unique users per provider number that may have access to the system, as the number of reports available and the number of staff members utilizing these reports has increased.

Response: We thank the commenters for their support, and would like to take this opportunity to inform SNFs that users will no longer require a virtual private network (VPN) or CMSNet to access iQIES so providers will no longer have limited unique user ID's per provider.

After considering the comments, we are finalizing the regulatory text with the technical revision described above.

(3) Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the FY 2022 SNF QRP

As discussed in section III.E.1.d. of this final rule, we proposed to adopt the Transfer of Health Information to Provider—Post-Acute Care (PAC) and Transfer of Health Information to Patient—Post-Acute Care (PAC) quality measures beginning with the FY 2022 SNF QRP. We also proposed that SNFs would report the data on those measures using the MDS. SNFs would be required to collect data on both measures for residents beginning with October 1, 2020 discharges.

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

We invited public comment on this proposal and did not receive any comments.

We are finalizing the schedule for our proposal that SNFs report the data on Transfer of Health Information to the Provider—Post-Acute Care (PAC) and Transfer of Health Information to the Patient—Post-Acute Care (PAC) quality measures using the MDS as proposed. SNFs will be required to collect data on both measures for residents beginning with October 1, 2020 discharges for the FY 2022 SNF QRP.

(4) Schedule for Reporting Standardized Patient Assessment Data Elements

As discussed in section III.E.1.f. of this final rule, we proposed to adopt SPADEs beginning with the FY 2022 SNF QRP. We proposed that SNFs would report the data using the MDS. Similar to the proposed schedule for reporting the Transfer of Health Information to the Provider—Post-Acute Care (PAC) and Transfer of Health Information to the Patient—Post-Acute Care (PAC) quality measures, SNFs would be required to collect the SPADEs for residents beginning with October 1, 2020 admissions and discharges. SNFs that submit data with respect to admission for the Hearing, Vision, Race, and Ethnicity would be considered to have submitted data with respect to both admissions and discharges. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames that we finalized for the SNF QRP.

We invited public comment on this proposal. For a discussion of the comments and responses we received regarding this proposal we refer the reader to section III.E.1.f.

After consideration of the comments received, we are finalizing our proposal that SNFs must submit SPADEs for all patients discharged on or after October 1, 2020, with respect to both admission and discharge, using the MDS. SNFs that submit data with respect to admission for the Hearing, Vision, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs will be deemed to have submitted data with respect to both admissions and discharges.

(5) Data Reporting on All Residents for the SNF Quality Reporting Program Beginning With the FY 2022 SNF QRP

We received public input suggesting that the quality measures used in the SNF QRP should be calculated using data collected from all residents receiving SNF services, regardless of the residents' payer. This input was provided to us via comments requested about quality measure development on the CMS Measures Management System Blueprint website,[198] the TEPs held by our measure development contractor,[199]

[198] Public Comment Summary Report Posting for Transfer of Health Information and Care Preferences. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-Cross-Setting-Transfer-of-Health-Information-Quality-Meas.pdf.*

[199] Technical Expert Panel Summary Report: Development and Maintenance of Quality Measures

Continued

as well as through comments we received from stakeholders via our SNF QRP mailbox, and feedback received from the NQF-convened Measure Applications Partnership (MAP) as part of their recommendations on Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement.[200] Further, in the FY 2018 SNF PPS proposed rule (82 FR 21077), we sought input on expanding the reporting of quality data to include all residents, regardless of payer, so as to ensure that the SNF QRP makes publicly available information regarding the quality of the services furnished to the SNF population as a whole, rather than just those residents who have Medicare.

In response to that request for public input, several commenters, including MedPAC, submitted comments stating that they would be supportive of an effort to collect data specified under the SNF QRP from all SNF residents regardless of their payer. Benefits highlighted by commenters included that such data would serve to better inform beneficiaries on the broader quality of the entire SNF, as well as more comprehensive quality improvement efforts across payers. MedPAC also highlighted that while the data collection activity incurs some cost, some providers currently assess all residents routinely. For a more detailed discussion we refer readers to the FY 2018 final rule (82 FR 36603 through 36604).

Further, we believe that the most accurate representation of the quality provided in SNFs to Medicare residents would be best conveyed using data collected via the MDS on all SNF residents, regardless of payer.

Accordingly, we proposed that for purposes of meeting the requirements of the SNF QRP, SNFs would be required to collect and submit MDS data on all SNF residents regardless of their payer. We believe that this will ensure that Medicare residents are receiving the same quality of SNF care as other residents.

While we appreciate that collecting quality data on all residents regardless of payer may create additional burden, we are aware that many SNFs currently collect MDS data on all residents, regardless of their payer, and that some SNFs may consider it burdensome to separate out Medicare beneficiaries from other residents for purposes of submitting the assessments to CMS.

We also note that collecting data on all SNF residents, regardless of their payer, would align our data collection requirements under the SNF QRP with the data collection requirements we have adopted for the LTCH QRP and Hospice QRP.

We proposed that, if finalized, this policy would be effective beginning with the FY 2022 program year.

We invited public comment on this proposal.

Commenters submitted the following comments on the proposed Data Reporting on Residents for the SNF Quality Reporting Program Beginning with the FY 2022 SNF QRP. Below is a summary of the comments as well as our responses.

Comment: Several commenters expressed support for the collection of data on all SNF residents regardless of payer. One commenter stated that ensuring that the quality of care is not conditional based on payer source is essential to the overall wellbeing of all SNF residents. Another commenter stated that collecting data on all patients regardless of payer is consistent with other quality programs. This commenter noted that collecting data from all payers gives consumers a more complete picture of quality of care within a SNF. Similarly, another commenter stated that requiring SNFs to report data on all patients regardless of payer would more accurately represent quality of care within a SNF.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS delay implementation until after FY 2022 SNF QRP to allow for added transition time for adoption of the SPADEs. One commenter requested that CMS make this requirement voluntary in the short-term. Several commenters expressed concern for the collection of data on all SNF residents regardless of payer and requested clarification on the details of this proposal including which residents the required data collection pertained to, the intended use of the data from payers other than Medicare, and how this proposal would affect penalties for non-compliance in the SNF QRP. One commenter questioned how this proposal would change the types and number of assessments applicable to this requirement, and how CMS would define which residents would be used to determine compliance with this requirement. This commenter requested that CMS consider staffing constraints and the technical complexity/coding rules required for accurate completion of SNF QRP items and suggested that CMS provide quarterly feedback via QIES that would display the SNF QRP all-payer MDS data submission to allow providers an opportunity to ensure they are meeting the data submission requirements or establish performance improvement processes. Another commenter has long been concerned about the attention to quality measurement for fee-for-service SNF patients compared to the paucity of information on corresponding quality measures regarding Medicare Advantage patients in a SNF, and suggested Medicare Advantage patients be included in quality measures displayed on Nursing Home Compare.

Response: We appreciate the feedback we have received for the all payer proposal and agree with the comments that providing clear policy and implementation guidelines would be most appropriate for the intended purposes of this proposal. We understand that more information is needed to better understand which residents the required data collection pertains to, the intended use of the data, and how this proposal would affect penalties for non-compliance in the SNF QRP. We acknowledge the feedback provided by some commenters with respect to administrative challenges such as staffing, the assessments that would be required for collection, the technicalities of coding, and the desire for detailed policy and training. We understand the concerns raised by commenters that more details for this proposal are needed in order to better understand which residents the implementation of all payer would affect. We recognize the commenters' concerns about this proposal's implementation timeline and the implementation activities of for the SPADEs. We would like to note that the implementation of the SPADEs and the timeline proposed for this all payer proposal do not overlap, and therefore we do not believe the implementation of the SPADEs would have an effect on this proposal. Further, while we appreciate the suggestion that CMS make this requirement voluntary in the short-term, we believe that making this proposal a voluntary requirement would not further the intent to conduct a meaningful comparison of quality data. However, after consideration of the public comments we received on these issues, we have decided that at this time

for Skilled Nursing Facility Quality Reporting Program. April 2018. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/TEP-Summary-Report_April-2018_Development-and-Maintenance-of-Quality-Measures-for-SNF-QRP.pdf.*

[200] MAP Coordination Strategy for Post-Acute Care and Long-Term Care Performance Measurement. Feb 2012. *http://www.qualityforum.org/Publications/2012/02/MAP_Coordination_Strategy_for_Post-Acute_Care_and_Long-Term_Care_Performance_Measurement.aspx.*

to not finalize the all payer proposal. Although we believe that the reporting of all-payer data under the SNF QRP would add value to the program and provide a more accurate representation of the quality provided by SNFs, we believe we need to better quantify the new reporting burden on SNFs there is from this proposal for stakeholders to comment on. We agree that it would be useful to assess further how to best implement the collection of data for all payers for the SNF QRP. As part of this effort, we intend to further evaluate which assessments are appropriate for reporting and define the population of residents. We plan to propose to expand the reporting of MDS data used for the SNF QRP to include data on all residents, regardless of their payer, in future rulemaking.

Comment: Some of the commenters expressed that this proposal would present additional burden challenges for providers and suggested that CMS conduct an analysis on the burden associated with collecting data on all patients regardless of payer. One commenter believed this proposal will add substantially to the reporting burden associated with the SNF QRP, since facilities will be expected to respond to additional questions on virtually all MDS assessments performed for a much larger number of residents to meet QRP requirements. One commenter suggested that collection of data on all payers would expand the use of the assessment tool from the current Fee-for-Service (FFS) population to patients covered by other payers and noted for CMS that significant variation currently exists in SNFs for the percentage of patients having the MDS 3.0 completed for the SNF QRP. This commenter identified that the percentage may be high in some SNFs with a large portion of FFS patients. In other SNFs, the greater portion of patients may be covered by Medicare Advantage and SNFs may be completing other assessments for other payers, particularly as it relates to payment systems that continue to utilize older versions of the Resource Utilization Group (RUG) system. One commenter stated they could only support this proposal if the burden associated with the reporting requirements is sufficiently funded.

