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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2014–0279; Airspace Docket No. 14–ANM–3]

Modification of Class D and Class E Airspace; Pasco, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Class D and Class E airspace at Tri-Cities Airport, Pasco, WA. Controlled airspace is necessary to accommodate the new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at the airport. This action, initiated by the biennial review of the Pasco, WA, enhances the safety and management of IFR operations at the airport.

DATES: Effective 0901 UTC, August 20, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/airtraffic/publications/*. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4517.

SUPPLEMENTARY INFORMATION:

History

On July 3, 2014, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to modify controlled airspace at Tri-Cities Airport, Pasco, WA (79 FR 37967). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D airspace and Class E airspace designations are published in paragraphs 5000, 6004 and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in that Order. Except for editorial corrections this rule is the same as published in the NPRM.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Y, airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this final rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace, Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface at Tri-Cities Airport, Pasco, WA. After a biennial review of the airspace, the FAA found modification of the airspace necessary for the safety and management of aircraft departing and arriving under IFR operations at the airport. The Class D airspace area is expanded from the existing 4.3 miles to 4.8 miles, west of the airport, from the 255° radial to the 12° radial, and two segments extending 5.8 miles southwest and northeast of the airport is added. The cutout of the Class D airspace area for Vista Airport is eliminated, as Vista Airport is closed. The Class E surface airspace is adjusted to coincide with the dimensions of the Class D airspace area. Class E airspace designated as an extension to the Class D and Class E surface area is removed as it is no longer needed for IFR operations. The Class E airspace extending 700 feet above the surface is decreased to an 11-mile radius of the airport with segments extending from the 11-mile radius to 13 miles northeast and southeast of the airport, and a segment 4 miles south and 9 miles north of a 226° bearing from the airport extending to 15 miles southwest of the airport. These actions are necessary to accommodate RNAV (GPS) standard instrument approach procedures at the airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority

described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Tri-Cities Airport, Pasco, WA.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment:

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g) 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM WA D Pasco, WA [Modified]

Pasco, Tri-Cities Airport, WA
(Lat. 46°15′53″ N., long. 119°07′09″ W.)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.3-mile radius of Tri-Cities Airport, and that airspace within a 4.8-mile radius of the airport from the 256° bearing from the airport clockwise to the 11° bearing from the airport, and that airspace within a 5.8-mile radius of the airport from the 11° bearing from the airport clockwise to the 83° bearing from the airport, and within a 5.8-mile radius of the airport from the 213° bearing clockwise to the 256° bearing from the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as surface areas.

* * * * *

ANM WA E2 Pasco, WA [Modified]

Pasco, Tri-Cities Airport, WA
(Lat. 46°15′53″ N., long. 119°07′09″ W.)

That airspace extending upward from the surface within a 4.3-mile radius of Tri-Cities Airport and that airspace within 4.8-mile radius of the airport from the 256° bearing from the airport clockwise to the 11° bearing from the airport and that airspace within a 5.8-mile radius of the airport from the 11° bearing from the airport clockwise to the 83° bearing from the airport and within 5.8-mile radius of the airport from 213° bearing clockwise to the 256° bearing from the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E airspace areas designated as an extension to Class D or Class E surface area.

* * * * *

ANM WA E4 Pasco, WA [Removed]

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM WA E5 Pasco, WA [Modified]

Pasco, Tri-Cities Airport, WA
(Lat. 46°15′53″ N., long. 119°07′09″ W.)

That airspace extending upward from 700 feet above the surface within 7.8-mile radius of the Tri-Cities Airport, and that airspace within an 11-mile radius of the airport from the 265° bearing from the airport clockwise to 16° bearing from the airport, and that airspace from the 54° bearing from the airport clockwise to the 112° from the airport, and that airspace 3.5 miles either side of the 35° bearing of the airport extending from the 11-mile radius to 13 mile northeast of the airport, and that airspace and that airspace 4.0 miles either side of the 133° bearing extending from the airport to 13 miles southeast of the airport, and that airspace 4 miles southeast and 9 miles northwest of the 226° bearing from the airport extending from the airport 15 miles southwest; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 45°49′00″ N., long. 118°00′00″ W.; to lat. 45°49′00″ N., long. 119°45′00″ W.; to lat. 47°00′00″ N., long. 119°45′00″ W.; to lat. 47°00′00″ N., long. 118°00′00″ W.; thence to the point of origin.

Issued in Seattle, Washington, on May 8, 2015.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–12019 Filed 5–18–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2015–0190; Amdt. No. 91–337]

RIN 2120–AK69

Prohibition of Fixed-Wing Special Visual Flight Rules Operations at Washington-Dulles International Airport; Withdrawal

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; withdrawal.

SUMMARY: The FAA is withdrawing a previously published direct final rule that would have prohibited fixed-wing special visual flight rules operations at Washington-Dulles International Airport. The FAA is withdrawing this action because it has received an adverse comment.

DATES: The direct final rule published on March 26, 2015, at 80 FR 15887, is withdrawn, effective May 19, 2015.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact David Maddox, Airspace Policy and Regulation Group, AJV–113, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8783; email *david.maddox@faa.gov.*

For legal questions concerning this action, contact Robert Frenzel, Office of the Chief Counsel, AGC–200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3073; email *robert.frenzel@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On March 26, 2015 (80 FR 15887), the FAA published in the **Federal Register** a direct final rule prohibiting fixed-wing special visual flight rules (SVFR) operations at Washington-Dulles International Airport (IAD). The direct final rule was to become effective on May 26, 2015.

Reason for Withdrawal

The FAA is withdrawing the direct final rule because the agency received

an adverse comment to the rule and is required by 14 CFR 11.31(c) to withdraw a direct final rule if the agency receives any adverse comment or notice of intent to file any adverse comment. We received a comment from an individual pilot who objected to the prohibition of fixed-wing SVFR operations at IAD. The commenter stated that the blanket prohibition of SVFR was inappropriate and unnecessary. The commenter further stated that he had personally used SVFR twice in the last few years to land at IAD to participate in an event at the Smithsonian National Air and Space Museum's Steven F. Udvar-Hazy Center, which is located adjacent to IAD. The commenter further suggested that the IAD control tower should approve or disapprove SVFR operations on a case-by-case basis.

The FAA has determined that the comment meets the requirements for consideration as an adverse comment per § 11.31(a). In accordance with the provisions of § 11.31(c), the FAA withdraws the direct final rule.

Conclusion

Withdrawal of Amendment No. 91–337 does not preclude the FAA from issuing rulemaking on the subject in the future, nor does it commit the agency to any future course of action. The agency may also make any future necessary changes to the Code of Federal Regulations through a notice of proposed rulemaking with opportunity for public comment. Therefore, the FAA withdraws Amendment No. 91–337 published at 80 FR 15887, March 26, 2015.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on May 13, 2015.

Jodi S. McCarthy,

Director, Airspace Services.

[FR Doc. 2015–12047 Filed 5–18–15; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 680

[Docket No. 130820737–5408–02]

RIN 0648–BD61

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Program; Amendment 45; Pacific Cod Sideboard Allocations in the Gulf of Alaska

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

ACTION: Final rule.

SUMMARY: NMFS publishes regulations to implement Amendment 45 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (Crab FMP). Amendment 45 establishes, for a limited period of time, a process for NMFS to permanently remove Pacific cod catch limits, known as sideboard limits, which are applicable to certain hook-and-line catcher/processors in the Central and Western Gulf of Alaska (GOA) Regulatory Areas. This action authorizes NMFS to remove these Pacific cod sideboard limits in the Central and/or Western GOA if each eligible participant in the hook-and-line catcher/processor sector in a regulatory area signs and submits a request that NMFS remove the sideboard limit. Each eligible participant will be required to submit the request to NMFS within 1 year of the date of publication of this final rule. This action is necessary to provide participants in the Central and Western GOA hook-and-line catcher/processor sectors with an opportunity to cooperatively coordinate harvests of Pacific cod through private arrangement to the participants' mutual benefit, which would remove the need for sideboard limits in these regulatory areas. This action is intended to promote the goals and objectives of the Crab FMP, the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and other applicable law.

DATES: Effective June 18, 2015.

ADDRESSES: Electronic copies of the following documents may be obtained from *http://www.regulations.gov* or from the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov:*

- The Regulatory Impact Review/Initial Regulatory Flexibility Analysis (RIR/IRFA), and the Categorical Exclusion prepared for this action (collectively referred to as the ''Analysis'');
- The Harvest Specifications Supplemental Information Report (SIR) prepared for the final 2015 and 2016 harvest specifications;
- The Final Environmental Assessment/Final RIR/IRFA for Amendment 83 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (GOA FMP) Allocation of Pacific Cod Among Sectors in the Western and Central GOA; and
- The Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Harvest Specifications EIS).

Written comments regarding the burden-hour estimates or other aspects of the collection of information requirements contained in this final rule may be submitted by mail to NMFS, Alaska Region, P.O. Box 21668, Juneau, AK 99802–1668, Attn: Ellen Sebastian, Records Officer; in person at NMFS, Alaska Region, 709 West 9th Street, Room 420A, Juneau, AK; or by email to *OIRA_submission@omb.eop.gov* or fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Rachel Baker, 907–586–7228

SUPPLEMENTARY INFORMATION: This final rule implements Amendment 45 to the Crab FMP. The king and Tanner crab fisheries in the exclusive economic zone (EEZ) of the Bering Sea and Aleutian Islands are managed under the Crab FMP. While the groundfish fisheries in the EEZ of the Gulf of Alaska are managed primarily under the Fishery Management Plan for Groundfish of the Gulf of Alaska (GOA FMP), some aspects of groundfish fishing in the Gulf of Alaska are managed under the Crab FMP.

NMFS published the Notice of Availability for Amendment 45 in the **Federal Register** on February 2, 2015 (80 FR 5499), with a 60-day comment period that ended April 3, 2015. The Secretary approved Amendment 45 on April 29, 2015, after accounting for information from the public, and determining that Amendment 45 is consistent with the Crab FMP, the Magnuson-Stevens Act, and other applicable law. NMFS published a proposed rule for Amendment 45 on February 12, 2015 (80 FR 7817). The 30-day comment period on the proposed rule ended March 16, 2015. NMFS received one comment letter during the comment periods on Amendment 45 and the proposed rule. A summary of

the comment and NMFS' response is provided in the Comment and Response section of this preamble.

Background

A detailed review of the provisions of Amendment 45, the implementing regulations, and the rationale for these regulations is provided in the preamble to the proposed rule (79 FR 36702, June 30, 2014) and is not repeated here. The proposed rule is available from the NMFS Alaska Region Web site (see **ADDRESSES**).

This final rule establishes, for a limited period of time, a regulatory process for NMFS to permanently remove Pacific cod catch limits, known as sideboard limits, that are applicable to some participants in the Central GOA Regulatory Area (Central GOA) and Western GOA Regulatory Area (Western GOA) hook-and-line catcher/processor sectors. This final rule preamble provides a brief description of Pacific cod fishery management for the Central and Western GOA hook-and-line catcher/processor sectors and the management provisions that apply to Amendment 45 and this final rule.

Management of Pacific Cod in the Central and Western GOA

NMFS implements conservation and management measures, such as catch limits, to prevent overfishing while achieving the optimum yield in federally managed fisheries. Catch limits for GOA Pacific cod are established as part of the annual harvest specifications process for GOA groundfish. The North Pacific Fishery Management Council (Council) annually recommends, and NMFS specifies, an amount of catch at which overfishing is occurring (*i.e.,* overfishing limit or OFL), an acceptable biological catch (ABC), and a total allowable catch (TAC) for each stock or stock complex (*i.e.,* species or species group). Separate TACs are calculated using the apportionment of TAC for specific regulatory areas to limit catch and ensure that fisheries can be effectively managed. Specific to this final rule, the Council recommends, and NMFS implements an OFL and ABC for Pacific cod in the GOA, and separate TACs for the Eastern, Central, and Western GOA Pacific cod fisheries. NMFS apportions each TAC among various gear types (*e.g.,* pot or trawl gear), operation types (*e.g.,* catcher vessels and catcher/processors), and sectors (*e.g.,* hook-and-line catcher/processors) as required by regulation (see regulations at § 680.20(a)). Similarly, the Council recommends and NMFS establishes sideboard limits as part of the harvest specifications process. Sideboard limits constrain harvests by specific vessels based on regulatory requirements established under various management programs. Sideboard limits are calculated as a portion of the TACs for some groundfish species and established in the annual harvest specifications. The resulting sideboard limits for Pacific cod, expressed in metric tons, are published in the annual GOA groundfish harvest specification notices (for the most recent example, see 80 FR 10250, February 25, 2015).

Under this final rule, the GOA Pacific cod OFL, ABC, TACs, and sector allocations will continue to be established through the annual GOA harvest specifications process. NMFS will continue to manage Pacific cod in the GOA by limiting harvests to the established TACs and sector allocations. Therefore, this final rule does not increase the likelihood that an OFL, ABC, TAC, or sector catch limit will be exceeded. See the preamble to the proposed rule and sections 1.5.2 and 3.2 of the Analysis for additional details.

NMFS also manages Pacific cod fisheries through the License Limitation Program (LLP). A vessel is required to be named on an LLP license before it can be deployed to directed fish (*i.e.,* specifically target) for Pacific cod in Federal waters of the GOA. NMFS has issued a specific number of LLP licenses, which establish an upper limit on the total number of potential participants in GOA Pacific cod fisheries. LLP licenses must have the necessary endorsements to directed fish for Pacific cod in the GOA. Specific to this final rule, participants in the Central GOA and Western GOA hook-and-line catcher/processor sectors must have an LLP license with endorsements assigned for (1) Central GOA or Western GOA, (2) hook-and-line gear, (3) catcher/processor, and (4) Pacific cod.

GOA Pacific Cod Sideboard Limits Established Under the BSAI Crab Rationalization Program

The Bering Sea and Aleutian Islands (BSAI) Crab Rationalization Program (CR Program) was implemented in 2005 and established a catch share program that allocates BSAI crab resources among harvesters, processors, and coastal communities. As part of the CR Program, eligible vessel owners and vessel captains were allocated quota share (QS) in several valuable crab fisheries, including the Bering Sea snow crab (*Chionoecetes opilio*) fishery. The CR Program provides increased flexibility for crab fishermen to choose when and where to fish or whether to lease their crab QS and fish for species other than crab. The Council and NMFS recognized that the benefits of the CR Program could create incentives for recipients of snow crab QS to increase their level of participation in groundfish fisheries, especially Pacific cod fisheries in the Central and Western GOA. Therefore, Federal regulations implementing the CR Program established CR Program GOA sideboards to limit the potential adverse effects of the CR Program on GOA groundfish fisheries. These sideboards prevent CR Program participants from preempting fishermen in the GOA that did not receive benefits from the CR Program.

During a fishing year, NMFS manages CR Program GOA Pacific cod sideboard limits by tracking all catch of vessels subject to a sideboard limit to make sure the sideboard limits are not exceeded. NMFS will prohibit directed fishing for GOA Pacific cod in a specific regulatory area by vessels subject to the CR Program GOA Pacific cod sideboard limit through the annual harvest specifications if NMFS determines at the start of the fishing year that the CR Program GOA Pacific cod sideboard limit is insufficient to support a directed fishery by those vessels (see regulations at § 680.22(e)(2) and (3)).

The preamble to the proposed rule and section 1.6 of the Analysis describe that some of the vessels and LLP licenses active in the hook-and-line catcher/processor sector are subject to CR Program GOA Pacific cod sideboard limits. The hook-and-line catcher/processor sector operating in the EEZ off Alaska currently consists of 36 vessels. NMFS has determined that eight of these 36 vessels are subject to the CR Program GOA Pacific cod sideboard limits. The Federal Fisheries Permit (FFP) issued by NMFS to each of these eight vessels includes a designation indicating that the vessel is subject to the CR Program GOA Pacific cod sideboard limits. Of the LLP licenses that authorize a vessel to participate in the Central and/or Western GOA Pacific cod hook-and-line catcher/processor sector, NMFS has determined that five LLP licenses are subject to the CR Program GOA Pacific cod sideboard limits. These five LLP licenses include a designation indicating that the license is subject to the CR Program GOA Pacific cod sideboard limits.

Allocations of Pacific Cod in the GOA

CR Program GOA Pacific cod sideboard limits constrain the harvest of GOA Pacific cod by vessels and holders of license limitation program (LLP) licenses that were used to harvest specific amounts of Pacific cod in the GOA and snow crab in the Bering Sea

and Aleutian Islands Management Area. Originally, the CR Program GOA Pacific cod sideboard limits for the Eastern, Central, and Western GOA were calculated using the Pacific cod TACs for each area. With the implementation of Amendment 83 to the Fishery Management Plan for Gulf of Alaska Groundfish in 2012, the CR Program GOA Pacific cod sideboard limits in the Central and Western GOA are calculated using the apportionment of Pacific cod TAC established for specific gear types (*e.g.,* hook-and-line gear, pot gear) and by operation type (*i.e.,* catcher/processor vessels, catcher vessels). CR Program GOA Pacific cod sideboard limits in the Central and Western GOA for vessels using hook-and-line gear and operating as catcher/processors (the hook-and-line catcher/processor sector) are now much smaller than they were prior to Amendment 83. As a result, NMFS prohibits directed fishing for Pacific cod in the Central and Western GOA by participants in the hook-and-line catcher/processor sector who are subject to CR Program GOA Pacific cod sideboard limits so that these small sideboard limits are not exceeded. The proposed rule preamble describes that Amendment 83 did not change Pacific cod management in the Eastern GOA because the same level of competition, or race for fish, did not exist in the Eastern GOA compared to the Central and Western GOA. As a result, the CR Program GOA Pacific cod sideboard limits in the Eastern GOA were not recalculated for gear and operation type.

The Effect of Pacific Cod Sideboard Limits on Hook-and-Line Catcher/Processors in the Central and Western GOA

The CR Program GOA Pacific cod sideboard limits affected the eight vessels and the five LLP licenses subject to the sideboard limits differently starting in 2012 under Amendment 83 than under management provisions when the CR Program was first implemented in 2006 through 2011. Since the implementation of Amendment 83, NMFS has prohibited directed fishing by participants subject to CR Program GOA Pacific cod sideboard limits in the hook-and-line catcher/processor sector in the Central and Western GOA. NMFS has made this determination each year based on the small amount of the sideboard limits, the need to account for incidental catch of Pacific cod by sideboarded hook-and-line catcher/processors in other groundfish fisheries in the Central and Western GOA, and the potential catch rates of Pacific cod by sideboarded hook-and-line catcher/processors relative to the sideboard limits. The proposed rule preamble and sections 1.5 and 1.6 of the Analysis provide additional detail on the impacts of Amendment 83 on participants in the Central and Western GOA hook-and-line catcher/processor sectors who are subject to CR Program GOA Pacific cod sideboard limits.

Implementation of This Action

This final rule is necessary to provide participants in the Central and Western GOA hook-and-line catcher/processor sectors with an opportunity to cooperatively coordinate harvests of Pacific cod through private arrangement to the participants' mutual benefit, which would remove the need for current regulations that impose sideboard harvest restrictions on some participants in the sectors. This final rule establishes regulatory conditions that must be met prior to the removal of CR Program GOA Pacific cod sideboard limits for the hook-and-line catcher/processor sectors in the Central and/or Western GOA. NMFS will remove the sideboard limits if each person holding an LLP license or LLP licenses with endorsements that authorize directed fishing for Pacific cod as a hook-and-line catcher/processor in the Central or Western GOA (*i.e.,* eligible participants) provides NMFS with a signed form requesting that NMFS remove the Pacific cod sideboard limit for that regulatory area.