Response: We are sensitive to the issue of burden associated with data collection and acknowledge the commenters' concerns about the additional burden required to collect quality data on all residents. We intend to identify and report the burden in future rulemaking when we propose a new all-payer policy that addresses the concerns raised by comments. Once these residents are identified, CMS would only require data elements designated for the SNF QRP to be reported. To be clear, many payment items are collected on the PPS admission and PPS discharge assessments which would not be required to satisfy the proposal to collect data on all SNF residents regardless of payer. While we have acknowledged that collecting quality data on all residents regardless of payer may create additional burden, we are aware that that many SNFs currently collect MDS data on all residents for OBRA and other purposes regardless of their payer, and that some SNFs may consider it burdensome to separate out Medicare beneficiaries from other residents for purposes of submitting the assessments to CMS. As stated prior, we are not finalizing the all payer proposal, and we intend to identify and report the burden in future rulemaking when we propose a new all-payer policy that addresses the concerns raised by comments.

We appreciate feedback we received from commenters on our proposal to collect data on all SNF residents regardless of the resident's payer. We believe that the collection of quality data to include all residents would help to ensure that Medicare residents receive the same quality of care as other residents who are treated by SNFs. We appreciate the thoughtful questions and comments we received specific to this proposal. Therefore, after careful consideration of the public comments we received, we have decided not to finalize the proposal to expand the reporting of SNF quality data to include all patients, regardless of payer, at this time. We plan to use the input received in this cycle of rulemaking to revise our policy and propose it in future rulemaking whereby SNFs would be required to collect and submit MDS data on all SNF residents regardless of their payer.

i. Policies Regarding Public Display of Measure Data for the SNF QRP

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public after ensuring that SNFs have the opportunity to review their data prior to public display. Measure data are currently displayed on the Nursing Home Compare website, an interactive web tool that assists individuals by providing information on SNF quality of care. For more information on Nursing Home Compare, we refer readers to the website at *https://www.medicare.gov/nursinghomecompare/search.html*. For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

In the proposed rule, we proposed to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure beginning CY 2020 or as soon as technically feasible. We finalized the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure in the FY 2017 SNF PPS final rule (81 FR 52034 through 52039).

Data collection for this assessment-based measure began with patients admitted and discharged on or after October 1, 2018. We proposed to display data based on four rolling quarters, initially using discharges from January 1, 2019 through December 31, 2019 (Quarter 1 2019 through Quarter 4 2019). To ensure the statistical reliability of the data, we proposed that we would not publicly report a SNF's performance on the measure if the SNF had fewer than 20 eligible cases in any four consecutive rolling quarters. SNFs that have fewer than 20 eligible cases would be distinguished with a footnote that states, ''The number of cases/resident stays is too small to publicly report''. We invited public comment on our proposal.

Commenters submitted the following comments related to the proposed rule's discussion of the Policies Regarding Public Display of Measure Data for the SNF QRP. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters supported the proposal to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure in CY 2020 or as soon as technically feasible, including the exception for SNFs with fewer than 20 eligible cases.

Response: We appreciate the commenters support.

After consideration of the public comments, we are finalizing our proposal to begin publicly displaying data for the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF)

Quality Reporting Program (QRP) measure beginning CY 2020 or as soon as technically feasible.

2. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

a. Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, and adopted policies on performance standards, performance scoring, and sought comment on an exchange function methodology to translate SNF performance scores into value-based incentive payments, among other topics. In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments. Additionally, in the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.

The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. We continue to believe the implementation of the SNF VBP Program is an important step towards transforming how care is paid for, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410). We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51986 through 52009) for discussion of the policies that we adopted related to the potentially preventable hospital readmission measure, scoring, and other topics. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36608 through 36623) for discussions of the policies that we adopted related to value-based incentive payments, the exchange function, and other topics. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), where we adopted a corrections policy for numerical values of performance standards, a scoring adjustment for low-volume facilities, and addressed other topics.

We received the following general comment on the SNF VBP Program.

Comment: A commenter suggested that CMS consider recognizing special patient populations, such as patients living with HIV/AIDS, for purposes of the SNF VBP Program. The commenter suggested that we incorporate states' recognition of special patient populations into the SNF VBP Program in some way to ensure that SNFs that treat these populations do not experience unintended consequences.

Response: We appreciate the commenter's concern about special populations. We would like to clarify that the readmission measure used for this program is risk-adjusted to account for a SNF resident's clinical characteristics, including HIV/AIDs, to ensure a fair comparison across SNFs with different case-mixes. However, our monitoring and evaluation activities for this program are intended, in part, to ensure that the program does not cause unintended consequences, and we will take this issue into consideration as we conduct those activities.

b. Measures

(1) Background

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute.

We received the following general comments on the SNF VBP Program measures.

Comment: A commenter recommended that CMS incorporate risk adjustment for socioeconomic status (SES) in the SNFRM to guard against unduly penalizing facilities that predominantly serve very low-income residents. The commenter acknowledged that the SNF VBP statute requires a MedPAC study of SES effects on beneficiaries but stated that the report that MedPAC will prepare for Congress will not be sufficient to address the issue in the Program. The commenter specifically suggested that CMS adjust the SNFRM for dual eligibility status as a proxy for SES until better data are available.

Response: The SNFRM was included in the initial phase of the National Quality Forum (NQF) SES trial period, in which this and other measures were assessed by NQF to determine if risk adjustment for SES is appropriate for these measures. As part of this process, we tested dual eligibilty as a potential risk-adjuster for the SNFRM and found that it was associated with lower odds of readmission. We intend to continue to monitor the effects of the SNF VBP Program on SNFs that serve different types of populations and we will consider the MedPAC report, which is due from MedPAC to Congress by June 30, 2021, as well as ongoing stakeholder feedback, as we consider whether to incorporate SES-based adjustments in the Program.

Comment: A commenter stated that the SNFPPR measure's calculations should not be based on the Statewide Planning and Research Cooperative System (SPARCS) because that system is inaccessible to nursing home providers. Commenter suggested that CMS explore a mechanism that would have performance information readily accessible to nursing home providers.

Response: We would like to clarify that the SNF VBP Program assesses SNF performance on a hospital readmission measure that is calculated using Medicare fee-for-service claims data submitted to CMS by acute care hospitals and SNFs. We do not use SPARCS data. We appreciate the commenter's concern that SNFs may not have access to all-payer state data; however, we use a different data source (Medicare claims) and furnish quarterly confidential feedback reports to SNFs that contain detailed data derived from Medicare claims data so that all SNFs have access to the underlying data.

Comment: A commenter requested that CMS work with Congress to include additional measures beyond measures of hospital readmissions in the SNF VBP Program. The commenter suggested that additional measures could draw from

sources like Nursing Home Compare and from the SNF QRP. The commenter specifically suggested measures of turnover as a percentage of nursing staff, total CNA hours per patient day, and total licensed nursing hours per patient day.

Response: We thank the commenter for these suggestions and will take them into account if Congress should expand the Program's authority to allow us to adopt other measures.

Comment: A commenter requested that CMS align the measure specifications for the potentially preventable hospital readmissions measures used in our value-based purchasing and quality reporting programs.

Response: As we noted in the FY 2020 SNF PPS proposed rule (84 FR 17680), the SNFPPR utilizes a 30-day post-hospital discharge readmission window, while the SNF QRP's potentially preventable readmission measure utilizes a 30-day post-SNF discharge readmission window, which is consistent with the discharge readmission window specified in other measures that we have developed with respect to domains described in section 1899B of the Act. Those other measures include the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility QRP and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health QRP.

As we explained in the proposed rule, with reference to the FY 2017 SNF PPS final rule (81 FR 51992), our rationale for having adopted two different measures of potentially preventable hospital readmissions for use in the SNF VBP Program and SNF QRP was that the readmission window associated with each measure assesses different aspects of care. We continue to believe that this distinction is useful, and we are finalizing our policy to rename the SNFPPR to minimize confusion between these measures.

(2) SNFPPR Update—Change of Measure Name

In the FY 2017 SNF PPS final rule (81 FR 51987 to 51995), we adopted the SNFPPR as the SNF all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF VBP Program to meet the requirements in section 1888(g)(2) of the Act. This claims-based measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for SNF patients within 30 days of discharge from a prior admission to an Inpatient Prospective Payment System (IPPS) hospital, CAH, or psychiatric hospital. However, we have not yet transitioned the SNF VBP Program to using the SNFPPR.

The SNFPPR is one of two potentially preventable readmission measures specified for use in the SNF setting. The SNFPPR is specified for use for the SNF VBP Program and a second measure, the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting Program, is specified for use in the SNF QRP. While these two measures are aligned in terms of exclusion criteria and risk adjustment approach, they differ in their readmission windows. The SNFPPR utilizes a 30-day post-hospital discharge readmission window whereas the SNF QRP potentially preventable readmission measure utilizes a 30-day post-SNF discharge readmission window, consistent with the discharge readmission window specified in other measures we have developed with respect to domains described in section 1899B of the Act, such as the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Inpatient Rehabilitation Facility QRP and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health QRP.

As described in the FY 2017 SNF PPS final rule (81 FR 51992), our rationale for having two different measures was that the readmission window associated with each measure assesses different aspects of SNF care. The readmission window for the SNFPPR measure was developed to align with the SNFRM which was previously adopted for the SNF VBP Program. Both the SNFRM and SNFPPR measure specifications, including the readmission window, were designed to harmonize with CMS's Hospital Wide All-Cause Unplanned Readmission (HWR) measure used in the Hospital IQR Program. The advantage of this window is that it assesses readmissions both during the SNF stay and post-SNF discharge for most SNF patients, depending on the SNF length of stay (LOS).

The readmission window used for the SNF QRP measure aligns with the readmission window used in other readmission measures for post-acute care (PAC) providers. The focus of this post-PAC only discharge readmission window is on assessing potentially preventable hospital readmissions during the 30 days after discharge from the PAC provider.

While the SNFPPR and the SNF QRP potentially preventable readmission measures assess different aspects of SNF care, we have received stakeholder feedback that having two SNF potentially preventable readmission measures has caused confusion. To minimize the confusion surrounding these two different measures, we are changing the name of the SNFPPR to Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge. We believe this new measure name will clearly differentiate the SNF VBP potentially preventable readmission measure from the SNF QRP potentially preventable readmission measure, thereby reducing stakeholder confusion. We intend to submit the SNFPPR measure, hereafter referred to as the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure, to the National Quality Forum (NQF) for endorsement review as soon as that is feasible.

We received several comments on the proposed measure renaming and on the Program's plans to transition to the SNFPPR. The comments and our responses are discussed below.

Comment: Several commenters supported CMS' proposal to rename the SNFPPR. A commenter noted too many similarly named measures can be confusing. Another commenter stated that the new name will provide a more accurate description of the measure. Other commenters requested that CMS clarify what acronym they would prefer that stakeholders use to refer to the renamed measure and requested that CMS announce its plans to implement the measure as soon as possible.

Response: As we did in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to refer to the renamed measure as the SNFPPR measure, and we intend to assess when to transition the Program to the SNFPPR measure once we have submitted the measure to NQF for endorsement review.

Comment: A commenter applauded CMS' decision to submit the SNFPPR for NQF endorsement and suggested that CMS delay the measure's implementation until after endorsement has been received.

Response: We thank the commenter for its support. As stated above, we intend to assess when to transition the Program to the SNFPPR measure once we have submitted the measure to NQF for endorsement review.

Comment: A commenter encouraged CMS to provide plans for the SNFPPR's implementation in the SNF VBP Program as soon as possible. The commenter suggested that monitoring performance across multiple program years prior to transitioning to the SNFPPR will help SNFs track how their assessments change and how their

quality planning affects their performance.

Response: We intend to provide as much information as possible to SNFs about their performance under the Program when we propose to transition the measure.

Comment: Commenter urged CMS to transition the SNF VBP Program to the SNFPPR, stating that SNFs have incentives to treat low-acuity patients and avoid high-acuity patients since the Program uses a measure of all-cause hospital readmissions.

Response: As we stated in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to submit the measure for NQF endorsement review as soon as that is feasible, and we intend to assess when to transition the Program to the SNFPPR measure once we have submitted it for review. Regarding the commenter's concern that the SNFRM could create an incentive for SNFs to avoid high-acuity patients, as we stated in the FY 2016 SNF PPS final rule (80 FR 46413), the SNFRM, which was endorsed by the NQF, has been risk-adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized for factors that are outside of their control. However, we continually evaluate and monitor the Program for unintended consequences.

Comment: A commenter encouraged CMS to seek NQF endorsement of the SNFPPR. Two commenters requested that CMS provide a timeline for the measure's incorporation into the program as a replacement for the SNFRM.

Response: As we stated in the FY 2020 SNF PPS proposed rule (84 FR 17680), we intend to submit the measure for NQF endorsement review as soon as that is feasible, and intend to assess when to transition the Program to the SNFPPR measure once we have submitted it for review.

After consideration of the comments that we received, we are finalizing our proposal to rename the Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure as proposed.

c. FY 2022 Performance Period and Baseline Period

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. Based on those considerations, as well as public comment, we adopted CY 2017 as the performance period for the FY 2019 SNF VBP Program, with a corresponding baseline period of CY 2015.

Additionally, in the FY 2018 SNF PPS final rule (82 FR 36613 through 36614), we adopted FY 2018 as the performance period for the FY 2020 SNF VBP Program, with a corresponding baseline period of FY 2016. We refer readers to that rule for a discussion of the need to shift the Program's measurement periods from the calendar year to the fiscal year. Finally, we refer readers to the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), where we adopted FY 2019 as the performance period for the FY 2021 program year, with a corresponding baseline period of FY 2017. In that final rule, we also adopted a policy where we would adopt for each program year a performance period that is the 1-year period following the performance period for the previous program year. We adopted a similar policy for the baseline period, where we stated that we would adopt for each program year a baseline period that is the 1-year period following the baseline period for the previous year.

Under this policy, the performance period for the FY 2022 program year will be FY 2020, and the baseline period will be FY 2018.

d. Performance Standards

(1) Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy, as well as the numerical values for the achievement threshold and benchmark for the FY 2019 program year. We also responded to public comments on these policies in that final rule.

We published the final numerical values for the FY 2020 performance standards in the FY 2018 SNF PPS final rule (82 FR 36613) and published the final numerical values for the FY 2021 performance standards in the FY 2019 SNF PPS final rule (83 FR 39276). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

(2) FY 2022 Performance Standards

As we discussed in the proposed rule and in this final rule, we will adopt FY 2018 as the baseline period for the FY 2022 program year under our previously-adopted policy of advancing the performance and baseline period for each program year automatically.

Based on the baseline period for the FY 2022 program year, we estimated in the proposed rule that the performance standards would have the numerical values noted in Table 14. We stated that these values represented estimates based on the most recently-available data, and that we would update the numerical values in the FY 2020 SNF PPS final rule. For reference, we are displaying those values again in Table 14.

TABLE 14—ESTIMATED FY 2022 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79476	0.83212

We received the following comment on the estimated performance standards.

Comment: A commenter supported CMS' finalized methodology for performance standards calculation, but suggested that CMS consider adopting an ''optimal'' or ''appropriate'' rate of readmission that would not move with the national average. The commenter explained its concern that the financial incentives to reduce readmissions rates under the Program could create perverse incentives for providers to keep patients in SNFs when they should more appropriately be sent back to the hospital.

Response: We would like to clarify that the SNF VBP Program's achievement threshold is defined as the 25th percentile of SNFs' performance during the baseline period, not the mean of SNFs' performance during the baseline period. However, as we discussed in the FY 2017 SNF PPS final rule (81 FR 51996), we adopted the Program's performance standards definitions because we believe them to

represent achievable performance levels. We also note that our data analysis has found no evidence that the Program's performance standards will create perverse incentives for participating SNFs. We will continue monitoring SNFs' performance on the SNFRM for any unintended consequences of the Program as we assess when to transition the Program to the SNFPPR.

Table 15 contains the final numerical values for the FY 2022 SNF VBP Program based on the FY 2018 baseline period.

TABLE 15—FINAL FY 2022 SNF VBP PROGRAM PERFORMANCE STANDARDS *

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79025	0.82917

e. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program, along with responses to public comments on our policies and examples of scoring calculations. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted, our request for comments on SNFs with zero readmissions, and our request for comments on a potential extraordinary circumstances exception policy.

We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted (1) a scoring policy for SNFs without sufficient baseline period data, (2) a scoring adjustment for low-volume SNFs, and (3) an extraordinary circumstances exception policy.

We did not propose any updates to SNF VBP scoring policies in the proposed rule.

f. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

For estimates of FY 2020 SNF VBP Program incentive payment multipliers, we encourage SNFs to refer to FY 2019 SNF VBP Program performance information, available at *https://data.medicare.gov/Nursing-Home-Compare/SNF-VBP-Facility-Level-Dataset/284v-j9fz*. Our analysis of historical SNF VBP data shows that the Program's incentive payment multipliers appear to be relatively consistent over time. As a result, we believe that the FY 2019 payment results represent our best estimate of FY 2020 performance at this time.

We did not propose any updates to SNF VBP payment policies in the proposed rule. However, for the reader's information, we modeled the estimated impacts of the low-volume adjustment policy that we established in the FY 2019 SNF PPS final rule for FY 2020 and estimated that the application of the low-volume adjustment policy to the FY 2020 program year would redistribute an additional $8.1 million to these low-volume SNFs for that program year. This would increase the 60 percent payback percentage for FY 2020 by approximately 1.51 percent, resulting in a payback percentage for FY 2020 that is 61.51 percent of the estimated $534.1 million in withheld funds for that fiscal year.

We received several comments on SNF VBP incentive payments policy. The comments and our responses are discussed below.

Comment: Commenters expressed concern about the payback percentage that we finalized for the SNF VBP Program, stating instead that the full amount taken from SNFs' Medicare payments should be remitted to SNFs, similar to how the withheld funds are redistributed in the Hospital VBP Program.

Response: As we have explained in prior rulemaking (see, for example, the FY 2019 SNF PPS final rule, 82 FR 36620), section 1888(h)(5)(C)(ii)(III) of the Act provides that the total amount of value-based incentive payments for all SNFs in a fiscal year must be greater than or equal to 50 percent, but not greater than 70 percent of the total amount of the reductions to SNFs' Medicare payments for that fiscal year, as estimated by the Secretary. We do not have the authority to set the payback percentage higher than 70 percent as the commenter suggests.