Under this final rule, NMFS will not remove the Pacific cod sideboard limit for the Central or Western GOA unless each eligible participant in the Central or Western GOA submits to NMFS a completed Request to Extinguish Pacific Cod Sideboard Limit in the Central or Western GOA. As described in the preamble to the proposed rule, the holders of LLP licenses with the necessary endorsements, rather than vessels owners, represent the universe of eligible fishery participants in the Central and Western GOA hook-and-line catcher/processor sectors. This final rule adds Table 10 to Part 680 to identify the 23 LLP licenses with endorsements that authorize a vessel to catch and process Pacific cod at-sea using hook-and-line gear in the Central GOA, and the 18 LLP licenses with endorsements that authorize a vessel to catch and process Pacific cod at-sea using hook-and-line gear in the Western GOA. The holders of the LLP licenses listed in Table 10 to Part 680 comprise the universe of participants eligible to request removal of a GOA Pacific cod sideboard limit. Each holder of an LLP license with Central GOA endorsements listed in Table 10 to Part 680 will be required to complete and submit to NMFS the form requesting removal of the CR Program GOA Pacific cod sideboard limit in the Central GOA. Similarly, each holder of an LLP license with Western GOA endorsements listed in Table 10 to Part 680 will be required to complete and submit to NMFS the form requesting removal of the CR Program GOA sideboard limit in the Western GOA.

This final rule modifies regulations at 50 CFR 680.22(e) that require NMFS to establish Pacific cod sideboard limits for hook-and-line catcher/processors during the annual harvest specification process. Under this final rule, NMFS will not establish these sideboard limits for the Central or Western GOA if all participants eligible to use a hook-and-line catcher/processor to fish for Pacific cod in the regulatory area sign and submit to NMFS a request that NMFS remove the sideboard limit for that regulatory area.

Each eligible participant will be required to submit that request to NMFS on or before May 18, 2016. Each eligible participant in the Central and/or Western GOA must sign an affidavit, included on a form, to request that NMFS no longer establish Pacific cod sideboard limits for the hook-and-line catcher/processor sector in the Central and/or Western GOA. If NMFS receives the required affidavits during the 1-year period, NMFS will announce the permanent removal of the Central and/or Western GOA sideboard limits during the annual GOA groundfish specification process and will no longer establish Pacific cod sideboard limits for the hook-and-line catcher/processor sector in the Central and/or Western GOA. If NMFS does not receive the required affidavits on or before May 18, 2016, NMFS will continue to establish GOA Pacific cod sideboard limits for the hook-and-line catcher/processor sectors through the annual GOA groundfish specification process and the opportunity to remove them will expire.

Although this final rule is intended to provide an opportunity for coordination and cooperation among all eligible participants in both the Central and Western GOA, this final rule allows the eligible participants to submit requests for each regulatory area separately. Therefore, a CR Program GOA Pacific cod sideboard limit could be removed for one regulatory area without requiring all eligible participants in both areas to agree.

This final rule adds regulations at § 680.22(e)(1)(ii) to clarify that NMFS will not establish CR Program GOA Pacific cod sideboard limits for the hook-and-line catcher/processor sector in a regulatory area through the annual

harvest specification process if NMFS receives completed request forms from all eligible participants in a regulatory area by the deadline. CR Program GOA Pacific cod sideboard limits are currently implemented through the annual harvest specification process; therefore, CR program GOA Pacific cod sideboard limits could not be removed immediately upon receipt by NMFS of the required forms. NMFS will remove a CR Program GOA Pacific cod sideboard limit for the hook-and-line catcher/processor sector during the next annual harvest specification cycle for GOA groundfish.

This final rule does not require eligible participants to enter into a private contractual agreement to coordinate fishing practices within that regulatory area prior to submitting to NMFS the required forms requesting removal of a CR Program GOA Pacific cod sideboard limit. If the holders of the LLP licenses listed in Table 10 to Part 680 are unable, or unwilling, to agree to request that NMFS remove a CR Program GOA Pacific cod sideboard limit in a regulatory area within the time provided, the sideboard limit for that regulatory area will continue to apply. Maintaining the CR Program GOA Pacific cod sideboard limits—if unanimous agreement for their removal is not reached by the eligible participants—is consistent with the objectives of sideboard management as established by the CR Program and the sideboard limit calculation method established under regulations implementing Amendment 83. Removing sideboard limits without unanimous agreement of all of the eligible participants could indicate that eligible participants have not agreed to coordinate harvests. This could increase the likelihood of a race for fish and could allow those who received QS under the CR Program to expand their efforts in the GOA Pacific cod fisheries. Such a result would not be consistent with the goals of the CR Program or the Council's objectives for this action.

This final rule does not modify the CR Program GOA Pacific cod sideboard limits for hook-and-line catcher/processors in the Eastern GOA. As explained in the preamble to the proposed rule, this action does not remove the sideboard designations on the FFPs for the eight sideboarded vessels or the five sideboarded LLP licenses, and these vessels and LLP licenses will still be subject to a CR Program Pacific cod sideboard limit if they are used in the Eastern GOA.

Changes From the Proposed Rule

NMFS made no changes from the proposed to final rule.

OMB Revisions to Paperwork Reduction Act References in 15 CFR 902.1(b)

Section 3507(c)(B)(i) of the PRA requires that agencies inventory and display a current control number assigned by the Director, OMB, for each agency information collection. Section 902.1(b) identifies the location of NOAA regulations for which OMB approval numbers have been issued. Because this final rule revises and adds data elements within a collection-of-information for recordkeeping and reporting requirements, 15 CFR 902.1(b) is revised to reference correctly the sections resulting from this final rule.

Comment and Response

During the public comment periods for the Notice of Availability for Amendment 45 and the proposed rule to implement Amendment 45, NMFS received one comment letter that did not support Amendment 45 and the proposed rule. A summary of the comment received and NMFS' response follows.

Comment: Amendment 45 is not consistent with National Standard 1 of the Magnuson-Stevens Act because it does not prevent overfishing while achieving the optimum yield of fish stocks. Under Amendment 45, industry participants would utilize self-regulation and private contractual agreements to limit GOA Pacific cod harvests if all operations consent to eliminating GOA Pacific cod sideboard limits. This self-regulation would lead to overfishing because industry participants do not have sufficient biological information to establish sustainable catch limits. Furthermore, individual fishing operations have a significant economic incentive to agree to eliminate the Pacific cod sideboard catch limits and then engage in overfishing in order to increase fishing revenue.

Response: NMFS has determined that Amendment 45 and this final rule are consistent with the Magnuson-Stevens Act, the Crab FMP, and other applicable law. Under Amendment 45 and this final rule, the Council and NMFS will continue to manage the Pacific cod fisheries in the GOA to prevent overfishing while achieving, on a continuing basis, the optimum yield from each fishery, consistent with National Standard 1 of the Magnuson-Stevens Act and the GOA FMP. Section 3.2.1 of the GOA FMP defines the OFL as the level above which overfishing is occurring for a species or species group. NMFS manages fisheries in an effort to ensure that no OFLs are exceeded in any year. Section 3.2.4.3 of the GOA FMP clarifies that if catch is approaching an OFL, NMFS will prevent overfishing by closing specific fisheries identified by gear and area that incur the greatest catch. Closures expand to other fisheries if the rate of take is not sufficiently slowed. Regulations at § 679.20(d)(1), (d)(2), and (d)(3) define the process NMFS uses to limit or prohibit fishing to prevent overfishing and maintain total catch at or below the OFL.

Amendment 45 and this final rule establish a process for NMFS to remove GOA Pacific cod sideboard limits. The GOA Pacific cod sideboard limits are an additional level of harvest limits within the GOA Pacific cod sector allocations. Removal of sideboard limits does not mean the GOA Pacific cod fisheries will not have a harvest limit. The proposed rule preamble and sections 1.5.2 and 3.2 of the Analysis describe that Pacific cod OFLs, ABCs, TACs, and sector allocations will continue to be established through the annual GOA harvest specifications process. Amendment 45 and this final rule do not change or otherwise supersede that process. NMFS will continue to manage Pacific cod in the GOA by limiting harvests to the established TACs and sector allocations as specified in regulations at § 679.20. Therefore, this final rule does not increase the likelihood that an OFL, ABC, TAC, or sector catch limit will be exceeded. A detailed description of the annual harvest specification process is provided in the Harvest Specifications SIR prepared for the final 2015 and 2016 harvest specifications and the Alaska Groundfish Harvest Specifications EIS (see **ADDRESSES**).

The Council determined, and NMFS agrees, that Amendment 45 and this final rule are necessary to provide participants in the Central and Western GOA hook-and-line catcher/processor sectors with an opportunity to cooperatively coordinate harvests of Pacific cod through private arrangement to the participants' mutual benefit, which would remove the need for sideboard limits in these regulatory areas. The preamble to the proposed rule (79 FR 36702, June 30, 2014) and section 1.4 of the Analysis describe that Amendment 45 and this final rule are intended to balance the Council's competing objectives: (1) To relieve the CR Program GOA Pacific cod sideboard limits for some vessels and LLP licenses that benefitted from allocations under the CR program, and (2) to protect the

GOA-only participants from adverse impacts that may result from removal of those sideboard limits.

Classification

The Administrator, Alaska Region, NMFS, determined that Amendment 45 to the Crab FMP is necessary for the conservation and management of the GOA groundfish fishery and that it is consistent with the Crab FMP, GOA FMP, the Magnuson-Stevens Act, and other applicable laws.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis (FRFA), the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. The preamble to the proposed rule and this final rule serve as the small entity compliance guide. This action does not require any additional compliance from small entities that is not described in the preambles. Copies of this final rule are available from NMFS at the following Web site: *http://alaskafisheries.noaa.gov.*

Executive Order 12866

This rule has been determined to be not significant for purposes of Executive Order 12866.

Final Regulatory Flexibility Analysis

Section 604 of the Regulatory Flexibility Act (RFA) requires that, when an agency promulgates a final rule under section 553 of Title 5 of the U.S. Code, after being required by that section, or any other law, to publish a general notice of proposed rulemaking, the agency shall prepare a final regulatory flexibility analysis.

Section 604 describes the contents of a FRFA: (1) A statement of the need for, and objectives of, the rule; (2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments; (4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The ''universe'' of entities to be considered in a FRFA generally includes only those small entities that can reasonably be expected to be directly regulated by the final rule. If the effects of the rule fall primarily on a distinct segment of the industry, or portion thereof (*e.g.,* user group, gear type, geographic area), that segment would be considered the universe for purposes of this analysis.

The Small Business Administration (SBA) has established size standards for all major industry sectors in the U.S., including commercial finfish harvesters (NAICS code 114111), commercial shellfish harvesters (NAICS code 114112), other commercial marine harvesters (NAICS code 114119), for-hire businesses (NAICS code 487210), marinas (NAICS code 713930), seafood dealers/wholesalers (NAICS code 424460), and seafood processors (NAICS code 311710). A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $20.5 million, for all its affiliated operations worldwide. For commercial shellfish harvesters, the same qualifiers apply, except the combined annual gross receipts threshold is $5.5 million. For other commercial marine harvesters, for-hire fishing businesses, and marinas, the same qualifiers apply, except the combined annual gross receipts threshold is $7.5 million.

A business primarily involved in seafood processing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual employment, counting all individuals employed on a full-time, part-time, or other basis, not in excess of 500 employees for all its affiliated operations worldwide. For seafood dealers/wholesalers, the same qualifiers apply, except the employment threshold is 100 employees. In determining a concern's number of employees, SBA counts all individuals employed on a full-time, part-time, or other basis. This includes employees obtained from a temporary employee agency, professional employee organization or leasing concern. SBA will consider the totality of the circumstances, including criteria used by the Internal Revenue Service (IRS) for Federal income tax purposes, in determining whether individuals are employees of a concern. Volunteers (*i.e.,* individuals who receive no compensation, including no in-kind compensation, for work performed) are not considered employees. Where the size standard is number of employees, the method for determining a concern's size includes the following principles: (1) The average number of employees of the concern used (including the employees of its domestic and foreign affiliates) based upon numbers of employees for each of the pay periods for the preceding completed 12 calendar months; (2) part-time and temporary employees are counted the same as full-time employees.

Need for and Objectives of This Action

A statement of the need for, and objectives of, the rule is contained in the preamble to this final rule and is not repeated here.

Summary of Significant Issues Raised During Public Comment

NMFS published a proposed rule on February 12, 2015 (80 FR 7817). An initial regulatory flexibility analysis (IRFA) was prepared and summarized in the ''Classification'' section of the preamble to the proposed rule. The comment period closed on March 16, 2015. NMFS received one letter of public comment on the proposed rule. This comment letter did not address the IRFA or the economic impacts of the rule generally. The Chief Counsel for Advocacy of the SBA did not file any comments on the proposed rule.

Number and Description of Small Entities Regulated by This Action

This action would directly regulate eight entities. These eight entities include the owners of the eight vessels,

and the holders of the five LLP licenses currently subject to CR Program GOA Pacific cod sideboard limits in the Central and Western GOA hook-and-line catcher/processor sectors. The owners of the eight vessels and holders of the five LLP licenses directly regulated by this action are affiliated through their membership in the Freezer Longline Conservation Cooperative (FLCC). The FLCC represents LLP holders and the owners and operators of vessels that participate in the Pacific cod hook-and-line catcher/processor sector in the Federal waters of the BSAI. The FLCC is comprised of businesses that are engaged in the harvesting and processing of finfish. The annual revenue of members of the FLCC has exceeded $130 million per year since its formation, and $172 million in 2012, the most recent year of available revenue data (see Table 1–14 in Section 1.6 of the Analysis for additional detail). Members of the FLCC are not considered small entities because the annual revenue of the cooperative exceeds the size standards for small entities.

Three entities hold LLP licenses and own vessels that operate only in the GOA as hook-and-line catcher/processors. These three entities are not directly regulated by the CR Program GOA Pacific cod sideboard limits, and are not members of the FLCC. One entity owns a vessel named on an LLP license with Central GOA Pacific cod hook-and-line catcher/processor endorsements; the other two entities each own a vessel named on LLP licenses with Western GOA Pacific cod hook-and-line catcher/processor endorsements. These three entities are not directly regulated by this action because this action would not impose regulations on these vessels or the associated LLP licenses, or relieve them from regulation. These three entities may voluntarily choose to submit a request for removal of the sideboard limits under this action, but are not required to do so.

Reporting, Recordkeeping, and Other Compliance Requirements

The reporting, recordkeeping, and other compliance requirements will increase slightly under the action if eligible participants in the Central or Western GOA agree to submit an affidavit to NMFS requesting removal of the CR Program GOA sideboard limits. The reporting, recordkeeping, and other compliance requirements will not change under the action if eligible participants in the Central or Western GOA do not submit an affidavit to NMFS requesting removal of the CR Program GOA sideboard limits.

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

A FRFA also requires a description of the steps the agency has taken to minimize the significant impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative (Alternative 2 as modified by Option 1, described below) adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency that affect the economic impact on small entities was rejected. The suite of potential actions includes two alternatives, one associated option, and one associated suboption. A detailed description of these alternatives and options is provided in section 1.6 of the Analysis prepared for this action.

The Council considered two alternatives for this action. Alternative 1 is the status quo, which does not meet the objectives of the action. Alternative 2 would remove the CR Program GOA Pacific cod sideboard limits in either the Central GOA, Western GOA, or both regulatory areas. As part of Alternative 2, the Council and NMFS also considered an option and a suboption for removing the CR Program GOA Pacific cod sideboard limits. The option (*i.e.,* this action) removes the CR Program GOA Pacific cod sideboard limits for the hook-and-line catcher/processor sector permanently if certain conditions are met by a specified date. The sub-option would have suspended the CR Program GOA Pacific cod sideboard limits for the hook-and-line catcher/processor sector on an annual basis if certain conditions are met annually.

The option requires all hook-and-line catcher/processor LLP license holders that are authorized to target Pacific cod in the Central or Western GOA (*i.e.,* eligible participants) to submit a form to NMFS requesting the permanent removal of the GOA Pacific cod sideboard limit in that regulatory area on a one-time basis. The option also requires the request to be submitted within one year of the date of publication in the **Federal Register** of the final rule implementing Amendment 45, if approved by the Secretary.

The sub-option would have required all eligible participants to annually submit a form to NMFS requesting removal of the GOA Pacific cod sideboard limit in that regulatory area for the upcoming fishing year. Under the sub-option, if the annual form is not received by NFMS, the sideboard limits would not be removed for the following fishing year (*i.e.,* January 1 through December 31).

This action implements Alternative 2 with the option to permanently remove the CR Program GOA sideboard limits if each eligible participant in a regulatory area submits to NMFS a form requesting removal and provides that form to NMFS within the required timeline. The Council rejected the sub-option because the annual suspension of sideboards could create uncertainty for participants, result in additional administrative burden and costs, and potentially create management instability. Although this action does not directly regulate small entities, the preferred alternative is the only alternative in the suite of options and alternatives considered that reduces the burden on directly regulated entities and best meets the purpose and need for this action.

Collection-of-Information Requirements

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by Office of Management and Budget (OMB) under control number 0648–0334. Public reporting burden for the Request to Extinguish Pacific Cod Sideboard Limits for Hook-and-Line Catcher/Processors in the Western or Central GOA is estimated to average 30 minutes per individual response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments on this burden estimate or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (see **ADDRESSES**), and by email to *OIRA_Submission@omb.eop.gov,* or fax to 202–395–5806.

Notwithstanding any other provision 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 of information displays a currently valid OMB control number. All currently approved NOAA collections of information may be viewed at: *http://www.cio.noaa.gov/services_programs/prasubs.html.*

List of Subjects

15 CFR Part 902

Reporting and recordkeeping requirements.

50 CFR Part 680

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: May 11, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 15 CFR part 902 and 50 CFR part 680 as follows:

Title 15—Commerce and Foreign Trade

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, in the table in paragraph (b), under the entry ''50 CFR'',add an entry in alphanumeric order for ''680.22'' to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

(b) * * *

CFR part or section where the information collection requirement is located	Current OMB Control No. (all numbers begin with 0648–)
* * * * *	
50 CFR:	
* * * * *	
680.22	–0334
* * * * *	

Title 50—Wildlife and Fisheries

PART 680—SHELLFISH FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 3. The authority citation for part 680 continues to read as follows:

Authority: 16 U.S.C. 1862; Pub. L. 109–241; Pub. L. 109–479.

■ 4. In § 680.22, revise paragraph (e) heading and introductory text, and paragraph (e)(1) to read as follows:

§ 680.22 Sideboard protections for GOA groundfish fisheries.

* * * * *

(e) *Conversion of sideboard ratios into annual sideboard harvest limits.* NMFS will convert sideboard ratios into annual sideboard harvest limits according to the following procedures.

(1) *Annual sideboard harvest limits.* (i) Except as provided in paragraph (e)(1)(ii) of this section, annual sideboard harvest limits for each groundfish species, except fixed-gear sablefish, will be established by multiplying the sideboard ratios calculated under paragraph (d) of this section by the proposed and final TACs in each area for which a TAC is specified. If a TAC is further apportioned by season, the sideboard harvest limit also will be apportioned by season in the same ratio as the overall TAC. The resulting harvest limits expressed in metric tons will be published in the annual GOA groundfish harvest specification notices.

(ii) NMFS will not establish an annual sideboard harvest limit for Pacific cod for vessels that catch and process Pacific cod using hook-and-line gear in the Central GOA Regulatory Area if all eligible participants request that the sideboard harvest limit be removed in accordance with the requirements of paragraph (e)(1)(ii)(A) of this section. NMFS will not establish an annual sideboard harvest limit for Pacific cod for vessels that catch and process Pacific cod using hook-and-line gear in the Western GOA Regulatory Area if all eligible participants request that the sideboard harvest limit be removed in accordance with the requirements of paragraph (e)(1)(ii)(B) of this section. NMFS will publish notification of the removal of the sideboard harvest limit for Pacific cod for vessels that catch and process Pacific cod using hook-and-line gear in the Central GOA Regulatory Area or the Western GOA Regulatory Area through the annual GOA groundfish harvest specifications (see § 679.20(c)(1)(iii) and (c)(3)(ii)).

(A) *Central GOA.* For the Central GOA Regulatory Area (Statistical Areas 620 and 630; see Figure 3 to 50 CFR part 679), the holders of all LLP licenses listed in Column A of Table 10 to this part must submit to NMFS a completed Request to Extinguish Pacific Cod Sideboard Limits for Hook-and-Line Catcher/Processors in the Western or Central GOA, and the request must be received by NMFS on or before May 18, 2016.

(B) *Western GOA.* For the Western GOA Regulatory Area (Statistical Area 610; see Figure 3 to 50 CFR part 679), the holders of all LLP licenses listed in Column B of Table 10 to this part must submit to NMFS a completed Request to Extinguish Pacific Cod Sideboard Limits for Hook-and-Line Catcher/Processors in the Western or Central GOA, and the request must be received by NMFS on or before May 18, 2016.

* * * * *

■ 5. Add Table 10 to part 680 to read as follows:

TABLE 10 TO PART 680—LICENSE LIMITATION PROGRAM LICENSE NUMBERS THAT AUTHORIZE THE OWNERS AND OPERATORS OF CATCHER/PROCESSORS TO DIRECTED FISH FOR PACIFIC COD WITH HOOK-AND-LINE GEAR IN THE CENTRAL GULF OF ALASKA REGULATORY AREA (COLUMN A) AND IN THE WESTERN GULF OF ALASKA REGULATORY AREA (COLUMN B)

Column A:	Column B:
LLG1125	LLG1400.
LLG1128	LLG1401.
LLG1400	LLG1576.
LLG1576	LLG1578.
LLG1713	LLG1785.
LLG1785	LLG1916.
LLG1916	LLG1917.
LLG1917	LLG2026.
LLG1989	LLG2081.
LLG2081	LLG2112.
LLG2112	LLG2892.
LLG2238	LLG2935.
LLG2705	LLG3090.
LLG2783	LLG3602.
LLG2892	LLG3617.
LLG2958	LLG3676.
LLG3609	LLG4004.
LLG3616	LLG4823.
LLG3617.	
LLG3676.	
LLG3681.	
LLG3973.	
LLG4823.	

[FR Doc. 2015–12066 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 635

RIN 0702–AA62

[Docket No. USA–2010–0020]

Law Enforcement Reporting

AGENCY: Department of the Army, DoD.

ACTION: Interim rule; request for comments.

SUMMARY: The Department of the Army amends its regulation concerning law enforcement reporting for a number of statutory requirements to better coordinate law enforcement work and

personnel both within the Department of the Army, across DoD, and with other Federal, State, and local law enforcement officials. It meets law enforcement reporting requirements for selected criminal and national security incidents and provides law enforcement agencies, such as the Department of Homeland Security and Transportation Security Administration, with the most current information available. It also provides the Army chain of command with timely criminal information to respond to queries from the Department of Defense, the news media, and others. The rule establishes policies and procedures for offense and serious-incident reporting with the Army; for reporting to the Department of Defense and the Department of Justice, as appropriate; and for participating in the Federal Bureau of Investigation's National Crime Information Center, the Department of Justice's Criminal Justice Information System, the National Law Enforcement Telecommunications System, and State criminal justice systems. It also updates various reporting requirements described in various Federal statutes.

DATES: Effective May 22, 2015. Consideration will be given to all comments received by: July 20, 2015.

ADDRESSES: You may submit comments, identified by 32 CFR part 635, Docket No. USA–2010–0020 and or RIN 0702–AA62, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Katherine Brennan, (703) 692–6721.

SUPPLEMENTARY INFORMATION:

Justification for Interim Final Rule

Publication of this rule as interim is necessary to maintain national security, ensure the safety and wellbeing of the Soldiers, and/or to avoid legal action against the DOD. While DOD and the Army have implemented many of these requirements through official messages and memorandum, they are not yet published in the internal Army Regulation until this rule becomes final.

For example, until this rule is published:

- Army law enforcement does not have a regulation directing them to report Suspicious activity to the FBI's threat reporting system, eGuardian.
- Sexual assaults are not properly reported using the 2012 National Defense Authorization Act Sexual Assault definition.
- Offense codes used by Army law enforcement to describe the complaint or offense as used in reports to congress are not adequately updated.
- Changes to the restricted sexual assault evidence kits retention schedule from one year to 5 years per the most recent version of the NDAA is causing confusion regarding proper procedures which could result in inconsistency in retaining sexual assault evidence.

In addition, the rule adds the requirement to report positive drug urinalysis tests to the National Instant Checks System (NICS) under the authority of the Brady Handgun Violence Prevention Act of 1993 as amended (18 U.S.C. 922). While the United States Army Criminal Records Center is currently providing these reports to NICS, it may be happening inconsistently.

The Lautenberg Amendment to the Gun Control Act of 1968, requires commanders and family advocacy programs report all domestic violence incidents to the local Installation Provost Marshal Office/Directorate of Emergency Services (PMO/DES). This rule provides guidance to Army Commanders on reporting domestic violence to the PMO/DES in accordance with the Lautenberg Amendment. Without this rule in place, it is possible for a soldier who is prohibited from carrying a weapon due to a qualifying conviction not being properly identified and continuing in assignments and missions which are prohibited.

The rule ensures crime victims and witness are notified about their rights according to the Victim Rights and Restitution Act (42 U.S.C. 10601) and Victim and Witness Protection Act (Sections 1512–1514 of Title 18, U.S.C.). The Army currently must advise the victim or witness of their rights using the Department of Defense Form 2701 (Initial Information for Victims and Witnesses of Crime) in accordance with Army Regulation (AR) 190–45. This rule requires victim witness notifications to be reported on the Department of the Army Form 3975 which feeds into the Army's law enforcement records management system, Centralized Operations Police Suite (COPS). This provides the Army an ability to query the number of victim witness notifications for congressional inquiries.

The rule adds the requirement to input Army crime data into the Defense Incident-Based Reporting System (DIBRS) to comply with the Uniform Federal Crime Reporting Act, Section 534 note of title 28, U.S.C.

The rule adds registration of sex offenders on Army installation to effectuate federal and state registration requirements including the Sex Offender Registration and Notification Act (SORNA), 42 U.S.C. 16901 *et seq,.* This ensures all registered sex offenders who reside or are employed on an Army installation register with the installation PMO or DES. This allows the Army to track or monitor sex offender registration compliance on Army installations which impacts the safety of all personnel residing on Army installations.

The rule ensures compliance with the requirement from the Protecting the Force: Lessons from Ft. Hood, report of the DoD Independent Review, January 2010, which requires reporting of Suspicious Activity to the FBI's eGuardian.

I. Purpose of the Regulatory Action

a. The publication of this rule will ensure the Army is in compliance with multiple Department of Defense and Federal requirements.

This regulatory action will add policy pertaining to the collection of fingerprints and DNA from individuals suspected of certain offenses through the Department of the Defense Instruction 5505.14, Deoxyribonucleic Acid (DNA) collection requirements for criminal investigations, found at: *http://www.dtic.mil/whs/directives/corres/pdf/550514p.pdf* and Department of Defense Instruction 5505.11, Fingerprint Card and Final Disposition Report Submission Requirements, found at: *http://www.dtic.mil/whs/directives/corres/pdf/550511p.pdf.*

This rule adds policy on sex offenders on Army Installations and thus ensures the safety of our Soldiers, family members, and civilians that live and work on Army installation through identifying, monitoring and tracking sex offenders on Army installations.

This rule includes policy pertaining to the release of Military Police (MP) records by adding reporting requirement of domestic incidents to the Army Family Advocacy Program. This rule authorizes the limited use of the Federal

Bureau of Investigations (FBI), National Crime Information Center (NCIC) pursuant to FBI regulations and policy to conduct checks of visitors to an installation.

The rule implements the reporting requirements of DODD 7730.47, Defense Incident-Based Reporting System (DIBRS), found at *http://www.dtic.mil/whs/directives/corres/pdf/773047p.pdf,* by mandating the use of the Centralized Operations Police Suite (COPS) Military Police Reporting System. This implements reporting requirements of Section 534 of Title 28, United States Code (also known as ''The Uniform Federal Crime Reporting Act of 1988''), the victim and witness assistance notifications of Sections 10607 10608 of Title 42 (also known as ''The Victims' Rights and Restitution Act of 1990''), Section 922 of Title 18, United States Code (also known as ''The Brady Handgun Violence Prevention Act and The Lautenberg Amendment to the Gun Control Act''), Sections 16901 through 16928 of Title 42, United States Code (Sex Offender Registration and Notification Act (SORNA)), Section 1701, NDAA FY 14, DoDD 1030.01, DoDI 1030.2. and Public Law 107–188, ''Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' June 12, 2002.

The rule implements the sex offender registration requirements of DODI 1325.07, Administration of Military Correctional Facilities and Clemency and Parole Authority, found at *http://dtic.mil/whs/directives/corres/pdf/132507p.pdf.* The rule's registration requirements allow the Provost Marshal or Director of Emergency Services to provide all military sex offenders with the ''State registration'' document(s) and direct Soldiers to the local or State law enforcement agency, which will register them based on their physical residence address. If a MOU/MOA exists with the local or State law enforcement agency, they will notify the installation. Installation PMs and DESs in the United States will provide written notice of the conviction or transfer to the offender's gaining unit commander, the State's chief LE officer, the chief LE officer of the local jurisdiction in which the accused will reside, the State or local agency responsible for the receipt or maintenance of a sex offender registration where the person will reside, and upon request, governmental officials of foreign countries. Installation PM and DES notifications to State and local officials are described in DODI 1325.07, Administration of Military Correctional Facilities and Clemency and Parole Authority, found at *http://dtic.mil/whs/directives/corres/pdf/132507p.pdf.*

The rule implements the victim/witness requirements contained in DODI 1030.2, Victim and Witness Assistance Procedures, found at *http://dtic.mil/whs/directives/corres/pdf/103002p.pdf,* which implements Sections 1512–1514 of Title 18, United States Code and Sections 113 (note), 1058, 1059 and 1408 of Title 10, United States Code by providing guidance on assisting victims and witnesses of crime from initial contact through investigation, prosecution, and confinement.

The Army will use eGuardian to report, share and analyze unclassified suspicious activity information regarding potential threats or suspicious activities affecting DOD personnel, facilities, or forces in transit in both CONUS and OCONUS. eGuardian is the Federal Bureau of Investigation's (FBI) sensitive-but-unclassified web-based platform for reporting, and in some instances, sharing, suspicious activity and threat related information with other federal, state, tribal, and territorial law enforcement and force protection entities. Information entered into eGuardian by the Army may be either shared with all eGuardian participants or reported directly to the FBI. All information entered into eGuardian by the Army will comply with the policy framework for the system and any existing agency agreements, which incorporate privacy protections.

Analysis of Suspicious Activity Reporting (SARs) will assist Criminal Intelligence analysts and commanders in mitigating potential threats and vulnerabilities, and developing annual threat assessments.

b. The Department is issuing this interim final rule pursuant to its authority under 28 U.S.C. 534, Acquisition, preservation, and exchange of identification records and information, 42 U.S.C. 10607, Services to Victims, 18 U.S.C. 922, Unlawful Act,, 10 U.S.C. 1562, Database on domestic violence incidents, 10 U.S.C. Chap. 47, Uniform Code of Military Justice, Section 1701, National Defense Authorization Act for Fiscal Year 2014, Sexual Assault Prevention and Response and Related Reforms, DoDD 1030.01, Victim and Witness Assistance, and DoDI 1030.2, Victim and Witness Assistance Procedures. Implements crime reporting requirements of the Uniform Federal Crime Reporting Act (Title 10, United States Code, Section 534), the Brady Handgun Violence Prevention Act (18 U.S.C. 922), and the Victim Rights and Restitution Act (42 U.S.C. 10607).

II. Summary of the Major Provisions of the Regulatory Action in Question

The major provisions of this regulatory action include: Records administration, release of information, offense reporting, victim and witness assistance procedures, and the National Crime Information Center policy.

The records administration section includes procedures for safeguarding official information, special requirements of the Privacy Act of 1974 to protect personal information, purpose of gathering police intelligence/criminal information, name checks for criminal background check purposes using the Army's law enforcement databases, registration of sex offenders on Army Installations in the Continental United States and Outside the Continental United States (CONUS and OCONUS), and collection by law enforcement officials of deoxyribonucleic acid (DNA) from subjects of certain offenses. The System of Records Notice, SORN A0190–45, Military Police Reporting Program Records (MRRP) describes the policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system, it can be found at: *http://dpcld.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/569993/a0190-45-opmg.aspx* The Privacy Impact Assessment can be found at: *http://ciog6.army.mil/Portals/1/PIA/2014/CIMS-CID.pdf.*

The release of information section discusses release of information from Army records, under the Freedom of Information Act (FOIA) and Privacy Act of 1974, and release of law enforcement information furnished by foreign governments or international organizations. The section also contains procedures for requesting amendment of records and accounting for military police record disclosure.

The section on offense reporting provides information on completing the DA Form 4833 (Commander's Report of Disciplinary or Administrative Action), found at: *http://www.apd.army.mil/pub/eforms/pdf/a4833.pdf,* for civilian subjects, requirements for submitting fingerprint card and final disposition reports, releasing of domestic incidents reports to the Army Family Advocacy Program (FAP). This section also includes reporting of domestic violence incidents to law enforcement, issuing of protective orders, procedures for establishing Memoranda of Understanding with civilian law enforcement agencies, and reporting of Suspicious Activity to the FBI's eGuardian.

The victim and witness assistance procedures ensure Army personnel involved in the detection, investigation, and prosecution of crimes protect victims and witnesses rights. The National Crime Information Center (NCIC) policy section authorizes NCIC checks, pursuant to FBI regulations and policy, of visitors to a military installation.

III. Cost and Benefits

This rule will not have a monetary effect upon the public. This rule facilitates information sharing between authorized agencies to enhance protection of personnel and resources critical to DoD mission assurance.

IV. Retrospective Review

The revisions to this rule will be reported in future status updates as part of DoD's retrospective plan under Executive Order 13563 completed in August 2011. DoD's full plan can be accessed at: *http://www.regulations.gov/#!docketDetail;D=DOD-2011-OS-0036.*

V. Regulatory Procedures

A. Regulatory Flexibility Act

The Department of the Army has determined that the Regulatory Flexibility Act does not apply because the rule does not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

B. Unfunded Mandates Reform Act

The Department of the Army has determined that the Unfunded Mandates Reform Act does not apply because the rule does not include a mandate that may result in estimated costs to State, local or tribal governments in the aggregate, or the private sector, of $100 million or more.

C. National Environmental Policy Act

The Department of the Army has determined that the National Environmental Policy Act does not apply because the rule does not have an adverse impact on the environment.

D. Paperwork Reduction Act

The Department of the Army has determined that the Paperwork Reduction Act (PRA) does apply to this rule's sex offender registration requirement; all other requirements are exempted since it is information collected during a criminal investigation.

DoD has submitted the sex offender registration requirement to OMB under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

Title: Army Sex Offender Information.

Type of Request: New.

Number of Respondents: 550.

Responses per Respondent: 1.

Annual Responses: 550.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 183 hours.

Needs and Uses: The Army requires tracking and management of sex offenders that reside or are employed on an Army installation due to the transient nature of the Army community. Without such a requirement, the Army would have difficulty tracking sex offenders once they transfer to other states or overseas without anyone's knowledge. All registered sex offenders who reside or are employed on an Army installation will submit their registration information with the installation Provost Marshal Office (PMO).

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer:

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, DoD Desk Officer, Room 10102, New Executive Office Building, Washington, DC 20503, with a copy to the Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.. Comments can be received from 30 to 60 days after the date of this notice, but comments to OMB will be most useful if received by OMB within 30 days after the date of this notice.

You may also submit comments, identified by docket number and title, by the following method:

* *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

E. Executive Order 12630 (Government Actions and Interference With Constitutionally Protected Property Rights)

The Department of the Army has determined that Executive Order 12630 does not apply because the rule does not impair private property rights.

F. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

The Department of the Army has determined that according to the criteria defined in Executive Order 12866 and Executive Order 13563 this rule is a significant regulatory action and has been reviewed by OMB.

G. Executive Order 13045 (Protection of Children From Environmental Health Risk and Safety Risks)

The Department of the Army has determined that the criteria of Executive Order 13045 do not apply because this rule does not implement or require actions impacting environmental health and safety risks on children.

H. Executive Order 13132 (Federalism)

The Department of the Army has determined that the criteria of Executive Order 13132 do not apply because this rule will not have a substantial 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.

List of Subjects in 32 CFR Part 635

Crime, Law, Law enforcement, Law enforcement officers, Military law.

Thomas Blair

Chief, Law Enforcement Branch, Operations Division, Office of the Provost Marshal General, DA.

For reasons stated in the preamble the Department of the Army revises 32 CFR part 635 to read as follows:

PART 635—LAW ENFORCEMENT REPORTING

Subpart A—Records Administration

Sec.
635.1 General.
635.2 Safeguarding official information.
635.3 Special requirements of the Privacy Act of 1974.
635.4 Police Intelligence/Criminal Information.
635.5 Name checks.
635.6 Registration of Sex Offenders on Army Installations (inside and outside the Continental United States).
635.7 Collection of deoxyribonucleic acid.

Subpart B—Release of Information

635.8 General.
635.9 Release of information.
635.10 Release of information under the Freedom of Information Act (FOIA).
635.11 Release of information under the Privacy Act of 1974.
635.12 Amendment of records.
635.13 Accounting for military police record disclosure.
635.14 Release of law enforcement information furnished by foreign governments or international organizations.

Subpart C—Offense Reporting

635.15 DA Form 4833 (Commander's Report of Disciplinary or Administrative Action) for Civilian Subjects.
635.16 Fingerprint Card and Final Disposition Report Submission Requirements.
635.17 Release of domestic incidents reports to the Army Family Advocacy Program (FAP).
635.18 Domestic violence.
635.19 Protection Orders.
635.20 Establishing Memoranda of Understanding.
635.21 Suspicious Activity Reporting (SAR).

Subpart D—Victim and Witness Assistance Procedures

635.22 Procedures.

Subpart E—National Crime Information Center Policy

635.23 Standards.

Authority: 28 U.S.C. 534, 42 U.S.C. 10601, 18 U.S.C. 922, 10 U.S.C. 1562, 10 U.S.C. Chap. 47, 42 U.S.C. 16901 *et seq.,* 10 U.S.C. 1565, 42 U.S.C. 14135a.

Subpart A—Records Administration

§ 635.1 General.

The proponent of this part is the Provost Marshal General. The proponent has the authority to approve exceptions or waivers to this Part that are consistent with controlling law and regulations. In distributing information on juvenile victims or subjects, the installation Freedom of Information Act (FOIA) Office will ensure that only individuals with a need to know of the personally identifiable information (PII) of a juvenile are provided the identifying information on the juvenile. For example, a community commander is authorized to receive pertinent information on juveniles under their jurisdiction. When a MPR identifying juvenile offenders must be provided to multiple commanders or supervisors, the FOIA Office must sanitize each report to withhold juvenile information not pertaining to that commander's area of responsibility.

§ 635.2 Safeguarding official information.

(a) Military police records are unclassified except when they contain national security information as defined in AR 380–5 (Available at *http://www.apd.army.mil/pdffiles/r380_5.pdf*), Department of the Army Information Security Program.

(b) Military police records will also be released to Federal, state, local or foreign law enforcement agencies as prescribed by 32 CFR part 505, The Army Privacy Program. Expanded markings will be applied to these records.

§ 635.3 Special requirements of the Privacy Act of 1974.

(a) Certain PII is protected in accordance with the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, as implemented by 32 CFR part 310, DoD Privacy Program, 32 CFR part 505, The Army Privacy Program, and OMB guidance defining PII.

(b) Pursuant to 5 U.S.C. 552a(e)(3), when an Army activity asks an individual for his or her PII that will be maintained in a system of records, the activity must provide the individual with a Privacy Act Statement (PAS). A PAS notifies individuals of the authority, purpose, and use of the collection, whether the information is mandatory or voluntary, and the effects of not providing all or any part of the requested information.