Comment: Commenters urged CMS to revisit the payback percentage policy and remit 70 percent of the amount withheld from SNFs' Medicare payments instead of the finalized 60 percent. Commenters also recommended that CMS use the remaining 30 percent of funds for quality improvement initiatives in SNFs.

Response: We responded to numerous comments recommending that we adopt a 70 percent payback percentage in the FY 2018 SNF PPS final rule (82 FR 36620 through 36621) and we do not believe, at this time, that it is appropriate to change the payback percentage since the SNF VBP Program is only entering its second year of incentive payments. We believe that additional time is necessary for CMS to assess the Program's impacts on the quality of care provided to Medicare beneficiaries. We will continue monitoring the SNF VBP Program's effects on SNFs' Medicare payments and quality improvement practices and will consider revisiting our finalized payback percentage policy in the future. Additionally, we note that the funds that are not paid back to SNFs as incentive payments represent savings to the Medicare program, and those funds cannot be allocated separately for quality improvement initiatives in SNFs.

g. Public Reporting on the Nursing Home Compare Website

(1) Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF Performance Scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF Performance Scores and the number of SNFs receiving value-based incentive payments, and the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP Program. We also sought and responded to public comments on issues that we should consider when posting performance information on Nursing Home Compare or a successor website. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF measure performance information under the SNF VBP Program on Nursing Home Compare after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Corrections process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and stakeholders with the necessary information to evaluate SNFs' performance under the Program.

(2) Public Reporting of SNF Performance Scores, Achievement and Improvement Scores, and Ranking

As we have considered issues associated with public reporting of SNFs' performance information on the Nursing Home Compare website, we have identified an issue that we believe warrants additional discussion. We are concerned that the performance information available for display for a specific SNF may, as a result of the application of two policies we have finalized for the Program, be confusing to the public. Specifically, SNFs with fewer than 25 eligible stays during the baseline period for a fiscal year will only be scored on achievement and will not have improvement information available for display. In addition, a SNF with fewer than 25 eligible stays during a performance period will receive an assigned SNF performance score for that Program year that results in a value-based incentive payment amount equal to the adjusted federal per diem rate that the SNF would have received for the fiscal year in the absence of the Program.

In these cases, we stated that we did not believe it would be appropriate to suppress the SNF's information entirely given the statutory requirements in section 1888(h)(9)(A) of the Act to publicly report SNF-specific information, but we stated our concerns about publishing performance information that is not based on enough data to convey a complete and reliable picture of a SNF's performance for the Program year.

Based on these considerations, we proposed to suppress the SNF information available to display as follows: (1) If a SNF has fewer than 25 eligible stays during the baseline period for a Program year, we would not display the baseline RSRR or improvement score, though we would still display the performance period RSRR, achievement score and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25 eligible stays during the performance period for a Program year and receives an assigned SNF performance score as a result, we would report the assigned SNF performance score and we would not display the performance period RSRR, the achievement score or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a Program year, we would not display any information for that SNF. Based on historical data, we estimated that approximately 16 percent of SNFs will have fewer than 25 eligible stays during the performance period and similarly, approximately 16 percent of SNFs will have fewer than 25 stays in the baseline period for FY 2020.

We stated our belief that this policy will ensure that we publish as much information as possible about the SNF VBP Program's performance assessments while ensuring that the published information is reliable and based on a sufficient quantity of information. We further stated that we believed that this policy will provide stakeholders with meaningful information about SNFs' performance under the Program.

We welcomed public comment on this proposal.

Comment: Several commenters supported CMS' proposed public reporting policies. Some commenters suggested that CMS explain on the Nursing Home Compare website why scores are suppressed so that consumers can accurately interpret the data presented.

Response: We agree with the commenters. We intend to provide as much information as possible so that the Nursing Home Compare website's users clearly understand the performance information presented about the Program.

After consideration of the public comments that we have received, we are finalizing our changes to the public reporting of SNF Performance Scores, Achievement and Improvement Scores, and Ranking as proposed.

h. Update to Phase One Review and Correction Deadline

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We explained that we would accept corrections to the quality measure data used to calculate the measure rates that are included in any SNF's quarterly confidential feedback report, and that we would provide SNFs with an annual confidential feedback report containing the performance information that will be made public. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to any quarterly report provided during a calendar year until the following March 31.

However, as we have continued implementation of the SNF VBP Program, we have reconsidered what deadline would be appropriate for the Phase One correction process. Our experience managing the FY 2019 SNF VBP Program has shown that fewer than 10 facilities submitted sufficient correction information under the Phase One correction process after October 1, 2018 and before March 31, 2019. Additionally, we stated our concerns about the effects of the March 31 deadline on value-based incentive payment calculations since the deadline is currently 6 months after payment incentives begin. For example, performance score reports for the FY 2019 SNF VBP Program were provided in August 2018 and incentive payments for that FY were made beginning with services provided on October 1, 2018, but SNFs still had until March 31, 2019 to make a correction. We stated our belief that the March 31 deadline also creates uncertainty for SNFs because, as shown above in the timeline that applied to the FY 2019 Program, their

payment incentives could potentially change 6 months after they take effect. If we were to approve a correction request, we would then need to reprocess several months of claims for the SNF in question and potentially need to adjust the exchange function for the fiscal year depending on the scope of the correction and its effects on the payback percentage pool for the fiscal year. We stated that we did not believe these outcomes are beneficial to the Program or to SNFs that would have less predictability about their incentive payment percentages for the fiscal year. We stated our belief that the lack of predictability for SNF payment percentages might adversely impact SNF financial planning because payment amounts would not be set for all SNFs until after the March 31 deadline.

We stated our belief that we could mitigate this uncertainty by adopting a 30-day deadline for Phase One correction requests, and noted that this proposal would align the Phase One review and correction process with the Phase Two process. Under current Program operations, we issue a report in June that contains all of the underlying claim information used to calculate the measure rate for the program year, as well as the measure rate itself. We proposed that SNFs would have 30 days from the date that we issue that report to review the claims and measure rate information and to submit to us a correction request if the SNF believes that any of that information is inaccurate. We noted that this proposal would not preclude a SNF from submitting a correction request for any claims for which it discovers an error prior to receiving the June report. However, the 30 day review and correction period would commence on the day that we issue the June report, and a SNF would not be able to request that we correct any underlying claims or its measure rate after the conclusion of that 30 day period.

We proposed this 30-day deadline in lieu of the current March 31 deadline for Phase One corrections. We noted that we initially proposed to adopt a 30-day deadline for Phase One corrections in the FY 2017 SNF PPS proposed rule (81 FR 24255), though we finalized a deadline of March 31 following the calendar year in which we provide the report. We adopted that extended deadline to balance our desire to ensure that measure data are sufficiently accurate with SNFs' need for sufficient information with which to evaluate those reports, as well as to provide SNFs with more time to review each quarter's data. In addition, we encouraged SNFs to review the quarterly reports provided with stay-level information and make any corrections to claims before the proposed deadline. However, for the reasons discussed above, we stated that we now believe that a 30-day timeframe is sufficient for SNFs to determine if there were errors in the measure calculation by CMS or its contractor.

We stated our belief that this policy will ensure that the underlying claims data that we use to calculate quality measure performance for the SNF VBP Program will be finalized prior to their use in scoring and payment calculations. We also stated our belief that this policy will also ensure that any corrections submitted under Phase One do not result in changes to quality measure data months after incentive payment calculations, which will also avoid changes to the exchange function, and as a result, changes to other SNFs' value-based incentive payment percentages for a fiscal year because of data errors for any SNFs. Our experience managing the 2019 SNF VBP Program indicated that very few SNFs would be adversely impacted by the earlier deadline. We also sought to provide SNFs with earlier final annual payment percentage information for their financial planning purposes.

We welcomed public comments on this proposal.

Comment: A commenter agreed that the current Phase One Review and Corrections deadline may not be ideal, but expressed concern about the proposed 30-day deadline. The commenter suggested that 30 days may not provide enough time for SNFs to complete Phase One corrections, especially if they must collaborate with hospitals, and recommended that CMS adopt a 60-day deadline instead. Another commenter suggested a 90-day deadline, stating that smaller SNFs often do not have the manpower available to review feedback reports promptly.

Response: As we stated in the proposed rule, our proposal would not forestall SNFs from submitting correction requests prior to their receipt of the June report if they believe that an error has occurred, after reviewing data from quarterly reports delivered prior to the June report. Our intention with this proposal is, as we stated, to ensure that any corrections submitted under Phase One do not result in changes to quality measure data months after the incentive payment calculations are completed, which would necessitate changes to the exchange function, and as a result, changes to other SNFs' value-based incentive payment percentages for a fiscal year. Additionally, we note that we previously received public comments supportive of a 30-day deadline for Review and Corrections to which we provided responses in the FY 2017 SNF PPS final rule (81 FR 52008). We believe that SNFs have, by now, accumulated extensive experience with the SNF VBP Program's report system, as well as the finalized Review and Corrections processes. Further, the 30-day review and correction deadline would align the SNF VBP Program with other similar CMS programs.

We will continue to conduct outreach and education to ensure that SNFs are fully aware of the Program's operational deadlines, and we will strive to be as clear as possible about the timeline for corrections once we provide each report to SNFs.