(c) Army law enforcement personnel performing official duties often require an individual's PII, including SSN, for identification purposes. This PII can be used to complete MPRs and records. In addition to Executive Order 9397, as amended by Executive Order 13478, the solicitation of the SSN is authorized by paragraph 2.c.(2) of DoD Instruction 1000.30, ''Reduction of Social Security Number (SSN) Use Within DoD'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/100030p.pdf*). The purpose is to provide commanders and law enforcement officials with means by which information may accurately be identified. The SSN is used as an additional/alternate means of identification to facilitate filing and retrieval. The following procedures will be used for identification:

(1) Retired military personnel are required to produce their Common Access Card or DD Form 2 (Ret) (U.S. Armed Forces of the United States General Convention Identification Card), or other government issued identification, as appropriate.

(2) Family members of sponsors will be requested to produce their DD Form 1173 (Uniformed Services Identification and Privilege Card). Information contained thereon (for example, the sponsor's SSN) will be used to verify and complete applicable sections of MPRs and related forms.

(3) Non-Department of Defense (DoD) civilians, including military family members and those whose status is unknown, will be advised of the provisions of the Privacy Act Statement when requested to disclose their PII, including SSN, as required.

(d) Notwithstanding the requirement to furnish an individual with a PAS when his or her PII will be maintained in a system of records, AR 340–21, The Army Privacy Program, *http://www.apd.army.mil/pdffiles/r340_21.pdf,* provides that records contained in SORN A0190–45, Military Police Reporting Program Records (MRRP), *http://dpcld.defense.gov/Privacy/SORNsIndex/tabid/5915/Article/6066/a0190-45-opmg.aspx,* that fall within 5 U.S.C. 552a(j)(2) are exempt from the requirement in 5 U.S.C. 552a(e)(3) to provide a PAS.

§ 635.4 Police Intelligence/Criminal Information.

(a) The purpose of gathering police intelligence is to identify individuals or groups of individuals in an effort to anticipate, prevent, or monitor possible criminal activity. Police intelligence aids criminal investigators in developing and investigating criminal cases. 32 CFR part 633 designates the U.S. Army Criminal Investigation Command (USACIDC) as having the primary responsibility to operate a criminal intelligence program. Criminal Intelligence will be reported through the

Army Criminal Investigation and Criminal Intelligence (ACI2) System and other criminal intelligence products. The crimes listed in paragraphs (a)(1)–(9) of this section, as well as the reportable incidents, behavioral threat indicators, and other matters of counterintelligence interest specified by AR 381–12, Threat Awareness and Reporting Program, (available at *http://www.apd.army.mil/pdffiles/r381_12.pdf*) will be reported to the nearest Army counterintelligence office.

(1) Sedition;

(2) Aiding the enemy by providing intelligence to the enemy;

(3) Spying;

(4) Espionage;

(5) Subversion;

(6) Treason;

(7) International terrorist activities or material support to terrorism (MST);

(8) Unreported contacts with foreigners involved in intelligence activities;

(9) Unauthorized or intentional disclosure of classified info.

(b) Information on persons and organizations not affiliated with DoD may not normally be acquired, reported, processed or stored. Situations justifying acquisition of this information include, but are not limited to—

(1) Theft, destruction, or sabotage of weapons, ammunition, equipment facilities, or records belonging to DoD units or installations.

(2) Protection of Army installations and activities from potential threat.

(3) Information received from the FBI, state, local, or international law enforcement agencies which directly pertains to the law enforcement mission and activity of the installation Provost Marshal Office/Directorate of Emergency Services (PMO/DES), Army Command (ACOM), Army Service Component Command (ASCC) or Direct Reporting Unit (DRU) PMO/DES, or that has a clearly identifiable military purpose and connection. A determination that specific information may not be collected, retained or disseminated by intelligence activities does not indicate that the information is automatically eligible for collection, retention, or dissemination under the provisions of this part. The policies in this section are not intended and will not be used to circumvent any federal law that restricts gathering, retaining or dissemination of information on private individuals or organizations.

(c) Retention and disposition of information on non-DoD affiliated individuals and organizations are subject to the provisions of DoD Directive 5200.27 (available at *http://www.dtic.mil/whs/directives/corres/pdf/*520027p.pd), AR 380–13, Acquisition and Storage of Information Concerning Non-Affiliated Persons and Organizations (available at *http://www.apd.army.mil/pdffiles/r380_13.pdf*) and AR 25–400–2, The Army Records Information Management System (ARIMS) (available at *http://www.apd.army.mil/pdffiles/r25_400_2.pdf*).

(d) Local police intelligence files may be exempt from 32 CFR part 518 and the FOIA's disclosure requirements.

§ 635.5 Name checks.

(a) Information contained in military police records will be released under the provisions of 32 CFR part 505, The Army Privacy Program, to authorized personnel for valid background check purposes. Examples include child care/youth program providers, sexual assault response coordinator, unit victim advocate, access control, unique or special duty assignments, security clearance procedures and suitability and credentialing purposes. Any information released must be restricted to that necessary and relevant to the requester's official purpose. Provost Marshals/Directors of Emergency Services (PM/DES) will establish written procedures to ensure that release is accomplished in accordance with 32 CFR part 505.

(b) Checks will be accomplished by a review of the COPS Military Police Reporting System (MPRS). Information will be disseminated according to Subpart B of this part.

(c) In response to a request for local files or name checks, PM/DES will release only founded offenses with final disposition. Offenses determined to be unfounded will not be released. These limitations do not apply to requests submitted by law enforcement agencies for law enforcement purposes, and counterintelligence investigative agencies for counterintelligence purposes.

(d) A successful query of COPS MPRS would return the following information:

(1) Military Police Report Number;

(2) Report Date;

(3) Social Security Number;

(4) Last Name;

(5) First Name;

(6) Protected Identity (Y/N);

(7) A link to view the military police report; and

(8) Whether the individual is a subject, victim, or a person related to the report disposition.

(e) Name checks will include the information derived from COPS MPRS and the United States Army Crime Records Center (USACRC). All of the policies and procedures for such checks will conform to the provisions of this part. Any exceptions to this policy must be coordinated with Headquarters Department of the Army (HQDA), Office of the Provost Marshal General (OPMG) before any name checks are conducted. The following are examples of appropriate uses of the name check feature of COPS MPRS:

(1) Individuals named as the subjects of serious incident reports.

(2) Individuals named as subjects of investigations who must be reported to the USACRC.

(3) Individuals seeking employment as child care/youth program providers.

(4) Local checks of the COPS MPRS as part of placing an individual in the COPS MPRS system.

(5) Name checks for individuals seeking employment in law enforcement positions.

§ 635.6 Registration of Sex Offenders on Army Installations (inside and outside the Continental United States).

(a) *Sex Offenders on US Army Installations.* Garrison Commander's responsibilities: Garrison Commanders will ensure that sex offenders, as defined in paragraph (b) of this section that reside or are employed on an Army Installation register with the installation PM/DES. This includes service members, civilian employees, accompanying dependent family members, and contractors.

(b) Sex offender is defined as:

(1) Any person, including but not limited to a Service member, Service member's family member, Civilian employee, Civilian employee's family member, or contractor, who either is registered or required to register as a sex offender by any law, regulation or policy of the United States, the Department of Defense, the Army, a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, America Samoa, The Northern Mariana Islands, the United States Virgin Islands, or a Federally recognized Indian tribe. This definition is not limited to persons convicted for felony sex offenses but includes all persons who are registered or required to register as a sex offender regardless of the classification of their offenses, including felonies, misdemeanors, and offenses not classified as a felony or misdemeanor.

(2) The persons who are sex offenders as defined in paragraph (b)(1) include those convicted by a foreign government of an offense equivalent or closely analogous to a covered offense under the Uniform Code of Military Justice as provided in AR 27–10, Military Justice (available at *http://www.apd.army.mil/*

pdffiles/r27_10.pdf), Chapter 24.'' See 42 U.S.C. 16911(5)(B) and U.S. Department of Justice, Office of the Attorney General, The National Guidelines for Sex Offender Registration and Notification, Final Guidelines, 73 FR 38030, 38050–1 (July 2, 2008) for guidelines and standards. Contact the servicing Office of the Staff Judge Advocate for assistance in interpreting or applying this provision.

(c) Sex Offender Registration Requirements. Sex offenders, as defined in paragraph (b)(1) of this section must register with the installation PMO/DES within three working days of first arriving on an installation. Sex offenders must provide the installation PMO/DES with evidence of the qualifying conviction. The PMO/DES will enter the registering sex offender's conviction information on a Department of the Army Form 3975 as an information entry into the Army's Centralized Operations Police Suite (COPS) with the state the sex offender was convicted, date of conviction, and results of conviction, to include length of time required to register and any specific court ordered restrictions. Registration with the PMO/DES does not relieve sex offenders of their legal obligation to comply with applicable state and local registration requirements for the state in which they reside, work, or attend school (see, AR 190–47 (available at *http://www.apd.army.mil/pdffiles/r190_47.pdf*), chapter 14 and AR 27–10 (available at *http://www.apd.army.mil/pdffiles/r27_10.pdf*), chapter 24). Registration with the state is also required under the Sex Offender Registration and Notification Act (SORNA), 42 U.S.C. 16901 *et seq.,* and implemented by AR 27–10 (Available at *http://www.apd.army.mil/pdffiles/r27_10.pdf*), Military Justice, and DoDI 1325.7 (Available at *http://www.dtic.mil/whs/directives/corres/pdf/132507p.pdf*). In addition, upon assignment, reassignment, or change of address, sex offenders will inform the installation PM/DES within three working days. Failure to comply with registration requirements is punishable under Federal or State law and/or under the UCMJ. ''State'' in this paragraph includes any jurisdiction listed in paragraph (b)(1) of this section in which a sex offender is required to register.

(d) Installation PMOs and DESs will maintain and update a monthly roster of current sex offenders names and provide it to the Sexual Assault Review Board; the Army Command PM and DES and the garrison commander.

(e) Installation PMs and DESs will complete the following procedures for all other sex offenders required to register on the installation—

(1) Complete a DA Form 3975 as an information entry into COPS.

(2) Complete ''Section III—Subject (1a–7)'' on the DA Form 3975 to identify the sex offender. Ensure the sex offender produces either evidence of the qualifying conviction or the sex offender registration paperwork in order to complete ''Section VII—Narrative'' with the state in which the sex offender was convicted, date of conviction, and results of conviction, to include length of time required to register and any specific court ordered restrictions.

(f) DoD civilians, contractors, and family members that fail to register at the installation PMO/DES are subject to a range of administrative sanctions, including but not limited to a complete or limited bar to the installation and removal from military housing.

§ 635.7 Collection of deoxyribonucleic acid.

(a) Army Law Enforcement (LE) personnel will collect deoxyribonucleic acid (DNA) pursuant to DoDI 5505.14 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550514p.pdf*), DNA Collection Requirements for Criminal Investigations. Per this subpart, a sample of an individual's DNA is to allow for positive identification and to provide or generate evidence to solve crimes through database searches of potentially matching samples. DNA samples will not be collected from juveniles.

(b) Army LE personnel will obtain a DNA sample from a civilian in their control at the point it is determined there is probable cause to believe the detained person violated a Federal statute equivalent to the offenses identified in DoDI 5505.11 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550511p.pdf*), Fingerprint Card and Final Disposition Report Submission Requirements, and 32 CFR part 310, Department of Defense Privacy Program, except for the listed violations that are exclusively military offenses. For the purposes of this rule, DNA shall be taken from all civilian drug offenders, except those who are arrested or detained for the offenses of simple possession and personal use.

(1) When Army LE personnel make a probable cause determination concerning a civilian not in their control, Army LE personnel are not required to collect DNA samples. Likewise, Army LE personnel are not required to obtain DNA samples when another LE agency has, or will, obtain the DNA.

(2) Army LE personnel will use the U.S. Army Criminal Investigation Laboratory (USACIL) DNA kit which includes a DNA sample card and the USACIL DNA database collection eform. Army LE personnel will forward civilian DNA samples to the USACIL. Army LE personnel will document, in the appropriate case file, when civilian LE agencies handle any aspect of the DNA processing and whether the civilian LE agency forwarded the DNA sample to the FBI laboratory.

(c) DoD Instruction 5505.14 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550514p.pdf*) details the procedures former Soldiers and civilians must follow to request expungement of their DNA records. Former Soldiers and civilians from whom DNA samples have been taken, but who were not convicted of any offense giving rise to the collection of DNA, do not submit requests to have their DNA record expunged through installation PMO/DES channels. To request expungement of DNA records for civilians pursuant to Sections 14132 of title 42, United States Code, the requestor or legal representative must submit a written request to: FBI, Laboratory Division, 2501 Investigation Parkway, Quantico, VA 22135, Attention: Federal Convicted Offender Program Manager.

Subpart B—Release of Information

§ 635.8 General.

(a) The policy of HQDA is to conduct activities in an open manner and provide the public accurate and timely information. Accordingly, law enforcement information will be released to the degree permitted by law and Army regulations.

(b) Any release of military police records or information compiled for law enforcement purposes, whether to persons within or outside the Army, must be in accordance with the FOIA and the Privacy Act.

(c) Requests by individuals for access to military police records about themselves will be processed in compliance with FOIA and the Privacy Act.

(d) Military police records in the temporary possession of another organization remain the property of the originating law enforcement agency. The following procedures apply to any organization authorized temporary use of military police records:

(1) Any request from an individual seeking access to military police records will be immediately referred to the originating law enforcement agency for processing. The temporary custodian of

military police records does not have the authority to release those records.

(2) When the temporary purpose of the using organization has been satisfied, the military police records will be returned to the originating law enforcement agency or the copies will be destroyed.

(3) A using organization may maintain information from military police records in their system of records, if approval is obtained from the originating law enforcement agency. This information may include reference to a military police record (for example, MPR number or date of offense), a summary of information contained in the record, or the entire military police record. When a user includes a military police record in its system of records, the originating law enforcement agency will delete portions from that record to protect special investigative techniques, maintain confidentiality, preclude compromise of an investigation, and protect other law enforcement interests.

§ 635.9 Release of information.

(a) Release of information from Army records to agencies outside DoD will be governed by 32 CFR part 518, 32 CFR part 505, AR 600–37, Unfavorable Information (Available at *http://www.apd.army.mil/pdffiles/r600_37.pdf*), and this part. Procedures for release of certain other records and information is contained in AR 20–1, Inspector General Activities and Procedures (available at *http://www.apd.army.mil/pdffiles/r20_1.pdf*), AR 27–20, Claims (available at *http://www.apd.army.mil/pdffiles/r27_20.pdf*), AR 27–40, Litigation (available at *http://www.apd.army.mil/pdffiles/r27_40.pdf*), AR 40–66, Medical Record Administration and Healthcare Documentation (available at *http://www.apd.army.mil/pdffiles/r40_66.pdf*), AR 195–2, Criminal Investigation Activities (available at *http://www.apd.army.mil/pdffiles/r195_2.pdf*), AR 360–1, The Army Public Affairs Program (available at *http://www.apd.army.mil/pdffiles/r360_1.pdf*), and AR 600–85, The Army Substance Abuse Program (available at *http://www.apd.army.mil/pdffiles/r600_85.pdf*). Installation drug and alcohol offices may be provided an extract of DA Form 3997 (Military Police Desk Blotter) for offenses involving the use of alcohol or drugs (for example, drunk driving, drunk and disorderly conduct, or positive urinalysis).

(b) Installation PM/DES are the release authorities for military police records under their control. They may release criminal record information to other activities as prescribed in 32 CFR part 518 and 32 CFR part 505, and this part.

(c) Authority to deny access to criminal records information rests with the initial denial authority (IDA) for the FOIA and the denial authority for Privacy Acts cases, as addressed in 32 CFR part 518 and 32 CFR part 505.

§ 635.10 Release of information under the Freedom of Information Act (FOIA).

(a) The release and denial authorities for all FOIA requests concerning military police records include PM/DES and the Commander, USACIDC. Authority to act on behalf of the Commander, USACIDC is delegated to the Director, USACRC.

(b) FOIA requests from members of the press will be coordinated with the installation public affairs officer prior to release of records under the control of the installation PM/DES. When the record is on file at the USACRC the request must be forwarded to the Director, USACRC.

(c) Requests will be processed as prescribed in 32 CFR part 518 and as follows:

(1) The installation FOIA Office will review requested reports to determine if any portion is exempt from release.

(2) Statutory and policy questions will be coordinated with the local staff judge advocate (SJA).

(3) Coordination will be completed with the local USACIDC activity to ensure that the release will not interfere with a criminal investigation in progress or affect final disposition of an investigation.

(4) If it is determined that a portion of the report, or the report in its entirety will not be released, the request to include a copy of the Military Police Report or other military police records will be forwarded to the Director, USACRC, ATTN: CICR–FP, 27130 Telegraph Road, Quantico, VA 22134. The requestor will be informed that their request has been sent to the Director, USACRC, and provided the mailing address for the USACRC. When forwarding FOIA requests, the outside of the envelope will be clearly marked ''FOIA REQUEST.''

(5) A partial release of information by an installation FOIA Office is permissible when it is acceptable to the requester. (An example would be the redaction of a third party's social security number, home address, and telephone number, as permitted by law). If the requester agrees to the redaction of exempt information, such cases do not constitute a denial. If the requester insists on the entire report, a copy of the report and the request for release will be forwarded to the Director, USACRC. There is no requirement to coordinate such referrals at the installation level. The request will simply be forwarded to the Director, United States Army Crime Records Center (USACRC) for action.

(6) Requests for military police records that have been forwarded to USACRC and are no longer on file at the installation PMO/DES will be forwarded to the Director, USACRC for processing.

(7) Requests concerning USACIDC reports of investigation or USACIDC files will be referred to the Director, USACRC. In each instance, the requestor will be informed of the referral and provided the Director, USACRC address.

(8) Requests concerning records that are under the supervision of an Army activity, or other DoD agency, will be referred to the appropriate agency for response.

§ 635.11 Release of information under the Privacy Act of 1974.

(a) Military police records may be released according to provisions of the Privacy Act of 1974, 5 U.S.C. 552a, as implemented by 32 CFR part 310, DoD Privacy Program, 32 CFR part 505, The Army Privacy Program, and this part.

(b) The release and denial authorities for all Privacy Act cases concerning military police records are provided in § 635.9.

(c) Privacy Act requests for access to a record, when the requester is the subject of that record, will be processed as prescribed in 32 CFR part 505.

§ 635.12 Amendment of records.

(a) *Policy.* An amendment of records is appropriate when such records are established as being inaccurate, irrelevant, untimely, or incomplete. Amendment procedures are not intended to permit challenging an event that actually occurred. Requests to amend reports will be granted only if the individual submits new, relevant and material facts that are determined to warrant their inclusion in or revision of the police report. The burden of proof is on the individual to substantiate the request. Requests to delete a person's name from the title block will be granted only if it is determined that there is not probable cause to believe that the individual committed the offense for which he or she is listed as a subject. It is emphasized that the decision to list a person's name in the title block of a police report is an investigative determination that is independent of whether or not subsequent judicial, non-judicial or administrative action is taken against the individual.

(b) In compliance with DoD policy, an individual will still remain entered in the Defense Clearance Investigations Index (DCII) to track all reports of investigation.

§ 635.13 Accounting for military police record disclosure.

(a) 32 CFR part 505 prescribes accounting policies and procedures concerning the disclosure of military police records.

(b) PM/DES will develop local procedures to ensure that disclosure of military police records as described in 32 CFR part 505 are available on request.

(c) In every instance where records are disclosed; individuals, agencies or components are reminded that use or further disclosure of any military police reports, Military Police Investigator (MPI) reports, or other information received must be in compliance with DoDI 5505.7 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550507p.pdf*), paragraph 6.5.2. which states that ''judicial or adverse administrative actions shall not be taken against individuals or entities based solely on the fact that they have been titled or indexed due to a criminal investigation.''

§ 635.14 Release of law enforcement information furnished by foreign governments or international organizations.

(a) Information furnished by foreign governments or international organizations is subject to disclosure, unless exempted by 32 CFR part 518 and 32 CFR part 505, federal statutes or executive orders.

(b) Release of U.S. information (classified military information or controlled unclassified information) to foreign governments is accomplished per AR 380–10 (available at *http://www.apd.army.mil/pdffiles/r380_10.pdf*).

Subpart C—Offense Reporting

§ 635.15 DA Form 4833 (Commander's Report of Disciplinary or Administrative Action) for Civilian Subjects.

Civilian Subjects titled by Army Law Enforcement. PM/DES and USACIDC will complete and submit disposition reports to USACRC for civilian subjects, not subject to the UCMJ, who are titled by Army law enforcement. PM/DES and USACIDC will complete the DA Form 4833 and submit the form to USACRC for these subjects. PM/DES and USACIDC will not include these completed DA Form 4833 for civilian personnel in reporting compliance statistics for commanders. This ensures records of dispositions of civilian subjects titled by military LE are available in CJIS to support NCIC background checks for firearms purchases, employment, security clearances etc.

§ 635.16 Fingerprint Card and Final Disposition Report Submission Requirements.

(a) *General.* This paragraph implements DoDI 5505.11, Fingerprint Card and Final Disposition Report Submission Requirements, which prescribes procedures for Army LE to report offender criminal history data, by submitting FBI Form FD 249 (Suspect Fingerprint Card) to USACRC. USACRC forwards this data to the Criminal Justice Information Services (CJIS) division of the FBI for inclusion in the Next Generation Identification Database. This paragraph does not eliminate other requirements to provide criminal history data, including those concerning the DIBRS.

(b) Installation PM/DES will submit offender criminal history data to USACRC, based on a probable cause standard determined in conjunction with the servicing SJA or legal advisor for all civilians investigated for offenses equivalent to those listed in DoDI 5505.11. This includes foreign nationals, persons serving with or accompanying an armed force in the field in time of declared war or contingency operations, and persons subject to Public Law 106–523 in accordance with DoDI 5525.11 (Available at *http://www.dtic.mil/whs/directives/corres/pdf/552511p.pdf*), Criminal Jurisdiction Over Civilians Employed By or Accompanying the Armed Forces Outside the United States, Certain Service Members, and Former Service Members.

(c) For purposes of this paragraph commanders will notify their installation PMO/DES when they become aware that a non-DoD and/or foreign LE organization has initiated an investigation against a Soldier, military dependent, or DoD civilian employee or contractor, for the equivalent of an offense listed in DoDI 5525.11 (available at *http://www.dtic.mil/whs/directives/corres/pdf/552511p.pdf*), Enclosure 2, or punishable pursuant to the U.S.C.

§ 635.17 Release of domestic incidents reports to the Army Family Advocacy Program (FAP).

(a) Installation PM/DES will comply with the reporting requirements set forth in AR 608–18 (available at *http://www.apd.army.mil/pdffiles/r608_18.pdf*).

(b) In addition to substantiated incidents of domestic violence, installation PM/DES will notify the Family Advocacy Program Manager (FAPM) and Social Work Services (SWS) of all incidents in which a preponderance of indicators reveal a potential risk of reoccurrence and increasing severity of maltreatment which could lead to domestic violence or child abuse. Installation PM/DES will ensure these notifications are recorded in the official military police journal in COPS. This is to:

(1) Establish a history of incidents that indicate an emerging pattern of risk of maltreatment/victimization to Soldiers and or Family members. See AR 608–18 for incidents that define maltreatment.

(2) Develop a trend history of unsubstantiated–unresolved incidents in order to prevent possible violence or maltreatment from occurring.

§ 635.18 Domestic violence.

(a) Responding to incidents of domestic violence requires a coordinated effort by LE, medical, and social work personnel, to include sharing information and records as permitted by law and regulation. AR 608–18, Chapter 3, contains additional information about domestic violence and protective orders. AR 608–18, Glossary, Section II refers to domestic violence as including the use, attempted use, or threatened use of force or violence against a person or a violation of a lawful order issued for the protection of a person, who is:

(1) A current or former spouse;

(2) A person with whom the abuser shares a child in common; or

(3) A current or former intimate partner with whom the abuser shares or has shared a common domicile.

(b) All domestic violence incidents will be reported to the local installation PMO/DES.

§ 635.19 Protection Orders.

(a) A DD Form 2873, Military Protective Order (MPO) is a written lawful order issued by a commander that orders a Soldier to avoid contact with those persons identified in the order. MPOs may be used to facilitate a ''cooling-off'' period following domestic violence and sexual assault incidents, to include incidents involving children. The commander should provide a written copy of the order within 24 hours of its issuance to the person with whom the member is ordered not to have contact and to the installation LE activity.

(b) *Initial notification.* In the event a MPO is issued against a Soldier and any individual involved in the order does not reside on a Army installation at any

time during the duration of the MPO, the installation PMO/DES will notify the appropriate civilian authorities (local magistrate courts, family courts, and local police) of:

(1) The issuance of the protective order;

(2) The individuals involved in the order;

(3) Any change made in a protective order;

(4) The termination of the protective order.

(c) A Civilian Protective Order (CPO) is an order issued by a judge, magistrate or other authorized civilian official, ordering an individual to avoid contact with his or her spouse or children. Pursuant to the Armed Forces Domestic Security Act, 10 U.S.C. 1561a, a CPO has the same force and effect on a military installation as such order has within the jurisdiction of the court that issued the order.

§ 635.20 Establishing Memoranda of Understanding.

(a) Coordination between military law enforcement personnel and local civilian law enforcement personnel is essential to improve information sharing, especially concerning investigations, arrests, and prosecutions involving military personnel. PM/DES or other law enforcement officials shall seek to establish formal Memoranda of Understanding (MOU) with their civilian counterparts to establish or improve the flow of information between their agencies, especially in instances involving military personnel. MOUs can be used to clarify jurisdictional issues for the investigation of incidents, to define the mechanism whereby local law enforcement reports involving active duty service members will be forwarded to the appropriate installation law enforcement office, to encourage the local law enforcement agency to refer victims of domestic violence to the installation Family Advocacy office or victim advocate, and to foster cooperation and collaboration between the installation law enforcement agency and local civilian agencies.

(b) Installation commanders are authorized to contract for local, state, or federal law enforcement services (enforcement of civil and criminal laws of the state) from civilian police departments. (Section 120 of the Water Resources Development Act of 1976). Section 120(a) of the Water Resources Development Act of 1976 authorizes the Secretary of the Army, acting through the Chief of Engineers, to contract with States and their political subdivisions for the purpose of obtaining increased law enforcement services at water resource development projects under the jurisdiction of the Secretary of the Army to meet needs during peak visitation periods.

(c) MOUs will address the following issues at a minimum:

(1) A general statement of the purpose of the MOU.

(2) An explanation of jurisdictional issues that affect respective responsibilities to and investigating incidents occurring on and off the installation. This section should also address jurisdictional issues when a civilian order of protection is violated on military property (see 10 U.S.C. 1561a).

(3) Procedures for responding to incidents that occur on the installation involving a civilian alleged offender.

(4) Procedures for local law enforcement to immediately (within 4 hours) notify the installation law enforcement office of incidents/investigations involving service members.

(5) Procedures for transmitting incident/investigation reports and other law enforcement information involving active duty service members from local civilian law enforcement agencies to the installation law enforcement office.

(6) Notification that a Solider is required to register as a sex offender either as the result of military judicial proceedings or civilian judicial proceedings.

(7) Procedures for transmitting civilian protection orders (CPOs) issued by civilian courts or magistrates involving active duty service members from local law enforcement agencies to the installation law enforcement office.

(8) Designation of the title of the installation law enforcement recipient of such information from the local law enforcement agency.

(9) Procedures for transmitting military protection orders (MPOs) from the installation law enforcement office to the local civilian law enforcement agency with jurisdiction over the area in which any person named in the order resides.

(10) Designation of the title of the local law enforcement agency recipient of domestic violence and CPO information from the installation law enforcement agency.

(11) Respective responsibilities for providing information to victims regarding installation resources when either the victim or the alleged offender is an active duty service member.

(12) Sharing of information and facilities during the course of an investigation in accordance with the Privacy Act of 1974 (see 5 U.S.C. 552a(b)(7)).

(13) Regular meetings between the local civilian law enforcement agency and the installation law enforcement office to review cases and MOU procedures.

§ 635.21 Suspicious Activity Reporting (SAR).

(a) The Army will use eGuardian to report, share and analyze unclassified suspicious activity information regarding potential threats or suspicious activities affecting DoD personnel, facilities, or forces in transit in both CONUS and OCONUS. USACIDC is the Army's eGuardian program manager.

(b) eGuardian is the Federal Bureau of Investigation's (FBI) sensitive-but-unclassified web-based platform for reporting, and in some instances, sharing, suspicious activity and threat related information with other federal, state, tribal, and territorial law enforcement and force protection entities. Information entered into eGuardian by the Army may be either shared with all eGuardian participants or reported directly to the FBI. All information entered into eGuardian by the Army will comply with the policy framework for the system and any existing agency agreements, which incorporate privacy protections. Analysis of SARs will assist CRIMINTEL analysts and commanders in mitigating potential threats and vulnerabilities, and developing annual threat assessments.

(c) Any concerned soldier or citizen can submit a SAR to the nearest installation PMO/DES, CI or CID office. The receiving office will then be responsible for reviewing the information and determining whether it is appropriate for submission into eGuardian.

Subpart D—Victim and Witness Assistance Procedures

§ 635.22 Procedures.

(a) As required by DoDD 1030.01 (Available at *http://www.dtic.mil/whs/directives/corres/pdf/103001p.pdf*), Army personnel involved in the detection, investigation, and prosecution of crimes must ensure that victims and witnesses rights are protected. Victim's rights include-

(1) The right to be treated with fairness, dignity, and a respect for privacy.

(2) The right to be reasonably protected from the accused offender.

(3) The right to be notified of court proceedings.

(4) The right to be present at all public court proceedings related to the offense,

unless the court determines that testimony by the victim would be materially affected if the victim heard other testimony at trial, or for other good cause.

(5) The right to confer with the attorney for the Government in the case.

(6) The right to restitution, if appropriate.

(7) The right to information regarding conviction, sentencing, imprisonment, and release of the offender from custody.

(b) [Reserved]

Subpart E—National Crime Information Center Policy

§ 635.23 Standards.

The use of NCIC is limited to authorized criminal justice purposes such as, stolen vehicle checks or wants and warrants. Subject to FBI regulations and policy, NCIC checks of visitors to a military installation may be authorized by the Installation/Garrison Commander as set forth in DoD 5200.08–R (Available at *http://www.dtic.mil/whs/directives/corres/pdf/520008r.pdf*) and DoDI 5200.08 (Available at *http://www.dtic.mil/whs/directives/corres/pdf/520008p.pdf*). Visitors to Army installations are non-DoD affiliated personnel.

[FR Doc. 2015–11943 Filed 5–18–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS JACKSON (LCS 6) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective May 19, 2015 and is applicable beginning May 7, 2015.

FOR FURTHER INFORMATION CONTACT: Commander Theron R. Korsak, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS JACKSON (LCS 6) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 3(c), pertaining to the task light's horizontal distance from the fore and aft centerline of the vessel in the athwartship direction. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended in Table Four, paragraph 15, by revising the entry for USS JACKSON (LCS 6) to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

Table Four

* * * * *

■ 15. * * *

Vessel	Number	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
*	*	*
USS JACKSON	LCS 6	Upper—0.10 meters Middle—1.31 meters Lower—1.31 meters

* * * * *

Approved: May 7, 2015.

A.B. Fischer,

Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).

Dated: May 11, 2015

N.A. Hagerty-Ford

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015–11908 Filed 5–18–15; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2012–1036]

Safety Zones and Special Local Regulations; Recurring Marine Events in Captain of the Port Long Island Sound Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce one special local regulation for a boat race, 16 safety zones for fireworks displays and one safety zone for a swim event in the Sector Long Island Sound area of responsibility on the dates and times listed in the tables below. This action is necessary to provide for the safety of life on navigable waterways during the events. During the enforcement periods, no person or vessel may enter the regulated area or safety zones without permission of the Captain of the Port (COTP) Sector Long Island Sound or designated representative.

DATES: The regulations in 33 CFR 100.100 and 33 CFR 165.151 will be enforced during the dates and times as listed in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Petty Officer Ian Fallon, Waterways Management Division, U.S. Coast Guard Sector Long Island Sound; telephone 203–468–4565, email *Ian.M.Fallon@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation listed in 33 CFR 100.100 and the safety zones listed in 33 CFR 165.151 on the specified dates and times as indicated in the following Tables.

TABLE TO § 100.100

	August
1.1 Harvard-Yale Regatta, Thames River, New London, CT	• Event type: Boat Race. • Date: June 7, 2015. • Time: 8:30 a.m. to 12:30 p.m. • Location: All waters of the Thames River at New London, Connecticut, between the Penn Central Draw Bridge 41°21′46.94″ N., 072°5′14.46″ W. to Bartlett Cove 41°25′ 35.9″ N., 072°5′42.89″ W. (NAD 83). • Additional stipulations: Spectator vessels must be at anchor within a designated spectator area or moored to a waterfront facility within the regulated area in such a way that they shall not interfere with the progress of the event at least 30 minutes prior to the start of the races. They must remain moored or at anchor until the men's varsity have passed their positions. At that time, spectator vessels located south of the Harvard Boathouse may proceed downriver at a reasonable speed. Vessels situated between the Harvard Boathouse and the finish line must remain stationary until both crews return safely to their boathouses. If for any reason the men's varsity crew race is postponed, spectator vessels will remain in position until notified by Coast Guard or regatta patrol personnel. The last 1000 feet of the race course near the finish line will be delineated by four temporary white buoys provided by the sponsor. All spectator craft shall remain behind these buoys during the event. Spectator craft shall not anchor: to the west of the race course, between Scotch Cap and Bartlett Point Light, or within the race course boundaries or in such a manner that would allow their vessel to drift or swing into the race course. During the effective period all vessels shall proceed at a speed not to exceed six knots in the regulated area. Spectator vessels shall not follow the crews during the races. Swimming is prohibited in the vicinity of the race course during the races. A vessel operating in the vicinity of the Submarine Base may not cause waves which result in damage to submarines or other vessels in the floating dry-docks.

TABLE 1 TO § 165.151

6.2 Town of Branford Fireworks	• Date: June 27, 2015. • Rain Date: June 28, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: Waters of Branford Harbor, Branford, CT in approximate position, 41°15′30″ N., 072°49′22″ W. (NAD 83).
6.3 Vietnam Veterans/Town of East Haven Fireworks	• Date: June 27, 2015. • Rain Date: June 29, 2015. • Time: 9:00 p.m. to 11:00 p.m. • Location: Waters off Cosey Beach, East Haven, CT in approximate position, 41°14′19″ N., 072°52′9.8″ W. (NAD 83).
7.1 Point O'Woods Fire Company Summer Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 10:00 p.m.

TABLE 1 TO § 165.151—Continued

	• Location: Waters of the Great South Bay, Point O'Woods, NY in approximate position 40°39′18.57″ N., 073°08′5.73″ W. (NAD 83).
7.4 Norwalk Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 8:30 p.m. to 10:30 p.m. • Location: Waters off Calf Pasture Beach, Norwalk, CT in approximate position, 41°04′50″ N., 073°23′22″ W. (NAD 83).
7.5 Lawrence Beach Club Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: Waters of the Atlantic Ocean off Lawrence Beach Club, Atlantic Beach, NY in approximate position 40°34′42.65″ N., 073°42′56.02″ W. (NAD 83).
7.6 Sag Harbor Fireworks	• Date: July 4, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: Waters of Sag Harbor Bay off Havens Beach, Sag Harbor, NY in approximate position 41°00′26″ N., 072°17′9″ W. (NAD 83).
7.7 South Hampton Fresh Air Home Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 8:45 p.m. to 10:00 p.m. • Location: Waters of Shinnecock Bay, Southampton, NY in approximate positions, 40°51′48″ N., 072°26′30″ W. (NAD 83).
7.18 Independence Day Celebration Fireworks	• Date: July 4, 2015. • Rain Date: July 5, 2015. • Time: 8:30 p.m. to 10:00 p.m. • Location: Waters off of Umbrella Beach, Montauk, NY in approximate position 41°01′44″ N., 071°57′13″ W. (NAD 83).
7.27 City of Long Beach Fireworks	• Date: July 10, 2015. • Rain Date: July 11, 2015. • Time: 8:30 p.m. to 10:00 p.m. • Location: Waters off Riverside Blvd, City of Long Beach, NY in approximate position 40°34′38.77″ N., 073°39′41.32″ W. (NAD 83).
7.33 Groton Long Point Yacht Club Fireworks	• Date: July 18, 2015. • Rain Date: July 19, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: Waters of Long Island Sound, Groton, CT in approximate position 40°59′41.40″ N., 072°06′08.70″ W. (NAD 83).
7.34 Devon Yacht Club Fireworks	• Date: July 4, 2015. • Rain Date: July 5, 2015. • Time: 8:45 p.m. to 10:00 p.m. • Location: Waters of Napeague Bay, in Block Island Sound off Amagansett, NY in approximate position 40°59′41.40″ N., 072°06′08.70″ W. (NAD 83).
7.40 Rowayton Fireworks	• Date: July 4, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 11:00 p.m. • Location: Waters of Long Island Sound south of Bayley Beach Park in Rowayton, CT in approximate position 41°03′11″ N., 073°26′41″ W. (NAD 83).
7.42 Connetquot River Summer Fireworks	• Date: July 2, 2015. • Rain Date: July 3, 2015. • Time: 8:45 p.m. to 9:55 p.m. • Location: Waters of the Connetquot River off Snapper Inn Restaurant, Oakdale, NY in approximate position 40°43′32.38″ N., 073°9′02.64″ W. (NAD 83).
8.4 Town of Babylon Fireworks	• Date: August 22, 2015. • Rain Date: August 23, 2015. • Time: 8:30 p.m. to 10:00 p.m. • Location: Waters off of Cedar Beach Town Park, Babylon, NY in approximate position 40°37′53″ N., 073°20′12″ W. (NAD 83).
9.1 East Hampton Fire Department Fireworks	• Date: August 29, 2015. • Rain Date: August 30, 2015. • Time: 8:45 p.m. to 10:15 p.m. • Location: Waters off Main Beach, East Hampton, NY in approximate position 40°56′40.28″ N., 072°11′21.26″ W. (NAD 83).
9.4 The Creek Fireworks	• Date: September 5, 2015. • Rain Date: September 6, 2015. • Time: 7:45 p.m. to 9:15 p.m. • Location: Waters of Long Island Sound off the Creek Golf Course, Lattingtown, NY in approximate position 40°54′13″ N., 073°35′58″ W. W. (NAD 83).

TABLE 2 TO § 165.151

1.6 Swim Across America Greenwich	• Date: June 27, 2015. • Time: 5:30 a.m. to 10:30 a.m. • Location: All navigable waters of Stamford Harbor within a half mile long and 1,000 foot wide polygon shaped box stretching from Dolphin Cove to Rocky Point between Stamford and Greenwich, CT. Formed by connecting the following points. Beginning at point (A) 41°01′32.03″ N., 073°33′8.93″ W., then south east to point (B) 41°01′ 15.01″ N., 073°32′55.58″ W.; then south west to point (C) 41°00′49.25 N., 073°33′ 20.36″ W.; then north west to point (D) 41°00′58.00″ N., 073°33′27.00″ W., then north east to point (E) 41°01′15.80″ N., 073°33′09.85″ W., then heading north and ending at point (A) (NAD 83).

Under the provisions of 33 CFR 100.100 and 33 CFR 165.151, the regatta, fireworks displays and swim event listed above are established as a special local regulation or safety zone. Under the provisions of 33 CFR 100.100 and 165.151, vessels may not enter the regulated area unless given permission from the COTP or a designated representative. Spectator vessels may transit outside the safety zones but may not anchor, block, loiter in, or impede the transit of other vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100, 33 CFR 165 and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners or marine information broadcasts. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: May 7, 2015.