After consideration of the public comments that we have received, we are finalizing our proposed update to the Phase One Review and Corrections deadline as proposed.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

In our April 25, 2019 proposed rule (84 FR 17620), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. As indicated in section IV.B.1. of this final rule, we received public comments and provide a summary of the comments and our responses in that section. Based on internal review, we have revised the number of items we are adding across the PPS 5-day and PPS discharge

assessments to 59.5 items, as compared to the proposed 60.5 items in the FY 2020 SNF PPS proposed rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2018 National Occupational Employment and Wage Estimates for all salary estimates (as compared to the FY 2020 SNF PPS proposed rule which used BLS' May 2017 estimates of $41.18/hr for a health information technician and $70.72/hr for a registered nurse) (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 16 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of the mean hourly wage), and the adjusted hourly wage. The adjusted wage is used to derive this section's average cost estimates.

TABLE 16—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Health Information Technician	29–2071	21.16	21.16	42.32
Registered Nurse	29–1141	36.30	36.30	72.60

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the mean hourly wage to help estimate the total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF Quality Reporting Program (QRP)

The following changes will be submitted to OMB for approval under control number 0938–1140 (CMS–10387). While the changes do not impose any new or revised burden, they revise our SNF QRP requirements by adding 59.5 items across the PPS 5-day and PPS discharge assessments. Costs have been adjusted to account for more recent wage data. An analysis of the impact for adding the 59.5 items can be found in section V. of this final rule. Subject to renewal, the control number is currently set to expire on February 28, 2022. It was last approved on February 12, 2019, and remains active.

The Minimum Data Set (MDS) is part of the process for the clinical assessment of all SNF residents and serves multiple purposes. It is used as a data collection tool for SNFs in the PPS to inform the PDPM for the purpose of reimbursement and for the SNF QRP for the purpose of monitoring the quality of care in SNFs.

The MDS assessments that are used to inform payment consist of the PPS 5-day assessment, the PPS discharge assessment, and the optional Interim Payment Assessment (IPA). The requirements necessary to administer the payment rate methodology described in 42 CFR 413.337 are subject to the PRA. Thus, the PPS 5-day, PPS discharge, and IPA assessments are subject to the PRA and are active under the aforementioned control number. For the readers' convenience, the active burden estimates are summarized in Table 17. It is important to note that SNFs currently collect and report data for the SNF QRP through the PPS 5-day and PPS discharge assessments, which are the same assessments used in the PDPM. The IPA is an optional assessment for the PDPM and is not used for the SNF QRP.

Section 2(a) of the IMPACT Act established section 1899B of the Act, which requires, among other things, SNFs to report standardized patient assessment data, data on quality measures, and data on resource use and other measures. Under section 1899B(m) of the Act, modifications to the MDS required to achieve standardization of patient assessment data are exempt from PRA requirements. Standardization has been met upon our adoption of the proposed data elements and standardized patient assessment data in this final rule. For FY 2020 and thereafter, the exemption of the SNF QRP from the PRA is no longer applicable such that the SNF QRP requirements and burden will be submitted to OMB for review and approval. The active ICR serves as the basis for which we now address the previously exempt requirements and burden.

Under our active information collection, only the PPS 5-day and PPS discharge assessments used in the PDPM are also used as the assessments for collecting quality measure and standardized patient assessment data under the SNF QRP. Our active burden sets out 51 minutes (0.85 hours) per PPS 5-day assessment and 51 minutes per PPS discharge assessment. *Consistent with the FY 2019 SNF PPS final rule (83 FR 39283) we continue to use the OMRA assessment (with 272 items) to estimate the amount of time to complete a PPS assessment. This is also consistent with our active information collection.* In sections III.E.1.d. and III.E.1.g. of this rule, we are adding 59.5 items across the PPS 5-day and PPS discharge assessments. Given that the PPS OMRA item set has 272 items (as compared to the PPS discharge assessment with 143 items) that are approved under our active collection, the added items, while increasing burden for each of the assessments, have no impact on our currently approved burden estimates since the active collection uses the PPS OMRA item set as a proxy for all assessments. Below, however, we are restating such burden, with updated cost estimates based on more recent BLS wage figures, as a courtesy to interested parties.

When calculating the burden for each assessment, we estimate it will take 40 minutes (0.6667 hours) at $72.60/hr for an RN to collect the information necessary for preparing the assessment, 10 minutes (0.1667 hours) at $57.46/hr (the average hourly wage for RN ($72.60/hr) and health information technician ($42.32/hr)) for staff to code the responses, and 1 minute (0.0167 hours) at $42.32/hr for a health information technician to transmit the results. In total, we estimate that it will take 51 minutes (0.85 hours) to complete a single PPS assessment. Based on the adjusted hourly wages for the noted staff, we estimate that it will cost $58.69 [($72.60/hr × 0.6667 hr) + ($57.46/hr × 0.1667 hr) + ($42.32/hr × 0.0167 hr)] to prepare, code, and transmit each PPS assessment.

Based on our most current data, there are 15,471 Medicare Part A SNFs. Based on FY 2017 data, we estimate that 2,406,401 5-day PPS assessments will be completed and submitted by Part A SNFs each year under the PDPM and SNF QRP. We used the same number of

assessments (2,406,401) as a proxy for the number of PPS discharge assessments that would be completed and submitted each year, since all residents who require a 5-day PPS assessment will also require a discharge assessment under the PDPM and SNF QRP. We use the Significant Change in Status Assessment (SCSA) as a proxy to estimate the number of IPAs as the criteria for completing an SCSA is similar to that for the IPA. Based on FY 2017 data, 92,240 IPAs would be completed per year under the PDPM.

The total number of PPS 5-day assessments, PPS discharge assessments, and IPAs that will be completed across all facilities is 4,905,042 assessments (2,406,401 + 2,406,401 + 92,240, respectively). In aggregate, we estimate an annual burden for all assessments across all facilities of 4,169,286 hours (4,905,042 assessments × 0.85 hours/assessment) at a cost of $287,876,914 (4,905,042 assessments × $58.69/assessment).

Given that adding 59.5 items across the PPS 5-day and PPS discharge assessments is accounted for by using the OMRA assessment as a proxy for all assessments, and given that our estimate for the number of Medicare Part A SNFs and for the number PPS 5-day and PPS discharge assessments completed and submitted by Part A SNFs each year remains unchanged, we are not revising or adjusting any of our active burden estimates, except for adjusting our cost estimates as indicated above. In this regard, we will be submitting a revised information collection request to OMB to account for the added items and adjusted costs.

Further, in section III.E.1.h.(2) of this final rule, there are no burden implications associated with updating the data submission system to the iQIES for the SNF QRP once it becomes available. This designation is a replacement of the existing QIES ASAP data submission system and imposes no additional requirements or burden on the part of SNFs.

We received the following comments on our collections of information estimates.

Comment: One commenter stated that adding items across the PPS 5-day and discharge assessments would result in increased burden, especially due to the time required to complete resident interview items.

Response: We acknowledge that adding items for the SNF QRP across the PPS 5-day and discharge assessments increases burden for providers. However, we continue to believe that these items are accounted for in our active burden estimates, given that we use the PPS OMRA as the proxy for all assessments. The PPS OMRA item set has 272 items (as compared to the PPS discharge assessment with 143 items) that are approved under our active collection. The 59.5 added items are accounted for since the PPS OMRA is used as a proxy for the shorter PPS discharge assessment. Therefore, we intend to move forward with the addition of these 59.5 items.

Comment: Another commenter requested that CMS consider staging additional SNF QRP requirements in a way that would allow SNFs more time to adapt the to the PDPM payment methodology.

Response: We note that the PDPM takes effect in the October 1, 2019, while SNFs are not required to begin data collection for the SNF QRP requirements finalized in this final rule until October 1, 2020, thereby by allowing a year to adjust to the PDPM before the finalized SNF QRP requirements take effect. Therefore, we intend to move forward with the addition of these 59.5 items.

2. ICRs Regarding the SNF VBP Program

We are not removing, adding, or revising any of our SNF VBP measure-related requirements or burden. Consequently, the rule contains no SNF–VBP related collections of information that are subject to OMB approval under the authority of the PRA.

C. Summary of Requirements and Annual Burden Estimates

TABLE 17—SUMMARY OF REQUIREMENTS AND ANNUAL BURDEN ESTIMATES UNDER OMB CONTROL NUMBER 0938–1140 (CMS–10387)

Program changes	Number of respondents	Responses (per respondent)	Total responses	Time per response (hr)	Total time (hr)	Labor cost per hour ($/hr)	Total cost ($)
Active Burden	15,471	317.04	4,905,042	0.85	4,169,286	varies	280,421,251
Changes under CMS–1718–F.	0	0	0	0	0	varies	+7,455,663
Total	15,471	317.04	4,905,042	0.85	4,169,286	varies	287,876,914

V. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This final rule updates the FY 2020 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach on these issues.

2. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). We estimate that the aggregate impact will be an increase of approximately $851 million in payments to SNFs in FY 2020, resulting from the SNF market basket update to the payment rates. We note that these impact numbers do not incorporate the SNF VBP reductions that we estimate will total $527.4 million in FY 2020. We would note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act, we update the FY 2019 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2020. The impact to Medicare is included in the total column of Table 18. In updating the SNF PPS rates for FY 2020, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 2020. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2020 SNF PPS payment impacts appear in Table 18. Using the most recently available data, in this case FY 2018, we apply the current FY 2019 wage index and labor-related share value to the number of payment days to simulate FY 2019 payments. Then, using the same FY 2018 data, we apply the FY 2020 wage index and labor-related share value to simulate FY 2020 payments. We tabulate the resulting payments according to the classifications in Table 18 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2019 payments to the simulated FY 2020 payments to determine the overall impact. The breakdown of the various categories of data Table 18 follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the transition to PDPM. This represents the effect on providers, assuming no changes in behavior or case-mix, from changing the case-mix classification model used to classify patients in a Medicare Part A SNF stay. The total impact of this change is 0.0 percent; however, there are distributional effects of this change.
- The fourth column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is 0.0 percent; however, there are distributional effects of the change.
- The fifth column shows the effect of all of the changes on the FY 2020 payments. The update of 2.4 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 2.4 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 18, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this final rule, providers in the urban Pacific region will experience a 1.6 percent increase in FY 2020 total payments.

TABLE 18—IMPACT TO THE SNF PPS FOR FY 2020

	Number of facilities FY 2020	PDPM impact (percent)	Update wage data (percent)	Total change (percent)
Group:				
Total	15,078	0.0	0.0	2.4
Urban	10,951	−0.7	0.0	1.7
Rural	4,127	3.7	0.2	6.2
Hospital-based urban	380	9.9	0.1	12.4
Freestanding urban	10,571	−1.0	0.0	1.4
Hospital-based rural	245	20.4	0.3	23.1
Freestanding rural	3,882	3.1	0.2	5.6
Urban by region:				
New England	775	2.0	−0.4	4.0
Middle Atlantic	1,470	−3.1	−0.1	−0.8
South Atlantic	1,868	−0.7	−0.2	1.5
East North Central	2,118	0.1	0.0	2.4
East South Central	536	0.7	−0.2	2.9
West North Central	921	3.8	0.6	6.8
West South Central	1,323	−1.3	0.2	1.3
Mountain	527	0.1	0.2	2.7
Pacific	1,407	−0.9	0.1	1.6
Outlying	6	58.5	−0.4	60.5

TABLE 18—IMPACT TO THE SNF PPS FOR FY 2020—Continued

	Number of facilities FY 2020	PDPM impact (percent)	Update wage data (percent)	Total change (percent)
Rural by region:				
New England	126	5.4	−1.5	6.3
Middle Atlantic	194	2.3	0.0	4.8
South Atlantic	462	4.2	0.4	7.0
East North Central	908	3.4	−0.1	5.7
East South Central	452	2.4	0.3	5.1
West North Central	1,020	10.2	0.4	13.1
West South Central	666	−0.5	0.3	2.2
Mountain	207	6.0	1.2	9.6
Pacific	92	1.4	0.3	4.1
Ownership:				
For profit	10,729	−0.6	0.0	1.8
Non-profit	3,469	1.5	0.0	3.9
Government	880	4.5	0.1	7.0

Note: The Total column includes the 2.4 percent market basket increase factor. Additionally, we found no SNFs in rural outlying areas.

5. Impacts for the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

As discussed in this final rule, we are adopting two new quality measures beginning with the FY 2022 SNF QRP (see section III.E.1.d. of this final rule). For these two quality measures, we are adding 4 data elements on discharge which would require an additional 1.2 minutes of nursing staff time per discharge. We estimate these data elements for these quality measures would be completed by Registered Nurses (25 percent of the time or 0.30 minutes) at $72.60/hr and by Licensed Practical Nurses (75 percent of the time or 0.90 minutes) at $45.24/hr. With 2,406,401 discharges from 15,471 SNFs annually (see section IV.B. of this final rule), we estimate an annual burden of 48,128 additional hours (2,406,401 discharges × 1.2 min/60) at a cost of $2,506,507 (2,406,401 × [(0.30/60 × $72.60/hr) + (0.90/60 × $45.24/hr)]). For each SNF we estimate an annual burden of 3.11 hours (48,128 hr/15,471 SNFs) at a cost of $162.01 ($2,506,507/15,471 SNFs).

We are finalizing requirements to collect 55.5 standardized patient assessment data elements consisting of 8 data elements on admission and 47.5 data elements on discharge beginning with the FY 2022 SNF QRP. We estimate that the data elements would take an additional 12.675 minutes of nursing staff time consisting of 1.725 minutes to report on each admission and 10.95 minutes to report on each discharge. We assume the added data elements would be performed by both Registered Nurses (25 percent of the time or 3.169 minutes) and Licensed Practical Nurses (75 percent of the time or 9.506 minutes). We estimate the reporting of these assessment items will impose an annual burden of 508,352 total hours (2,406,401 discharges × 12.675 min/60) at a cost of $26,474,983 ((508,352 hr × 0.25 × $72.60/hr) + (508,352 hr × 0.75 × $45.24/hr)). For each SNF the annual burden is 32.86 hours (508,352 hr/15,471 SNFs) at a cost of $1,711.27 ($26,474,983/15,471 SNFs).

The overall annual cost of the finalized changes associated with the newly added 59.5 assessment items is estimated at $1,873.28 per SNF annually ($162.01 + $1,711.27), or $28,981,490 ($2,506,507 + $26,474,983) for all 15,471 SNFs annually.

6. Impacts for the SNF VBP Program

The impacts of the FY 2020 SNF VBP Program are based on historical data and appear in Table 19. We modeled SNF performance in the Program using SNFRM data from CY 2015 as the baseline period and CY 2017 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we note that the 60 percent payback percentage for FY 2020 will adjust to account for the low-volume scoring adjustment that we adopted in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). Based on the 60 percent payback percentage (as modified by the low-income scoring adjustment), we estimate that we will redistribute approximately $320.4 million in value-based incentive payments to SNFs in FY 2020, which means that the SNF VBP Program is estimated to result in approximately $213.6 million in savings to the Medicare Program in FY 2020. We refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39280) for additional information about payment adjustments for low-volume SNFs in the SNF VBP Program.

Our detailed analysis of the impacts of the FY 2020 SNF VBP Program follows in Table 19.

TABLE 19—SNF VBP PROGRAM IMPACTS FOR FY 2020

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total incentive payment
Group:					
Total	15,421	19.42	37.2169	0.99309	100.00
Urban	11,007	19.47	36.1519	0.99262	85.16
Rural	4,414	19.31	39.8729	0.99426	14.84
Hospital-based urban	355	19.08	42.6453	0.99546	2.14
Freestanding urban	10,602	19.48	35.9056	0.99251	82.98

TABLE 19—SNF VBP PROGRAM IMPACTS FOR FY 2020—Continued

Characteristic	Number of facilities	Mean risk-standardized readmission rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total incentive payment
Hospital-based rural	246	18.98	46.9882	0.99756	0.57
Freestanding rural	3,943	19.32	39.3322	0.994	14.11
Urban by region:					
New England	786	19.54	33.0786	0.99119	5.75
Middle Atlantic	1,473	19.25	38.8823	0.99365	15.92
South Atlantic	1,869	19.56	35.6803	0.99256	17.39
East North Central	2,122	19.52	34.5595	0.99174	14.08
East South Central	551	19.69	32.2849	0.99095	3.68
West North Central	923	19.46	36.7211	0.99281	4.01
West South Central	1,336	19.84	31.4446	0.99065	7.32
Mountain	530	18.92	44.5446	0.99634	3.63
Pacific	1,411	19.20	40.4522	0.99475	13.36
Outlying	6	19.38	41.5899	0.99252	0.00
Rural by region:					
New England	134	19.12	39.8964	0.99396	0.67
Middle Atlantic	214	19.14	40.4625	0.99406	0.86
South Atlantic	493	19.42	36.8815	0.99294	2.22
East North Central	931	19.15	40.6763	0.99452	3.43
East South Central	520	19.60	34.5229	0.99178	2.31
West North Central	1,064	19.14	44.0171	0.99615	1.93
West South Central	738	19.85	33.6008	0.99171	2.16
Mountain	222	18.78	49.4262	0.99862	0.65
Pacific	97	18.30	55.1379	1.00141	0.62
Outlying:	1	18.98	37.0195	0.98788	0.00
Ownership:					
Government	982	19.11	43.3338	0.99568	3.70
Profit	10,810	19.52	35.3904	0.99229	75.38
Non-Profit	3,629	19.20	41.0027	0.99478	20.92

7. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2020 under the SNF PPS will be an increase of approximately $851 million in payments to SNFs, resulting from the SNF market basket update to the payment rates.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

8. Accounting Statement

As required by OMB Circular A-4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 20 through 22, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2020. Tables 18 and 20 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,078 SNFs in our database. Table 21 provides our best estimate of the costs for SNFs to submit data under the SNF QRP as a result of the policies in this final rule. Tables 19 and 22 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies in this final rule.

TABLE 20—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2019 SNF PPS FISCAL YEAR TO THE 2020 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$851 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

*The net increase of $851 million in transfer payments is a result of the market basket increase of $851 million.

TABLE 21—ACCOUNTING STATEMENT: ESTIMATED COST TO UPDATE THE SNF QUALITY REPORTING PROGRAM

Category	Cost
Cost for SNFs to Submit Data for QRP	$29 million.*

* Costs associated with the submission of data for the QRP will occur in FY 2021 and likely continue in the future years.

TABLE 22—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2020 SNF VBP PROGRAM

Category	Transfers
Annualized Monetized Transfers	$320.4 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* This estimate does not include the two percent reduction to SNFs' Medicare payments (estimated to be $527.4 million) required by statute.

9. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2020 are projected to increase by approximately $851 million, or 2.4 percent, compared with those in FY 2019. We estimate that in FY 2020 under PDPM, SNFs in urban and rural areas will experience, on average, a 1.7 percent increase and 6.2 percent increase, respectively, in estimated payments compared with FY 2019. Providers in the urban Outlying region will experience the largest estimated increase in payments of approximately 60.5 percent. Providers in the urban Middle Atlantic region will experience the largest estimated decrease in payments of 0.8 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's website at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2019 (83 FR 39162). Based on the above, we estimate that the aggregate impact for FY 2020 will be an increase of $851 million in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 18 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2020 wage indexes, PDPM transition and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2019 Report to Congress (available at *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf*), MedPAC states that Medicare covers approximately 11 percent of total patient days in freestanding facilities and 19 percent of facility revenue (March 2019 MedPAC Report to Congress, 197). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 18. As indicated in Table 18, the effect on facilities is projected to be an aggregate positive impact of 2.4 percent for FY 2020. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities for FY 2020.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals will be a positive impact. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2019 (83 FR 39288)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 18, the effect on facilities for FY 2020 is projected to be an aggregate positive impact of 2.4 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals for FY 2020.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately

$154 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule will have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is considered an E.O. 13771 regulatory action. We estimate the rule generates $20.68 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

F. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

G. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters is a fair estimate of the number of reviewers of this rule. In the FY 2020 SNF PPS proposed rule (84 FR 17689), we welcomed any comments on the approach in estimating the number of entities which will review the proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption in the FY 2020 SNF PPS proposed rule (84 FR 17689).

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $437.44 (4 hours × $109.36). Therefore, we estimate that the total cost of reviewing this regulation is $27,559 ($437.44 × 63 reviewers).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.30 [Amended]

■ 2. Section 409.30 is amended in the introductory text—

■ a. By removing the phrase ''the 5-day assessment'' and adding in its place the phrase ''the initial Medicare assessment''; and

■ b. By removing the phrase ''must occur'' and adding in its place the phrase ''must be set for''.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; and sec. 124 of Pub. L. 106–113, 113 Stat. 1501A–332; sec. 3201 of Pub. L. 112–96, 126 Stat. 156; sec. 632 of Pub. L 112–240, 126 Stat. 2354; sec. 217 of Pub. L. 113–93, 129 Stat. 1040; and sec. 204 of Pub. L. 113–295, 128 Stat. 4010; and sec. 808 of Pub. L. 114–27, 129 Stat. 362.

■ 4. Section 413.343 is amended by revising paragraph (b) to read as follows:

§ 413.343 Resident assessment data.

* * * * *

(b) *Assessment schedule.* In accordance with the methodology described in § 413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of an initial Medicare assessment with an assessment reference date that is set for no later than the 8th day of posthospital SNF care, and such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.

* * * * *

■ 5. Section 413.360 is amended by revising paragraphs (a) and (d)(1) and (4) to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the SNF as operating in the CMS designated data submission system. For purposes of this section, a program year is the fiscal year in which the market basket percentage described in § 413.337(d) is reduced by two percentage points if the SNF does not report data in accordance with paragraph (b) of this section.

* * * * *

(d) * * *

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

* * * * *

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

* * * * *

Dated: July 26, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–16485 Filed 7–30–19; 4:15 pm]

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Part III

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Chapter 1, et al.
Federal Acquisition Regulations; Federal Acquisition Circular 2019–04; Introduction; Ombudsman for Indefinite-Delivery Contracts; Federal Acquisition Regulation; Technical Amendments; Federal Acquisition Regulation; Federal Acquisition Circular 2019–04; Small Entity Compliance Guide; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2019–0002, Sequence No. 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2019–04; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2019–04. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC. The FAC, including the SECG, is available via the internet at *http://www.regulations.gov.*

DATES: For effective date see the separate documents, which follows.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to the FAR case. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2019–04

Item	Subject	FAR case	Analyst
I	Ombudsman for Indefinite-Delivery Contracts	2017–020	Jackson.
II	Technical Amendments.		

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these FAR rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2019–04 amends the FAR as follows:

Item I—Ombudsman for Indefinite-Delivery Contracts (FAR Case 2017–020)

DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a new clause for use in multiple-award indefinite-delivery indefinite-quantity (IDIQ) contracts that identifies the agency task-order and delivery-order ombudsman's responsibilities and contact information. This rule implements a standardized method to provide the requisite information to contractors via a single contract clause for use by all agencies. This rule intends to minimize the impact on contractors resulting from the variety of ways in which task-order and delivery-order ombudsman information is communicated by agencies.

Item II—Technical Amendments

Editorial changes are made at FAR 1.201–1 and 52.246–21.

Janet M. Fry,

Director, Federal Acquisition Policy Division, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2019–04 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2019–04 is effective August 7, 2019 except for FAR Case 2017–020, which is effective September 6, 2019.

Linda W. Neilson,

Director, Defense Pricing and Contracting, Defense Acquisition Regulations System Department of Defense.

Jeffrey A. Koses,

Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

William G. Roets, II,

Acting Assistant Administrator, Office of Procurement, National Aeronautics and Space Administration.

[FR Doc. 2019–16405 Filed 8–6–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 16 and 52

[FAC 2019–04; FAR Case 2017–020; Item I; Docket No. 2017–0020; Sequence No. 1]

RIN 9000–AN53

Federal Acquisition Regulation: Ombudsman for Indefinite-Delivery Contracts

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a new clause for use in multiple-award indefinite-delivery indefinite-quantity contracts that provides information on the task-order and delivery-order ombudsman.

DATES: *Effective Date:* September 6, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2019–04, FAR Case 2017–020.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** on November 1, 2018 at 83 FR 54901, to implement a new clause that provides the agency task-order and delivery-order ombudsman's responsibilities and contact information for use in multiple-award indefinite-delivery indefinite-quantity (IDIQ) contracts. FAR 16.504(a)(4)(v) required that the name, address, telephone number, facsimile number, and email address of the agency's task-order and delivery-order ombudsman be included in IDIQ solicitations and contracts, if multiple

awards may result from the solicitation. As a result, several agencies created an agency-level contract clause that provides this information to contractors. This rule intends to minimize any impact on contractors resulting from the variety of ways in which the information is communicated by agencies; as such, this rule implements a standardized method to provide the requisite information to contractors via a single contract clause for use by all agencies. Three respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. No changes were made to the final rule as a result of public comments. Edits were made to the final rule for accuracy and clarification. A discussion of the comments is provided as follows:

A. Analysis of Public Comments

1. *Comment:* A respondent expressed support for the rule.

Response: The Councils acknowledge the support for the rule.

2. *Comment:* A respondent advised that an agency should be able to designate its small business professional as the agency's task-order and delivery-order ombudsman.

Response: It is the discretion of each agency as to whom they designate as its task-order and delivery-order ombudsman. FAR 16.505(b)(8) only requires that the task-order and delivery-order ombudsman be a senior agency official who is independent of the contracting officer. This rule does not prohibit an agency's small business professional from serving as the task-order and delivery-order ombudsman.

3. *Comment:* A respondent suggested that the Councils consider elaborating on the policies and procedures to be used by a task-order and delivery-order ombudsman when evaluating and responding to a fair opportunity complaint, as well as the other roles of a task-order and delivery-order ombudsman that are outside of fair opportunity considerations.

Response: The purpose of this rule is to establish a standard way of providing contractors with the name and contact information for an agency's task-order and delivery-order ombudsman. Each agency has the discretion to develop the additional roles and responsibilities of, and policies and procedures for, its task-order and delivery-order ombudsman in execution of their statutory responsibilities; as such, this rule avoids prescribing procedural policies or requirements to be used by all Federal task-order and delivery-order ombudsmen.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule creates a new FAR clause 52.216–32, Task-Order and Delivery-Order Ombudsman, which serves as a single clause available for use by all agencies when awarding a multiple-award IDIQ contract and provides contractors with the requisite contact information for the agency task-order and delivery-order ombudsman.

This clause applies to solicitations and contracts for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items, as defined at FAR 2.101. This rule provides contractors with information on the basic responsibilities of and how to contact the task-order and delivery-order ombudsman. Not applying this guidance to contracts for the acquisition of commercial items, including COTS items, would exclude contracts intended to be covered by this rule and could prevent some contractors from receiving the requisite information needed to address a concern with an agency's task-order and delivery-order ombudsman. This rule does not apply to contracts at or below the simplified acquisition threshold (SAT), as the FAR prevents the use of the multiple-award approach when the total estimated value of the contract is less than the SAT.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

DoD, GSA, and NASA are amending the FAR to implement a new clause that provides information on the task-order and delivery-order ombudsman for multiple-award indefinite-delivery indefinite-quantity (IDIQ) contracts. FAR 16.504(a)(4)(v) required that the name, address, telephone number, facsimile number, and email address of the agency's task-order and delivery-order ombudsman be included in IDIQ solicitations and contracts, if multiple awards may result from the solicitation. As a result, several agencies created an agency-level contract clause that provides this information to contractors. This rule intends to minimize any impact on contractors resulting from the variety of ways in which the information is communicated by agencies; as such, this rule implements a standardized method to provide the requisite information to contractors via a single contract clause for use by all agencies. No public comments were received in response to the initial regulatory flexibility analysis.

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because it is not creating any new requirements or changing any existing requirements for contractors.

According to data from the Federal Procurement Data System, there were 6,207 new multiple-award contracts awarded in Fiscal Year 2017. Of the 6,207 new awards, 4,477 (72 percent) of these actions were awarded to 3,873 unique small business entities. The final rule applies to all entities that do business with the Federal Government and is not expected to have a significant impact on these entities, regardless of business size.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses. The rule minimizes any current impact on small entities by providing the name and contact information of the agency task-order and delivery-order ombudsman via a standardized method in multiple-award indefinite-delivery indefinite-quantity contracts and subsequent task and delivery orders, as necessary; as such, all entities awarded a contract or order that is subject to this rule will be able to locate the requisite task-order and delivery-order ombudsman's information without having to look in various locations for the information.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that

require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 16 and 52

Government procurement.