E.J. Cubanski, III,

Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.

[FR Doc. 2015–12103 Filed 5–18–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0314]

Drawbridge Operation Regulation; Long Island, New York Inland Waterway From East Rockaway Inlet to Shinnecock Canal, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the operation of the Loop Parkway Bridge, mile 0.7, across Long Creek, and the Meadowbrook State Parkway Bridge, mile 12.8, across Sloop Channel, both at Hempstead, New York. This temporary deviation is necessary to facilitate the 2015 Dee Snider's Ride to Fight Hunger on Long Island. This temporary deviation allows two bridges to remain in the closed position during this public event.

DATES: This deviation is effective from 11 a.m. to 1 p.m. on September 20, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0314] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140, on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, contact Ms. Judy K. Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, *judy.k.leung-yee@uscg.mil.* If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Loop Parkway Bridge, mile 0.7, across Long Creek has a vertical clearance in the closed position of 21 feet at mean high water and 25 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.799(f).

The Meadowbrook State Parkway Bridge, mile 12.8, across Sloop Channel has a vertical clearance in the closed position of 22 feet at mean high water and 25 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.799(h). Long Creek and Sloop Channel are transited by commercial fishing and recreational vessel traffic.

Long Island Cares, Inc. requested and the bridge owner for both bridges, the State of New York Department of Transportation, concurred with this temporary deviation from the normal operating schedule to facilitate a public event, the 2015 Dee Snider's Ride.

Under this temporary deviation, the Loop Parkway and the Meadowbrook State Parkway Bridges may remain in the closed position between 11 a.m. and 1 p.m. on September 20, 2015.

There are no alternate routes for vessel traffic; however, vessels that can pass under the closed draws during this closure may do so at any time. The bridges may be opened in the event of an emergency.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 8, 2015.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2015–12112 Filed 5–18–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0300]

RIN 1625–AA00

Safety Zone; Agat Marina, Agat, Guam

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will establish a safety zone in the waters of Agat Marina, Guam, to be enforced daily during the repairs to the Agat marina channel markers from 7:30 a.m. through 6:00 p.m. from May 25, 2015 through June 8, 2015 while the construction barge is in the channel. The safety zone will encompass all waters within 25 yards of the construction barge in the Agat Marina Channel. This safety zone is necessary to protect the crew working the channel markers, and the mariners from the hazards of the repairs taking place at the Agat Marina.

DATES: This rule is effective from 7:30 a.m. May 25, 2015 through 6:00 p.m., (local Kilo time) on August 8, 2015. This rule is enforced daily Monday through Saturday from 7:30 a.m. to 6:00 p.m. May 25, 2015 through June 8, 2015 (local Kilo time).

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2015–0300 and are available online by going to *http://www.regulations.gov,* inserting USCG–2015–0300 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Chief Kristina Gauthier, U.S. Coast Guard Sector Guam at (671) 355–4866.

If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations; telephone 202–366–9826, or 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
COTP Captain of the Port
PAG Port Authority Guam

Regulatory Information

The Coast Guard is issuing this temporary final 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 the official notification of Agat Marina Channel repairs, and the need for this safety zone, was not finalized 60 days prior to the start of the repairs. Publishing an NPRM and delaying the effective date would be contrary to the public interest since the event would occur before the rulemaking process was complete, thereby jeopardizing the safety of the people and property unknowingly transiting or remaining in the area.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM prior to making this rule effective 30 days after publication in the **Federal Register**. The COTP finds this good cause to be the immediate need for a safety zone to allay the aforementioned safety concerns surrounding the construction work to be undertaken at Agat Marina.

Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1.

A safety zone is a water area, shore area, or water and shore area, for which access is limited to authorized person, vehicles, or vessels for safety or environmental purposes. The purpose of this rulemaking is to protect mariners from the potential hazards associated with the construction barge operating in a narrow channel.

Discussion of Rule

In order to protect the public from the hazards of the construction associated with the channel marker replacement, the Coast Guard is establishing a temporary safety zone, enforced daily Monday through Saturday, from 7:30 a.m. to 6:00 p.m. May 25, 2015 through June 8, 2015 (Kilo, Local Time). Enforcement dates may need to be changed or adjusted in the event that sea or weather conditions are not conducive to safe operations. In the event of a change in dates the new dates and times will be broadcast in a Broadcast Notice to Mariners and transmited via email to all port partners. The safety zone is located within the Guam COTP Zone (See 33 CFR 3.70–15), and will cover all waters of the Agat Marina Channel located at 13 degrees 28 minutes 54 seconds North and 144 degrees 47 minutes 30 seconds East (NAD 1983), from the surface of the water to the ocean floor within 25 yards of the construction barge KIWI 1. There will be a no wake zone while transiting the entire channel. The general regulations governing safety zones contained in 33 CFR 165.23 apply. Any Coast Guard commissioned, warrant or petty officer, and any COTP representative permitted by law, may enforce the zone. The COTP may waive any of the requirements of this rule for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime safety. Vessels or persons violating this rule are subject to the penalties set forth in 33 U.S.C. 1232.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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. This rule would affect the following entities, some which might be small entities: The owners or operators of vessels intending to transit the Agat Marina Channel daily from 07:30 a.m. May 25, 2015 through 6 p.m. June 8, 2015. Due to the nature of the work to be undertaken to ensure the proper demarkation of the Agat Marina Channel, the channel will be adversely affected during the anticipated 14 days of construction. The narrowing of the channel in the area around the construction barge will require additional safety precautions be taken by local mariners. The safety zone will not have significant economic impact on a substantial number small entities for the following reasons. The nature of the work and location of the barge may cause some delays in the entering and exiting of the channel by small boat operators berthed in the Agat Marina, however traffic will still be allowed to transit around the construction barge with no wake. Before the activation of the zone, maritime advisories will be widely available to users of the channel.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 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.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves is categorically excluded from further environmental documentation because it is a regulation establishing a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record-keeping 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 AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14–300 to read as follows:

§ 165.T14–300 Safety Zone; Agat Marina, Agat, Guam.

(a) *Location.* The following area, within the Guam COTP Zone (See 33 CFR 3.70–15), from the surface of the water to the ocean floor, is a safety zone: 25 yards around the construction barge KIWI 1 in the waters of Agat Marina, Guam located at 13 degrees 28 minutes 54 seconds North and 144 degrees 47 minutes 30 seconds East (NAD 1983). There is a no wake zone established for the entire length of the Agat Channel.

(b) *Effective Dates.* This rule is effective from 7:30 a.m. May 25, 2015 through 6:00 p.m. on August 8, 2015 (Kilo, Local Time) while the construction barge KIWI 1 is in the channel.

(c) *Regulations.* The general regulations governing safety zones contained in 33 CFR 165.23 apply. Entry into, transit through or anchoring within this zone is prohibited unless authorized by the COTP or a designated representative thereof. Authorization can be requested from PAG Harbor Master via phone at (671) 477–5931 ext 533.

(d) *Enforcement.* This rule is enforced daily Monday through Saturday from 7:30 a.m. to 6:00 p.m. May 25, 2015 through June 8, 2015 (Kilo, Local Time) while the construction barge KIWI 1 is in the channel. Any Coast Guard commissioned, warrant, or petty officer, and any other COTP representative permitted by law, may enforce this temporary safety zone.

(e) *Waiver.* The COTP may waive any of the requirements of this rule for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime security.

(f) *Penalties.* Vessels or persons violating this rule are subject to the penalties set forth in 33 U.S.C. 1232.

Dated: April 30, 2015.

James B. Pruett,

Captain, U.S. Coast Guard, Captain of the Port Guam.

[FR Doc. 2015–12121 Filed 5–18–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2015–0032]

RIN 0651–AD00

Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board

AGENCY: Patent Trial and Appeal Board, United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the existing consolidated set of rules relating to the United States Patent and Trademark Office (Office or USPTO) trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings that implemented provisions of the Leahy-Smith America Invents Act (''AIA'') providing for trials before the Office.

DATES: *Effective Date:* This rule is effective May 19, 2015.

FOR FURTHER INFORMATION CONTACT: Susan L. C. Mitchell, Lead Administrative Patent Judge by telephone at (571) 272–9797.

SUPPLEMENTARY INFORMATION: *Executive Summary: Purpose:* This final rule increases the page limitations for briefing for Patent Owner's motion to amend and for Petitioner's reply brief in response to comments from the public. This final rule also addresses clarifying changes to the rules so that they conform to Office practice in conducting AIA proceedings.

Summary of Major Provisions: In an effort to gauge the effectiveness of the rules governing AIA trials, the Office conducted a nationwide listening tour in April and May of 2014, and in June 2014, published a **Federal Register** Notice asking for public feedback about the AIA trial proceedings. The Office has carefully reviewed the comments and, in response to public input, will issue two rules packages; a first, final rule package with more ministerial changes to the rules, and a second, proposed rule package that will issue later to address more involved changes to the rules and the Office Patent Trial Practice Guide. The Office presents the following final rules to address issues concerning Patent Owner's motion to amend and Petitioner's reply brief that involve ministerial changes, and will address public comments relating to those specific issues only, in this first, final rule package. For instance, the following final rules provide ten additional pages for a Patent Owner motion to amend, allow a claims appendix for a motion to amend, and provide ten additional pages for Petitioner's reply brief.

These final rules also provide changes to conform the rules to the Office's established practices in handling AIA proceedings. For instance, the final rules require a specific font to ensure readability of briefs, clarify that more than one back-up counsel can be named, and clarify how to count challenged claims to calculate fees. The final rules also clarify that providing a statement of material fact by a party is optional and that routine discovery contemplates only cross-examination of affidavit testimony prepared for the proceeding. The final rules further provide that uncompelled direct testimony must be in the form of an affidavit, not a deposition; that motions in limine are not used in AIA practice; that objections to evidence should be made part of the record by filing them; and that only a single request for rehearing may be filed as of right. Finally, with regard to covered business method patent reviews, the final rules clarify, consistent with the AIA, that such reviews may be extended in the case of joinder and that no petition for a covered business method patent review may be filed if the petitioner or real party-in-interest filed a civil action challenging the validity of a claim of the covered business method patent.

Costs and Benefits: This rulemaking is not economically significant, and is not significant, under Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

Background

Development of the Final Rule

On September 16, 2011, the AIA was enacted into law (Pub. L. 112–29, 125 Stat. 284 (2011)), and shortly thereafter in 2012, the Office implemented rules to govern Office trial practice for AIA proceedings, including *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings pursuant to 35 U.S.C. 135, 316 and 326 and AIA 18(d)(2). *See* Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 FR 48,612 (Aug. 14, 2012); Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 FR 48,680 (Aug. 14, 2012); Transitional Program for Covered Business Method Patents—Definitions of Covered Business Method Patent and Technological Invention, 77 FR 48,734 (Aug. 14, 2014). Additionally, the Office published a Patent Trial Practice Guide for the rules to advise the public on the general framework of the regulations, including the structure and times for taking action in each of the new proceedings. *See* Office Patent Trial Practice Guide, 77 FR 48,756 (Aug. 14, 2012).

In an effort to gauge the effectiveness of the rules governing AIA trials, the Office conducted a nationwide listening tour in April and May of 2014. During the listening tour, the Office focused particularly on transparency and public involvement in making trial proceedings more effective going forward by adjusting the rules and guidance where necessary. As a result, in June of 2014, the Office published a Request for Comments in the **Federal Register** and, at stakeholder request, extended the period for receiving comments to October 16, 2014. *See* Request for Comments on Trial Proceedings Under

the America Invents Act Before the Patent Trial and Appeal Board, 79 FR 36,474 (June 27, 2014).

The Request for Comments asked seventeen questions on ten broad topics, including a general catchall question, to elicit any proposed changes to the AIA post-grant program that stakeholders suggest would be beneficial. *See* Request for Comments, 79 FR at 36,476–77. The Office received thirty-seven comments from bar associations, corporations, law firms, and individuals, encompassing a wide range of issues. The Office expresses its gratitude for the thoughtful and comprehensive comments provided by the public, which are available on the USPTO Web site: *http://www.uspto.gov/page/comments-trial-proceedings-under-america-invents-act-patent-trial-and-appeal-board.*

Several commenters expressed satisfaction with the current AIA post-grant programs, and several commenters offered suggestions on how to strengthen the AIA post-grant programs. For example, some suggestions concerned the claim construction standard used by the PTAB, motions to amend, discovery procedures, and handling of multiple proceedings. The Office will address all public comments that do not involve changes to the page limitations for Patent Owner's motion to amend or Petitioner's reply brief in the second, proposed rule package.

Discussion of Specific Final Rules

Subpart A—Trial Practice and Procedure

Patent Owner's Motion To Amend

a. Amendments to the Rules

In response to comments received from the public concerning amendment practice in AIA proceedings, the Office is increasing the page limitation for Patent Owner's motion to amend by ten pages and allowing a claims appendix that is not included in the page limitation. To implement this increase in the page limitation for a motion to amend from fifteen to twenty-five pages, exclusive of any claims appendix, with a commensurate increase in the number of pages for an opposition to a motion to amend, the Office amends 37 CFR 42.24(a) and (c), 42.121(b), and 42.221(b) as follows:

- Amend 37 CFR 42.24(a)(1) to add the phrase ''or claim listing'' after ''or appendix of exhibits.''
- Amend 37 CFR 42.24(a)(1)(v) to read ''Motions (excluding Motions to Amend): 15 pages''; and add (vi) to read ''Motions to Amend: 25 pages.''
- Amend 37 CFR 42.24(c)(2) to read ''Replies to oppositions (excluding replies to oppositions to Motions to Amend): 5 pages''; and add (3) to read ''Replies to oppositions to Motions to Amend: 12 pages.''
- Amend 37 CFR 42.121(b) to read ''*Content.* A motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth . . . .''
- Amend 37 CFR 42.221(b) to read ''*Content.* A motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth . . . .''

b. Response to Comments

Comments: Although some comments advocated no change to the Office's motion to amend practice in AIA proceedings, numerous comments suggested relaxing the page limitation on Patent Owner's motion to amend. Several comments proposed a specific number of additional pages, and/or permitting the listing of claims in an appendix not counted toward the page limit. One comment suggested a flexible page limit based on the number of substitute claims proposed, and one comment suggested that the Board more freely grant requests for additional pages. Another comment suggested permitting the patent owner to allocate unutilized pages from the patent owner's response to the motion to amend.

Response: The overall request to relax the page limitation on Patent Owner's motion to amend is adopted. As set forth above, the Office amends 37 CFR 42.24(a) to increase the page limit for motions to amend from 15 pages to 25 pages. Applying the provision of 37 CFR 42.24(b)(3) mandating an equal page limitation for oppositions, the page limit for oppositions to motions to amend also increases from 15 pages to 25 pages. The Office also amends 37 CFR 42.24(c) to increase the page limit for replies to oppositions to motions to amend from 5 pages to 12 pages. Also, the Office amends 37 CFR 42.121(b) and 37 CFR 42.221(b) to permit an appendix for the claim listing accompanying a motion to amend that is not counted toward the 25-page limitation.

The specific request for a flexible page limit based on the number of substitute claims is not adopted. This procedure is not warranted in light of the above amendments relaxing the page limitation on Patent Owner's motion to amend. In addition, this approach may encourage parties to increase unnecessarily the number of substitute claims presented solely to procure additional pages for the motion. In accord with the specific request that the Board more freely grant requests for additional pages, however, the Board will continue to consider requests for additional pages on a case-by-case basis.

The specific request that a patent owner be able to allocate pages from the patent owner's response to a motion to amend is not adopted. This procedure is not warranted in light of the above amendments relaxing the page limitation on Patent Owner's motion to amend. In addition, this procedure would be difficult to administer in light of the above amendments, placing an undue administrative burden on the Office to determine and monitor the total number of pages allocated to the patent owner, to the petitioner's opposition to the motion to amend, and to any reply.

Petitioner's Reply

a. Amendments to the Rules

In response to comments received from the public, the Office is increasing the page limitation for Petitioner's reply brief to Patent Owner's response to petition by 10 pages. To implement this increase in the page limitation for Petitioner's reply brief from fifteen to twenty-five pages, the Office amends 37 CFR 42.24(c)(1) to read: ''Replies to patent owner responses to petitions: 25 pages.''

b. Response to Comments

Comments: Although at least one commenter wanted no change, several commenters suggested that the fifteen pages afforded for a Petitioner's reply brief is not commensurate with the number of pages afforded to Patent Owner, especially if Patent Owner raises new issues. Commenters suggested that increasing the page limitation for Petitioner's reply brief would allow a more complete record before the Office. One comment suggested that to provide Petitioner with a fair opportunity to respond, the number of pages afforded for Petitioner's reply brief may correspond to the number of pages in Patent Owner's post-institution response that is devoted to new issues.

Response: The overall request to relax page limitations on Petitioner's reply brief to Patent Owner's response is adopted. As set forth above, the Office amends 37 CFR 42.24(c)(1) to increase the page limit for Petitioner's reply brief from 15 to 25 pages.

The specific request for a flexible page limit based on new issues raised in Patent Owner's response is not adopted. This procedure is not warranted in light of the above amendment relaxing the page limitation on Petitioner's reply

brief. In addition, this procedure would be difficult to administer, placing an undue administrative burden on the Office to determine the total number of pages allocated by Patent Owner to new issues.

Required Font

In AIA post-grant proceeding filings, the Office has required either a proportional or monospaced font that is 14-point or larger, with an additional requirement that any monospaced font must not contain more than four characters per centimeter or ten characters per inch. *See* 37 CFR 42.6(a)(2)(ii). The Office has received briefs from parties that utilize narrow fonts that may be compliant with these requirements, but nevertheless, have proved difficult to read. To address this concern, the Office is amending 37 CFR 42.6(a)(2) to require 14-point, Times New Roman proportional font, with normal spacing, to ensure readability of all briefs.

Counsel

To clarify the rule regarding designation of counsel for an AIA proceeding that more than one back-up counsel may be designated, the Office amends 37 CFR 42.10 as follows:

• Replace the article ''a'' before ''back-up counsel'' with ''at least one'' in 37 CFR 42.10(a).

Fees

The Office has explained in the Office Patent Trial Practice Guide that to understand the scope of a dependent claim, the claim(s) from which the dependent claim depends must be construed along with the dependent claim. Therefore, to calculate any fee due under 37 CFR 42.15 that is based on the number of claims, each claim challenged will be counted as well as any claim from which a challenged claim depends, unless the parent claim is also separately challenged. *See* Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions; Final Rule, 77 FR 48,612, 48,619 (Aug. 14, 2012).

To clarify the fees rule to reflect explicitly this requirement to include unchallenged claims from which a challenged claim depends in the claim count for fee calculating purposes, the Office is amending 37 CFR 42.15 as follows:

• Add the content '', including unchallenged claims from which a challenged claim depends'' after the text ''each claim in excess of 20'' in 37 CFR 42.15(a)(3) and 42.15(b)(3).

• Delete the first instance of the phrase ''request fee'' in the following phrase ''Post-Grant or Covered Business Method Patent Review request fee Post-Institution request fee'' in 42.15(b)(4).

• Add the content '', including unchallenged claims from which a challenged claim depends'' after the text ''each claim in excess of 15'' in 37 CFR 42.15(a)(4) and 42.15(b)(4).

Oppositions and Replies and Page Limits for Petitions, Motions, Oppositions, and Replies

To clarify that supplying a statement of material fact by a party is optional, the Office amends 37 CFR 42.23 and 42.24 as follows:

• Replace the phrase ''and must include a statement identifying material facts in dispute'' from the first sentence of 37 CFR 42.23(a) with ''and, if the paper to which the opposition or reply is responding contains a statement of material fact, must include a listing of facts that are admitted, denied, or cannot be admitted or denied.''

• Replace the phrase ''the required'' with ''any'' in the first sentence of 37 CFR 42.24(c).