Janet M. Fry,

Director, Federal Acquisition Policy Division, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA are issuing a final rule amending 48 CFR parts 16 and 52 as set forth below:

■ 1. The authority citation for parts 16 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 16—TYPES OF CONTRACTS

16.504 [Amended]

■ 2. Amend section 16.504 by removing paragraph (a)(4)(v) and redesignating paragraphs (a)(4)(vi) and (a)(4)(vii) as paragraphs (a)(4)(v) and (a)(4)(vi), respectively.

■ 3. Amend section 16.506 by adding paragraph (j) to read as follows.

16.506 Solicitation provisions and contract clauses.

* * * * *

(j) Insert the clause at 52.216–32, Task-Order and Delivery-Order Ombudsman, in solicitations and contracts when a multiple-award indefinite-delivery indefinite-quantity contract is contemplated. Use the clause with its Alternate I when the contract will be available for use by multiple agencies (*e.g.,* Governmentwide acquisition contracts or multi-agency contracts). When placing orders under the multiple-award contract available for use by multiple agencies, the ordering activity's contracting officer shall complete paragraph (d)(2) and include Alternate I in the notice of intent to place an order, and in the resulting order.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Add section 52.216–32 to read as follows:

52.216–32 Task-Order and Delivery-Order Ombudsman.

As prescribed in 16.506(j), use the following clause: Task-Order and Delivery-Order Ombudsman (Sep 2019)

(a) In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract.

[*Contracting Officer to insert name, address, telephone number, and email address for the Agency Ombudsman or provide the URL address where this information may be found.*]

(b) Consulting an ombudsman does not alter or postpone the timeline for any other process (*e.g.,* protests).

(c) Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

(End of clause)

Alternate I. As prescribed in 16.506(j), add the following paragraph (d) to the basic clause.

(d) *Contracts used by multiple agencies.*

(1) This is a contract that is used by multiple agencies. Complaints from Contractors concerning orders placed under contracts used by multiple agencies are primarily reviewed by the task-order and delivery-order Ombudsman for the ordering activity.

(2) The ordering activity has designated the following task-order and delivery-order Ombudsman for this order:

[*The ordering activity's contracting officer to insert the name, address, telephone number, and email address for the ordering activity's Ombudsman or provide the URL address where this information may be found.*]

(3) Before consulting with the task-order and delivery-order Ombudsman for the ordering activity, the Contractor is encouraged to first address complaints with the ordering activity's Contracting Officer for resolution. When requested by the Contractor, the task-order and delivery-order Ombudsman for the ordering activity may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

(End of clause)

[FR Doc. 2019–16406 Filed 8–6–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1 and 52

[FAC 2019–04; Item II; Docket No. 2019–0002; Sequence No. 2]

Federal Acquisition Regulation; Technical Amendments

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This document makes amendments to the Federal Acquisition Regulation (FAR) in order to make needed editorial changes.

DATES: *Effective:* August 7, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Lois Mandell, Regulatory Secretariat Division (MVCB), 1800 F Street NW, 2nd Floor, Washington, DC 20405, 202–501–4755. Please cite FAC 2019–04, Technical Amendments.

SUPPLEMENTARY INFORMATION: In order to update certain elements in 48 CFR parts 1 and 52 this document makes editorial changes to the FAR.

List of Subjects in 48 CFR Parts 1 and 52

Government procurement.

Janet M. Fry,

Director, Federal Acquisition Policy Division, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 1 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. Amend section 1.201–1 by revising paragraph (b)(1) to read as follows:

1.201–1 The two councils.

* * * * *

(b) * * *

(1) Departments of Agriculture, Commerce, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, Interior, Justice, Labor,

State, Transportation, Treasury, and Veterans Affairs; and

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

52.246–21 [Amended]

■ 3. Amend section 52.246–21 by removing from the date of the clause ''(Apr 1984)'' and adding ''(Mar 1994)'' in its place.

[FR Doc. 2019–16407 Filed 8–6–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2019–0002, Sequence No. 3]

Federal Acquisition Regulation; Federal Acquisition Circular 2019–04; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rules appearing in Federal Acquisition Circular (FAC) 2019–04, which amends the Federal Acquisition Regulation (FAR). An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared. Interested parties may obtain further information regarding these rules by referring to FAC 2019–04, which precedes this document. These documents are also available via the internet at *http://www.regulations.gov.*

DATES: August 7, 2019.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2019–04 and the FAR Case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2019–04

Item	Subject	FAR case	Analyst
I*	Ombudsman for Indefinite-Delivery Contracts	2017–020	Jackson.
II	Technical Amendments.		

SUPPLEMENTARY INFORMATION:

Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2019–04 amends the FAR as follows:

Item I—Ombudsman for Indefinite-Delivery Contracts (FAR Case 2017–020)

DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a new clause for use in multiple-award indefinite-delivery indefinite-quantity (IDIQ) contracts that identifies the agency task-order and delivery-order ombudsman's responsibilities and contact information. This rule implements a standardized method to provide the requisite information to contractors via a single contract clause for use by all agencies. This rule intends to minimize the impact on contractors resulting from the variety of ways in which task-order and delivery-order ombudsman information is communicated by agencies.

Item II—Technical Amendments

Editorial changes are made at FAR 1.201–1 and 52.246–21.

Janet M. Fry,

Director, Federal Acquisition Policy Division, Office of Government-wide Policy.

[FR Doc. 2019–16408 Filed 8–6–19; 8:45 am]

BILLING CODE 6820–EP–P

FEDERAL REGISTER

Vol. 84 Wednesday,
No. 152 August 7, 2019

Part IV

The President

Executive Order 13884—Blocking Property of the Government of Venezuela

Federal Register
Vol. 84, No. 152
Wednesday, August 7, 2019

Presidential Documents

Title 3—

The President

Executive Order 13884 of August 5, 2019

Blocking Property of the Government of Venezuela

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, DONALD J. TRUMP, President of the United States of America, in order to take additional steps with respect to the national emergency declared in Executive Order 13692 of March 8, 2015 (Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Venezuela), as amended, as relied upon for additional steps taken in subsequent Executive Orders, and in light of the continued usurpation of power by Nicolas Maduro and persons affiliated with him, as well as human rights abuses, including arbitrary or unlawful arrest and detention of Venezuelan citizens, interference with freedom of expression, including for members of the media, and ongoing attempts to undermine Interim President Juan Guaido and the Venezuelan National Assembly's exercise of legitimate authority in Venezuela, hereby order:

Section 1. (a) All property and interests in property of the Government of Venezuela that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

(b) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in: any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any person included on the list of Specially Designated Nationals and Blocked Persons maintained by the Office of Foreign Assets Control whose property and interests in property are blocked pursuant to this order; or

(ii) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order.

(c) The prohibitions in subsections (a)–(b) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the effective date of this order.

Sec. 2. The unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in section 1(b) of this order would be detrimental to the interests of the United States, and entry of such persons into the United States, as immigrants or nonimmigrants, is hereby suspended, except when the Secretary of State determines that the person's entry would not be contrary to the interests of

the United States, including when the Secretary so determines, based on a recommendation of the Attorney General, that the person's entry would further important United States law enforcement objectives. In exercising this responsibility, the Secretary of State shall consult the Secretary of Homeland Security on matters related to admissibility or inadmissibility within the authority of the Secretary of Homeland Security. Such persons shall be treated in the same manner as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions). The Secretary of State shall have the responsibility for implementing this section pursuant to such conditions and procedures as the Secretary has established or may establish pursuant to Proclamation 8693.

Sec. 3. The prohibitions in section 1 of this order include:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 4. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 5. Nothing in this order shall prohibit:

(a) transactions for the conduct of the official business of the Federal Government by employees, grantees, or contractors thereof; or

(b) transactions related to the provision of articles such as food, clothing, and medicine intended to be used to relieve human suffering.

Sec. 6. For the purposes of this order:

(a) the term ''person'' means an individual or entity;

(b) the term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(c) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States; and

(d) the term ''Government of Venezuela'' includes the state and Government of Venezuela, any political subdivision, agency, or instrumentality thereof, including the Central Bank of Venezuela and Petroleos de Venezuela, S.A. (PdVSA), any person owned or controlled, directly or indirectly, by the foregoing, and any person who has acted or purported to act directly or indirectly for or on behalf of, any of the foregoing, including as a member of the Maduro regime. For the purposes of section 2 of this order, the term ''Government of Venezuela'' shall not include any United States citizen, any permanent resident alien of the United States, any alien lawfully admitted to the United States, or any alien holding a valid United States visa.

Sec. 7. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in Executive Order 13692, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 8. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including promulgating

rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to implement this order. The Secretary of the Treasury may, consistent with applicable law, redelegate any of these functions within the Department of the Treasury. All agencies of the United States Government shall take all appropriate measures within their authority to carry out the provisions of this order.

Sec. 9. (a) Nothing in this order shall be construed to impair or otherwise affect:

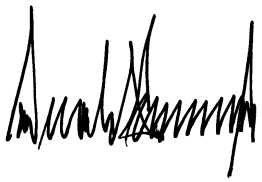
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 10. This order is effective at 9:00 a.m. eastern daylight time on August 5, 2019.



THE WHITE HOUSE,
August 5, 2019.

[FR Doc. 2019–17052
Filed 8–6–19; 11:15 am]
Billing code 3295–F9–P

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Federal Register

Vol. 84, No. 152

Wednesday, August 7, 2019

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FEDERAL REGISTER PAGES AND DATE, AUGUST

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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