Discovery

To clarify that routine discovery includes only the cross-examination of affidavit testimony prepared for the proceeding, the Office amends 37 CFR 42.51(b)(1)(ii) to add the phrase ''prepared for the proceeding'' after ''affidavit testimony.''

Taking Testimony

Because uncompelled direct testimony must be submitted in the form of an affidavit, the Office is amending 37 CFR 42.53(c)(2) as follows:

• Delete the word ''deposition'' from the phrase ''uncompelled direct deposition testimony.''

To clarify that either party is permitted to file testimony as an exhibit, the Office amends 37 CFR 42.53(f)(7) to delete the phrase ''by proponent'' in the second sentence.

Motion in Limine

The term motion in limine is included in the title for 37 CFR 42.64, but the rule does not provide for a motion in limine. To clarify the rule, the Office amends 37 CFR 42.64 to delete ''motion in limine'' from the title of the rule.

Objection

The Office amends 37 CFR 42.64(b)(1) for consistency with the Office Patent Trial Practice Guide. The Office Patent Trial Practice Guide requires that a party wishing to challenge admissibility of evidence must object timely to the evidence. Therefore, the Office Patent Trial Practice Guide states that a motion to exclude evidence requires a party to identify where in the record the objection originally was made, but 37 CFR 42.64(b)(1) merely requires service of objections to evidence, which does not make such objections part of the record. Therefore, the Office amends the first and second sentences of 37 CFR 42.64(b)(1) to replace ''served'' with ''filed'' so as to require filing of objections, which also requires service under 37 CFR 42.6(e)(2).

Decision on Petition or Motions

To clarify that a party may file only a single request for rehearing as of right, the Office amends 37 CFR 42.71(d) to add ''single'' before ''request for rehearing'' in the first sentence.

Subpart D—Transitional Program for Covered Business Method Patents

Procedure and Pendency

To clarify that the pendency of a covered business method patent review proceeding can be extended in the case of joinder and to harmonize the rule with similar rules in other post grant proceedings, the Office amends 37 CFR 42.300(c) to add '', or adjusted by the Board in the case of joinder'' at the end of the second sentence after ''Chief Administrative Patent Judge.''

Who May Petition for a Covered Business Method Patent Review

The Office may not institute a covered business method patent review of a challenged patent when the petitioner filed a civil action challenging the validity of a claim of the patent before filing the petition. *See* AIA section 18(a)(1); 35 U.S.C. 325(a)(1); *SecureBuy, LLC* v. *CardinalCommerce Corp.,* Case CBM2014–00035 (PTAB Apr. 25, 2014) (Paper 12) (precedential). To state this prohibition explicitly, the Office amends 37 CFR 42.302 to add a section (c) as set forth in the regulatory text of this rule.

Rulemaking Considerations

A. Administrative Procedure Act (APA): This final rule revises the consolidated set of rules relating to Office trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings. The changes being adopted in this rule do not change the substantive criteria of patentability. These changes involve rules of agency practice. *See, e.g.,* 35 U.S.C. 316(a)(5), as amended. *http://www.cruiseamerica.com/rent/our_vehicles/* These rules are procedural

and/or interpretive rules. *See Bachow Commc'ns Inc.* v. *F.C.C.,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive requirements for reviewing claims); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *JEM Broad. Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (rules are not legislative because they do not ''foreclose effective opportunity to make one's case on the merits'').

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). *See Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'') (quoting 5 U.S.C. 553(b)(A)); *U.S.* v. *Gould,* 568 F.3d 459, 476 (4th Cir. 2009) (''The APA also requires publication of any substantive rule at least 30 days before its effective date, 5 U.S.C. 553(d), except where the rule is interpretive . . . .'').

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601–612) is required. *See* 5 U.S.C. 603.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). This rulemaking does not add any additional information requirements or fees for parties before the Board. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the revisions in this rulemaking do not materially change the

information collections approved under OMB control number 0651–0069.

Notwithstanding any other provision of 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 Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 42

Administrative practice and procedure, inventions and patents.

For the reasons set forth in the preamble, 37 CFR part 42 is amended as follows.

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for 37 CFR part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, 321–326 and Public Law 112–29.

Subpart A—Trial Practice and Procedure

■ 2. Section 42.6 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 42.6 Filing of documents, including exhibits; service.

(a) * * *

(2) * * *

(ii) 14-point, Times New Roman proportional font, with normal spacing, must be used;

* * * * *

■ 3. Section 42.10 is amended by revising paragraph (a) to read as follows:

§ 42.10 Counsel.

(a) If a party is represented by counsel, the party must designate a lead counsel and at least one back-up counsel who can conduct business on behalf of the lead counsel.

* * * * *

■ 4. Section 42.15 is amended by revising paragraphs (a)(3), (a)(4), (b)(3), and (b)(4) to read as follows:

§ 42.15 Fees.

(a) * * *

(3) In addition to the *Inter Partes* Review request fee, for requesting review of each claim in excess of 20, including unchallenged claims from which a challenged claim depends: $200.00.

(4) In addition to the *Inter Partes* Post-Institution request fee, for requesting review of each claim in excess of 15, including unchallenged claims from which a challenged claim depends: $400.00.

(b) * * *

(3) In addition to the Post-Grant or Covered Business Method Patent Review request fee, for requesting review of each claim in excess of 20, including unchallenged claims from which a challenged claim depends: $250.00.

(4) In addition to the Post-Grant or Covered Business Method Patent Review Post-Institution request fee, for requesting review of each claim in excess of 15, including unchallenged claims from which a challenged claim depends: $550.00.

* * * * *

■ 5. Section 42.23 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 42.23 Oppositions and replies.

(a) Oppositions and replies must comply with the content requirements for motions and, if the paper to which the opposition or reply is responding contains a statement of material fact, must include a listing of facts that are admitted, denied, or cannot be admitted or denied. * * *

* * * * *

■ 6. Section 42.24 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(v), the first sentence of paragraph (c) introductory text, and paragraphs (c)(1) and (c)(2), and adding paragraphs (a)(1)(vi) and (c)(3) to read as follows:

§ 42.24 Page limits for petitions, motions, oppositions, and replies.

(a) *Petitions and motions.*

(1) The following page limits for petitions and motions apply and include any statement of material facts to be admitted or denied in support of the petition or motion. The page limit does not include a table of contents, a table of authorities, a certificate of service, or appendix of exhibits or claim listing.

* * * * *

(v) Motions (excluding Motions to Amend): 15 pages.

(vi) Motions to Amend: 25 pages.

* * * * *

(c) *Replies.* The following page limits for replies apply and include any statement of facts in support of the reply. * * *

(1) Replies to patent owner responses to petitions: 25 pages.

(2) Replies to oppositions (excluding replies to oppositions to Motions to Amend): 5 pages.

(3) Replies to oppositions to Motions to Amend: 12 pages.

■ 7. Section 42.51 is amended by revising paragraph (b)(1)(ii) to read as follows.

§ 42.51 Discovery.

* * * * *

(b) * * *

(1) * * *

(ii) Cross examination of affidavit testimony prepared for the proceeding is authorized within such time period as the Board may set.

* * * * *

■ 8. Section 42.53 is amended by revising paragraphs (c)(2) and (f)(7) to read as follows:

§ 42.53 Taking testimony.

* * * * *

(c) * * *

(2) Unless stipulated by the parties or ordered by the Board, cross-examination, redirect examination, and re-cross examination for uncompelled direct testimony shall be subject to the follow time limits: Seven hours for cross-examination, four hours for redirect examination, and two hours for re-cross examination.

* * * * *

(f) * * *

(7) Except where the parties agree otherwise, the proponent of the testimony must arrange for providing a copy of the transcript to all other parties. The testimony must be filed as an exhibit.

* * * * *

■ 9. Section 42.64 is amended by revising the section heading and the first two sentences of paragraph (b)(1) to read as follows.

§ 42.64 Objection; motion to exclude.

* * * * *

(b) * * *

(1) *Objection.* Any objection to evidence submitted during a preliminary proceeding must be filed within ten business days of the institution of the trial. Once a trial has been instituted, any objection must be filed within five business days of service of evidence to which the objection is directed. * * *

* * * * *

■ 10. Section 42.71 is amended by revising the first sentence of paragraph (d) to read as follows:

§ 42.71 Decisions on petitions or motions.

* * * * *

(d) *Rehearing.* A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. * * *

* * * * *

Subpart B—Inter Partes Review

■ 11. Section 42.121 is amended by revising paragraph (b) introductory text to read as follows:

§ 42.121 Amendment of the patent.

* * * * *

(b) *Content.* A motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth:

* * * * *

Subpart C—Post-Grant Review

■ 12. Section 42.221 is amended by revising paragraph (b) introductory text to read as follows:

§ 42.221 Amendment of the patent.

* * * * *

(b) *Content.* A motion to amend claims must include a claim listing, which claim listing may be contained in an appendix to the motion, show the changes clearly, and set forth:

* * * * *

Subpart D—Transitional Program for Covered Business Method Patents

■ 13. Section 42.300 is amended by revising paragraph (c) to read as follows:

§ 42.300 Procedure; pendency.

* * * * *

(c) A covered business method patent review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year. The time can be extended by up to six months for good cause by the Chief Administrative Patent Judge, or adjusted by the Board in the case of joinder.

* * * * *

■ 14. Section 42.302 is amended by adding paragraph (c) to read as follows:

§ 42.302 Who may petition for a covered business method patent review.

* * * * *

(c) A petitioner may not file a petition to institute a covered business method patent review of the patent where, before the date on which the petition is filed, the petitioner or real party-in-interest filed a civil action challenging the validity of a claim of the patent.

Dated: May 14, 2015.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2015–12117 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–16–P

Proposed Rules

Federal Register
Vol. 80, No. 96
Tuesday, May 19, 2015

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.

DELAWARE RIVER BASIN COMMISSION

18 CFR Part 410

Proposed Amendments to the Rules of Practice and Procedure To Allow Each Signatory Party and the DRBC To Administer a Single Process for the Review and Adjudication of Projects

AGENCY: Delaware River Basin Commission.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: The Commission will hold a public hearing to receive comments on proposed amendments to its *Administrative Manual Part III—Rules of Practice and Procedure* (18 CFR part 401) to provide for DRBC and each of the parties to the *Delaware River Basin Compact* (United States Public Law 87–328, Approved September 27, 1961, 75 Statutes at Large 688; 53 Delaware Laws, Chapter 71, Approved May 26, 1961; New Jersey Laws of 1961, Chapter 13, Approved May 1, 1961; New York Laws of 1961, Chapter 148, Approved March 17, 1961; and Pennsylvania Acts of 1961, Act No. 268, Approved July 7, 1961 (''the Compact'')—Delaware, New Jersey, New York, Pennsylvania and the federal government (''Signatory Parties'')—to coordinate and collaborate in the administration of a single process for the review and adjudication of projects. The program, called ''One Process/One Permit,'' (also herein, ''the Program'') will allow DRBC and administrative agencies of the Signatory Parties participating in the Program to incorporate the requirements and determinations of both DRBC and the Signatory Party agency into a single permit or other approval instrument.

DATES: The public hearing will start on or around 2 p.m. on Tuesday, June 9, 2015, during the Commission's regularly scheduled public hearing. The hearing will continue until all those wishing to testify have had an opportunity to do so. Depending upon the number of people wishing to speak, the hearing officer may impose time limits on speakers. Written comments will be accepted by any of the means described below and must be received by 5:00 p.m. on Wednesday, July 1, 2015. More information regarding the procedures for the hearing and comments is set forth in the section ''Oral Testimony and Written Comments.''

ADDRESSES: The public hearing will be held at the Washington Crossing Historic Park Visitor's Center at 1112 River Road in Washington Crossing, Pennsylvania. Please check *washingtoncrossingpark.org/contact/* for directions, as Internet mapping services provide unreliable directions to this location.

Oral Testimony and Written Comments: Persons wishing to testify at the hearing are asked to register in advance by contacting Paula Schmitt at 609–883–9500, ext. 224 or *paula.schmitt@drbc.state.nj.us.* Written comments may be submitted as follows: If by email (preferred), to *paula.schmitt@drbc.state.nj.us;* by fax, to Commission Secretary at 609–883–9522; by U.S. Mail, to Commission Secretary, DRBC, P.O. Box 7360, West Trenton, NJ 08628–0360; or by overnight mail, to Commission Secretary, DRBC, 25 State Police Drive, West Trenton, NJ 08628–0360. Comments also may be delivered by hand at any time during DRBC's regular office hours (Monday through Friday, 8:30 a.m. through 5:00 p.m. except on national holidays) until the close of the comment period. In all cases, please include the commenter's name, address and affiliation, if any, in the comment document and ''One Process/One Permit'' or ''OPOP'' in the subject line.

FOR FURTHER INFORMATION CONTACT: The rule text is available on the DRBC Web site, DRBC.net. Also posted to the Web site are an extensive FAQ document; DRBC Resolution No. 2015–4, authorizing the Executive Director to initiate rulemaking and enter into an administrative agreement with the New Jersey Department of Environmental Protection (NJDEP) for demonstration of the Program; and the administrative agreement between DRBC and the NJDEP to provide for the demonstration program, which includes provisions for fully implementing One Process/One Permit once a final rule has been adopted. Detailed procedures of the DRBC for public hearings, public meetings and ''Public Dialogue'' are available on the web at: *http://www.state.nj.us/drbc/library/documents/procedures120414.pdf.* For further information, please contact Commission Secretary Pamela M. Bush, 609–477–7203.

SUPPLEMENTARY INFORMATION:

Background

Because DRBC and its Signatory Parties share common water resource management objectives, sponsors of many water resource-related projects in the Delaware River Basin are currently required to apply to both the DRBC and a state agency, among others, for approvals. The proposed rule provides for DRBC and the administrative agencies of the Signatory Parties to identify regulatory programs that by mutual agreement will be managed through a single process resulting in one decision or approval. Agreements between DRBC and federal agencies are possible under the rule, but none are currently contemplated.

One Process/One Permit is intended to promote interagency cooperation and collaboration on shared mission objectives, achieve regulatory program efficiencies, avoid unnecessary duplication of effort, and reduce the potential for confusion on the part of regulated entities and the public. The regulatory standards and authorities of the DRBC and each of its Signatory Parties are expressly preserved by the Program, including in the proposed rule. The more protective of the applicable DRBC or Signatory Party agency's requirements will be included in each permit or approval issued under the Program.

The proposed rule provides for DRBC and each Signatory Party agency choosing to implement One Process/One Permit to enter into an administrative agreement that identifies the types of projects and approvals to be covered. Initially, the Program is expected to be implemented for (a) withdrawals of basin waters subject to both DRBC review and state allocation programs; and (b) wastewater discharges subject to DRBC review and the state-administered National Pollutant Discharge Elimination System (NPDES) program. For water withdrawals, the lead agency under One Process/One Permit may be the state or the DRBC, depending upon current state programs.

The delegated state environmental agencies will be lead agencies for the review of wastewater discharges. Other regulatory programs, such as programs relating to floodplain management, could be included in the future. All administrative agreements between DRBC and agencies of the Signatory Parties for implementing One Process/One Permit will be subject to Commission approval following a public hearing.

Authority

Sections 1.5 and 3.9 of the Compact and existing DRBC rules allow and encourage the Commission to use the agencies of the Signatory Parties wherever feasible and advantageous consistent with the Compact. Accordingly, under the proposed rule, permits issued by Signatory Party agencies may include a finding required by Section 3.8 of the Compact. Specifically, after the rule and amended agreements are in place, based on the appropriate level of review and a recommendation by the DRBC staff, approvals issued under the Program may include the finding that when operated in accordance with the terms and conditions of the approval, the activities regulated by the approval will not substantially impair or conflict with DRBC's comprehensive plan.

Operation of the Program

Under the proposed rule, an application for initial approval, renewal or revision of project activities subject to the One Process/One Permit program will be filed only with the lead agency. This does not mean that the DRBC or others will not be involved in the review of applications for new and renewal water withdrawal and discharge projects. Rather, DRBC and the Signatory Party agency will follow a single process, and reviews will be performed more efficiently and more collaboratively.

Consistent with the proposed rule, the agreements between DRBC and Signatory Party agencies will provide for a level of DRBC review appropriate to the circumstances. Some reviews, such as those for simple and standard renewals of existing permits, may be significantly streamlined or subject to inter-agency notifications only. Others, including to implement standards for which the DRBC staff have special expertise, will involve substantial DRBC staff effort. For example, under the wastewater discharge program, DRBC staff will continue to perform modeling to determine ''No Measurable Change'' requirements for the Commission's Special Protection Waters program and to calculate an alternative mixing zone for a discharge of treated industrial wastewater to the Delaware Estuary. For certain projects, DRBC staff also will continue to identify conditions of approval to ensure that projects subject to review under the Compact and implementing regulations do not impair or conflict with the Commission's comprehensive plan. The purpose of One Process/One Permit is to eliminate unnecessary effort, not to eliminate effort needed to fully review a project under all applicable standards and rules. Under the Program, each party continues to recognize the authority of the other to promulgate rules, regulations and standards. The rule does not change that authority.

Notably, a separate DRBC review and decision for water withdrawal and discharge activities will still be required in certain cases, such as when a new project must be incorporated into the Commission's comprehensive plan. Both parties also will retain the right to act separately, such as in the instances, anticipated to be rare, where the parties cannot agree on the terms and conditions of approval. Certain categories of projects that are subject to DRBC review will not be covered by the Program, and the Executive Director and Commissioners will have the ability to remove a project from the Program. However, the objective of One Process/One Permit is to encompass most, if not all, elements of the review and approval for covered projects.

The proposed rule does not modify the existing project review fee schedule of the DRBC or that of any Signatory Party agency. Although One Process/One Permit is expected to improve process efficiency, in many instances as described above, the DRBC will devote significant resources and work effort to review projects and support its regulatory programs. Accordingly, the DRBC regulatory program will continue for the present to be supported by its existing regulatory program fees. The Commission's fee schedule set forth in Resolution No. 2009–2 will remain in effect unless and until the Commission amends it through rulemaking or a comparable public process. Under One Process/One Permit, all DRBC fees applicable under current practices will continue to be paid directly to the Commission.

The proposed rule provides that persons aggrieved by the final action of a state agency on behalf of the Commission under One Process/One Permit must exhaust their administrative remedies under the law of the Signatory Party agency that issued the decision.

New Jersey Demonstration Program

By Resolution No. 2015–4 approved by the Commission on March 11, 2015, DRBC and NJDEP have agreed to ''practice'' using new collaborative processes between the two agencies for the review of wastewater discharge applications, pending the adoption of a new rule such as the one proposed today. The agreement between DRBC and NJDEP provides for the demonstration program and sets forth provisions needed to fully implement One Process/One Permit once a final rule has been adopted. In the event that a project reviewed under the New Jersey Demonstration Program reaches the stage where it is ready for final approval before DRBC has adopted a final rule, the application will be acted upon by DRBC and the NJDEP independently. As explained above, additional information about the New Jersey Demonstration Program is available on the Commission's Web site.

Preservation of the 1954 Supreme Court Decree

In accordance with Sections 3.3(a) and 3.5 of the Compact, the proposed rule expressly provides that it does not grant authority to any Signatory Party agency to impair, diminish or otherwise adversely affect the diversions, compensating releases, rights, conditions, obligations and provisions for administration thereof provided in the United States Supreme Court decree in *New Jersey* v. *New York,* 347 U.S. 995 (1954) (''Decree''). The rule further reiterates that any such action may be taken only by the Commission with the unanimous consent of the parties to the Decree or upon unanimous consent of the members of the Commission following a declaration of a state of emergency in accordance with Section 3.3(a) of the Compact.

No Effect on Section 401 State Water Quality Certification Programs

The proposed rule also does not affect the authority of Signatory Party states to issue water quality certifications under Section 401 of the Clean Water Act.

Dated: May 13, 2015.

Pamela M. Bush,

Commission Secretary.

[FR Doc. 2015–12076 Filed 5–18–15; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–0219]

RIN 1625–AA08

Special Local Regulations: 86th Major League Baseball (MLB) All-Star Week/Game, Ohio River Mile 469.5 to 471.2; Cincinnati, OH

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation for all waters of the Ohio River, surface to bottom, extending from Ohio River mile 469.5 to 471.2 at Cincinnati, OH July 10, 2015 through July 14, 2015. This special local regulation is necessary to protect persons and property from potential damage and safety hazards during the ''86th Major League Baseball (MLB) All-Star Week/Game'', an event which will likely involve a high density of boater traffic in the river miles specified. This proposed special local regulation is intended to temporarily restrict vessel traffic in a portion of the Ohio River during this event and implement a moving security zone for certain vessel traffic within the special local regulated zone.

DATES: Comments and related material must be received by the Coast Guard on or before June 1, 2015.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer James Robinson, Sector Ohio Valley, U.S. Coast Guard; telephone (502) 779–5432, email *James.C.Robinson@uscg.mil* or Petty Officer Caloeb Gandy, Sector Ohio Valley, U.S. Coast Guard; telephone (502) 779–5346, email *Caloeb.L.Gandy@uscg.mil* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number [USCG–2015–0219] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2015–0219) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

The Captain of the Port (COTP) Ohio Valley is proposing to establish a special local regulation for all waters of the Ohio River, surface to bottom, extending from Ohio River mile 469.5 to 471.2 at Cincinnati, OH July 10, 2015 through July 14, 2015. This special local regulation is necessary to protect persons and property from potential damage and safety hazards during the ''86th MLB All-Star Week/Game'', which may involve high density of boater traffic in the river miles specified. This proposed special local regulation is intended to temporarily restrict vessel traffic in a portion of the Ohio River during this event and implement a moving security zone for certain vessel traffic within the special local regulated zone. There is no

regulatory history related to this proposed special local regulation or the event triggering a need for the proposed special local regulation.

C. Basis and Purpose

The Coast Guard's authority for establishing a special local regulation for marine events is contained at 33 U.S.C. 1233.

Major League Baseball is holding the ''86th All-Star Week/Game'' July 10, 2015 through July 14, 2015. This event is planned to take place at the Great American Ballpark in the vicinity of the waters of the Ohio River, at Cincinnati, OH. Based on the need for additional safety measures to protect persons and property during this event on the waterway, the Coast Guard proposes to establish a special local regulation on specified waters of the Ohio River. The proposed special local regulation would be in effect from July 10, 2015 through July 14, 2015 and would encompass all waters of the Ohio River, mile 469.5–471.2.

D. Discussion of Proposed Rule

The Captain of the Port (COTP) Ohio Valley is proposing to establish a special local regulation for all waters of the Ohio River, surface to bottom, extending from Ohio River mile 469.5 to 471.2 at Cincinnati, OH July 10, 2015 through July 14, 2015. This special local regulation is necessary to protect persons and property from potential damage and safety hazards during the ''86th MLB All-Star Week/Game'', an event which will likely involve a high density of boater traffic in the river miles specified. This proposed special local regulation is intended to temporarily restrict vessel traffic in a portion of the Ohio River and implement a moving security zone for certain vessel traffic within the special local regulated zone during this event in order to promote the safety of life and property on the navigable waterway. There is no regulatory history related to this proposed special local regulation or the event triggering a need for the proposed special local regulation.

The effect of this proposed rule will be to restrict general navigation during the event. Vessels intending to transit the Ohio River through the designated mile markers will only be allowed to transit the area when the COTP Ohio Valley, or a designated representative, has deemed it safe to do so or at the completion of the event each day.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This proposed special local regulation restricts transit on the Ohio River from mile 469.5 to 471.2, for a short duration of four days; Broadcast Notices to Mariners and Local Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for this short restriction on transit. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted area.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit mile marker 469.5 to 471.2 on the Ohio River, from July 10, 2015 through July 14, 2015. The special local regulation will not have a significant economic impact on a substantial number of small entities for the following reasons. This special local regulation will be in effect for a limited duration for a period of four days. Although, the regulation would apply to the entire width of the river, traffic would be allowed to pass through the regulated area with the permission of the COTP Ohio Valley or a designated representative or at the completion of the event each day. Broadcast Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for temporary restrictions on transit.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

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 proposed 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**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

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 proposed rule under that Order and determined that this rule does not have implications for federalism.

6. 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.

7. 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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.

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 proposed rule involves a special local regulation involving a high media event and the potential for high boating traffic. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the U.S. Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERWAYS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Section 100.35T08–0219 is added to read as follows:

§ 100.35T08–0219 Special Local Regulation; Ohio River, Miles 469.5 to 471.2, Cincinnati, OH.

(a) *Location.* The following area is a special local regulation: All waters of the Ohio River, beginning at mile marker 469.5 to mile 471.2 at Cincinnati, OH.

(b) *Enforcement date.* This section is enforceable from: July 10, 2015 through July 14, 2015.

Dated: April 22, 2015.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2015–12122 Filed 5–18–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2009–0174; FRL–9927–80–OAR]

RIN 2060–AP63

Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that the period for providing public comments on the March 20, 2015, proposed ''Electronic Reporting and Recordkeeping Requirements for New Source Performance Standards'' is being extended by 30 days.

DATES: *Comments.* The public comment period for the proposed rule published March 20, 2015 (80 FR 15100), is being extended by 30 days to June 18, 2015, in order to provide the public additional time to submit comments and supporting information.

ADDRESSES: *Comments.* Written comments on the proposed rule may be submitted to the EPA electronically, by mail, by facsimile or through hand delivery/courier. Please refer to the proposal (80 FR 15100) for the addresses and detailed instructions.

Docket. Publicly available documents relevant to this action are available for public inspection either electronically at *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying. The EPA has established the official public docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2009–0174.

World Wide Web. The EPA Web site containing information for this rulemaking is at *http://www.epa.gov/ttn/atw/eparules.html.*

FOR FURTHER INFORMATION CONTACT: Ms. Gerri Garwood, Measurement Policy Group (MPG), Sector Policies and Programs Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–

2406; fax number: (919) 541–1039; and email address: *garwood.gerri@epa.gov.*

SUPPLEMENTARY INFORMATION:

Comment Period

After considering a request submitted by the Air Permitting Forum to extend the public comment period, the EPA has decided to extend the public comment period for an additional 30 days. Therefore, the public comment period will end on June 18, 2015, rather than May 19, 2015. This extension will ensure that the public has sufficient time to review and comment on all of the information available, including the proposed rule and other materials in the docket.

Dated: May 8, 2015.

Stephen D. Page,

Director.

[FR Doc. 2015–12100 Filed 5–18–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 130722646–5430–02]

RIN 0648–BD54

International Fisheries; Pacific Tuna Fisheries; Establishment of Tuna Vessel Monitoring System in the Eastern Pacific Ocean

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

ACTION: Supplemental proposed rule; request for comments.

SUMMARY: NMFS revises a proposed rule published on February 6, 2014, to implement Inter-American Tropical Tuna Commission (IATTC) Resolution C–04–06. Under the original proposed rule Vessel Monitoring Systems (VMS) would be required for any U.S. commercial fishing vessels that are 24 meters (78.74 feet) or more in overall length and used to target tuna in the eastern Pacific Ocean. After publication of the proposed rule on February 6, 2014, the IATTC adopted Resolution C–14–02, which expands the applicability of the VMS requirements to vessels engaged in fishing activities for either tuna or tuna-like species; this action would implement that expanded application. This action would also revise the original proposed rule by allowing additional conditions to authorize a vessel owner or operator to shut down a VMS unit, and in a few non-substantive ways as described below. This rule is intended to ensure full U.S. compliance with its international obligations under the IATTC Convention.

DATES: Written comments on this supplemental proposed rule must be received on or before June 18, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2013–0117, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0117,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Rachael Wadsworth, NMFS West Coast Region, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2013–0117'' in the comments.
- *Public Hearing:* The public is welcome to attend a public hearing and offer comments on this supplemental proposed rule from 1 p.m. to 4 p.m. PST, June 9, 2015, at 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802. The public may also participate in the public hearing via conference line: 888–790–6181; participant passcode: 64120.

Instructions: Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the draft Regulatory Impact Review (RIR) and other supporting documents prepared for the original proposed rule are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2013–0117 or by contacting the Regional Administrator, William W. Stelle, Jr., NMFS West Coast Region, 7600 Sand Point Way NE., Bldg 1, Seattle, WA 98115–0070 or by email to *RegionalAdministrator.WCRHMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Rachael Wadsworth, NMFS West Coast Region, 562–980–4036.

SUPPLEMENTARY INFORMATION: NMFS published a proposed rule in the **Federal Register** (79 FR 7152) on February 6, 2014, to broaden the existing Vessel Monitoring System (VMS) requirements in the Pacific Ocean and to clarify the applicability of VMS requirements to U.S. commercial fishing vessels, 24 meters (78.74 feet) or more in overall length, used to target tuna (*i.e.,* any fish of the genus *Thunnus* or of the species *Euthynnus* (*Katsuwonus*) *pelamis* (skipjack tuna)) in the waters of the Convention Area. The Convention Area is bounded by the west coast of the Americas and on the north, south, and west respectively, by the 50° N. and 50° S. parallels, and the 150° W. meridian. The original proposed rule was intended to ensure full U.S. implementation of Resolution C–04–06, adopted by the Inter-American Tropical Tuna Commission (IATTC) at its 72nd Meeting in June 2004.

After publication of the original proposed rule, the IATTC adopted Resolution C–14–02 at its 87th Meeting in July 2014, which amends and replaces Resolution C–04–06. This supplemental proposed rule revises the applicability of the VMS requirements to reflect Resolution C–14–02 and updates other sections of the regulatory text that was published in the original proposed rule. The regulatory text of the original proposed rule is republished in this supplemental proposed rule with the changes described above and in more detail below.

Background and Need for Action

A detailed description of the original proposed rule was published in the preamble to that rule, which is available online (*https://federalregister.gov/a/2014-02598*) and from NMFS (see **ADDRESSES**). The VMS requirements from the original proposed rule are briefly summarized here.

Commercial fishing vessels that are 24 meters or more in overall length are required to install, activate, carry and operate VMS units (also known as ''mobile transmitting units''). The VMS units and mobile communications service providers must be type-approved by NOAA for fisheries in the IATTC Convention Area. Information for current NOAA type-approved VMS units can be obtained from: NOAA,

Office of Law Enforcement (OLE), 1315 East-West Hwy, Suite 3301, Silver Spring, MD 20910–3282; telephone at (888) 210–9288; fax at (301) 427–0049. Or, by contacting NOAA OLE VMS Helpdesk: telephone: (888) 219–9228; email: *ole.helpdesk@noaa.gov;* or online by going to *http://www.nmfs.noaa.gov/ole/about/our_programs/vessel_monitoring.html,* and click ''approved VMS units.'' The business hours of the VMS Helpdesk are: Monday through Friday, except Federal holidays, 7 a.m. to 11 p.m., Eastern Time.

Compliance with the existing VMS requirements at 50 CFR 300.219, 50 CFR 660.712, 50 CFR 660.14, or 50 CFR 665.19 would satisfy these new requirements relating to the installation, carrying, and operation of VMS units, provided that the VMS unit and mobile communications service provider are type-approved by NOAA for fisheries in the Convention Area, and the VMS unit is operated continuously at all times while the vessel is at sea unless the Special-Agent-In-Charge, NOAA Office of Law Enforcement, Pacific Islands Division (or designee) (SAC) authorizes a VMS unit to be shut down and the same requirements proposed for the case of VMS unit failure are followed.

This supplemental proposed rule would revise the proposed rule in the following ways: (1) Expand the applicability of the VMS requirements to include fishing activities for tuna-like species in the Convention Area; (2) additional conditions to allow the SAC to authorize a vessel owner or operator to shut down a VMS unit; (3) update the address for the SAC; (4) update the definition of ''Convention Area;'' (5) revise the description of the purpose and scope of part 300, subpart C, section 300.20 of Title 50 of the Code of Federal Regulations (CFR); and (6) make minor revisions to the regulatory text for punctuation and clarify circumstances when a vessel owner *or* operator is responsible for an action. These changes are described in greater detail below.

First, IATTC Resolution C–14–02 expanded the scope of the initial IATTC Resolution. The original proposed rule would have applied only to commercial fishing vessels that are 24 meters or more in overall length and used to target tuna in the Convention Area. This supplemental proposed rule would apply to commercial fishing vessels engaging in fishing activities for tuna *or* tuna-like species, including those managed under the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species, in conformance with Resolution C–14–02. Therefore, this supplemental proposed rule would apply to any commercial fishing vessel of the United States that is 24 meters or more in overall length and engaging in fishing activities for tuna or tuna-like species in the Convention Area, and for which any of the following permits is required: Pacific highly migratory species permit under 50 CFR 660.707, or high seas fishing permit under 50 CFR 300.13.

Second, the supplemental proposed rule would allow additional conditions for the SAC to authorize a vessel owner or operator to shut down a VMS unit. Vessel owners or operators must submit requests to shut down their VMS unit to the SAC. See the regulatory text for more details on the specific conditions and procedures for obtaining SAC authorization for shutting down VMS units.

Third, the supplemental proposed rule would update the address for the SAC of the Pacific Islands Division, reflecting an address change that occurred after the publication of the original proposed rule.

Fourth, this supplemental proposed rule would also update the regulatory definition of the Convention Area, which is currently defined as the waters within the area bounded by the mainland of the Americas, lines extending westward from the mainland of the Americas along the 40° N. latitude and 40° S. latitude, and 150° W. longitude. The current regulatory definition would be updated to be consistent with the definition described in the preamble of the original proposed rule, and the Convention for the Strengthening of the Inter-American Tropical Tuna Commission (Antigua Convention). The Antigua Convention entered into force in 2010 and all IATTC resolutions adopted subsequent to 2010, such as Resolution C–14–02, are premised on the definition of ''Convention Area'' in the Antigua Convention. Accordingly, this supplemental proposed rule would define the Convention Area as all waters of the eastern Pacific Ocean within the area bounded by the west coast of the Americas and by the following lines: The 50° N. parallel from the coast of North America to its intersection with the 150° W. meridian; the 150° W. meridian to its intersection with the 50° S. parallel; and the 50° S. parallel to its intersection with the coast of South America.

If the proposed update to the regulatory definition of the Convention Area becomes effective, there would be no additional impacts to vessels. Although NMFS relied on the current definition (40° N. latitude and 40° S. latitude, and 150° W. longitude) of the Convention Area to modify the procedures and requirements for the Regional Vessel Register for the IATTC (74 FR 1607, January 13, 2009), NMFS uses permits rather than fishing area as a basis for providing the IATTC a list of U.S. vessels to be placed on the Regional Vessel Register. Specifically, NMFS considers vessels that are authorized to fish for highly migratory species in the Convention Area under the following fishing permits: Pacific highly migratory species permit under 50 CFR 660.707, and high seas fishing permit under 50 CFR 300.13. Therefore, the proposed update to the regulatory definition of the Convention Area would not affect the current process NMFS uses to provide the IATTC a list of U.S. vessels to place on the Regional Vessel Register.

Lastly, the supplemental proposed rule would update the purpose and scope of Title 50, part 300, subpart C, section 300.20 of the CFR for consistency with the updated definition for the Convention Area.

Classification

The NMFS Assistant Administrator has determined that this supplemental proposed rule is consistent with the Tuna Conventions Act of 1950 and other applicable laws, subject to further consideration after public comment.

National Environmental Policy Act

This action is categorically excluded from the requirement to prepare an environmental assessment in accordance with NAO 216–6. A memorandum for the file has been prepared that sets forth the decision to use a categorical exclusion.

Executive Order 12866

This supplemental proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

An Initial Regulatory Flexibility Analysis (IRFA) was prepared for the original proposed rule (79 FR 7152), published on February 6, 2014, as required by section 604 of the Regulatory Flexibility Act (RFA) and is not repeated here. As described above, this supplemental proposed rule would not result in different impacts than those described in the IRFA for the original proposed rule.

As discussed in the preamble, this supplemental proposed rule would expand the applicability of the VMS requirements to commercial fishing vessels that are 24 meters or more in overall length and engaging in fishing activities for tuna or tuna-like species in the Convention Area. To estimate the

number of affected entities for the original proposed rule, the number of vessels authorized to fish for highly migratory species in the Convention Area through fishing permits was considered a reasonable proxy. The permits used to estimate affected entities were those issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) through regulations codified at 50 CFR 660.707 or under the authority of the High Seas Fishing Compliance Act of 1995 (16 U.S.C. 5501 *et seq.*) through regulations codified at 50 CFR 300.13. NMFS also considers these fishing permits a reasonable proxy for estimating the number of vessels used to fish for tuna or tuna-like species in the Convention Area. Copies of the IRFA, prepared for the original proposed rule, are available from NMFS (see **ADDRESSES**).

Paperwork Reduction Act Collections of Information

This supplemental proposed rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and approved by OMB under control number (0648–0690) for the original proposed rule (79 FR 7152), published on February 6, 2014. This supplemental proposed rule does not result in changes to the burden hour estimates prepared for the original proposed rule. Public comment regarding the burden-hour estimates or other aspects of the collection-of-information requirements was requested in the original proposed rule.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: May 11, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart C—Eastern Pacific Tuna Fisheries

■ 1. The authority citation for 50 CFR part 300, subpart C continues to read as follows:

Authority: 16 U.S.C. 951–961 *et seq.*

■ 2. Section 300.20 is revised to read as follows:

§ 300.20 Purpose and scope.

The regulations in this subpart are issued under the authority of the Tuna Conventions Act of 1950 (Act) and apply to persons and vessels subject to the jurisdiction of the United States. The regulations implement resolutions of the Inter-American Tropical Tuna Commission (IATTC) for the conservation and management of stocks of highly migratory fish resources in the Convention Area.

■ 3. In § 300.21, the definition for ''Convention Area'' is revised and the definitions for ''Commercial'', ''Vessel monitoring system (VMS)'', and ''VMS unit'' are added, in alphabetical order, to read as follows:

§ 300.21 Definitions.

* * * * *

Commercial with respect to commercial fishing, means fishing in which the fish harvested, either in whole or in part, are intended to enter commerce through sale, barter or trade.

* * * * *

Convention Area or IATTC Convention Area, means all waters of the eastern Pacific Ocean within the area bounded by the west coast of the Americas and by the following lines: The 50° N. parallel from the coast of North America to its intersection with the 150° W. meridian; the 150° W. meridian to its intersection with the 50° S. parallel; and the 50° S. parallel to its intersection with the coast of South America.

* * * * *

Vessel monitoring system (VMS) means an automated, remote system that provides information about a vessel's identity, location and activity, for the purposes of routine monitoring, control, surveillance and enforcement of area and time restrictions and other fishery management measures.

VMS unit, sometimes known as a ''mobile transmitting unit,'' means a transceiver or communications device, including all hardware and software that is carried and operated on a vessel as part of a VMS.

■ 4. In § 300.24, paragraphs (y) through (bb) are added to read as follows:

§ 300.24 Prohibitions.

* * * * *

(y) Fail to install, activate, or operate a VMS unit as required in § 300.26(c).

(z) In the event of VMS unit failure or interruption; fail to repair or replace a VMS unit; fail to notify the Special-Agent-In-Charge, NOAA Office of Law Enforcement, Pacific Islands Division (or designee); and follow the instructions provided; or otherwise fail to act as provided in § 300.26(c)(4).

(aa) Disable, destroy, damage or operate improperly a VMS unit installed under § 300.26, or attempt to do any of the same, or fail to ensure that its operation is not impeded or interfered with, as provided in § 300.26(e).

(bb) Fail to make a VMS unit installed under § 300.26 or the position data obtained from it available for inspection, as provided in § 300.26(f) and (g).

■ 5. Section 300.26 is added to read as follows:

§ 300.26 Vessel monitoring system (VMS).

(a) *Special-Agent-In-Charge (SAC), NOAA Office of Law Enforcement, Pacific Islands Division (or designee) and VMS Helpdesk contact information and business hours:*

(1) The contact information for the SAC for the purpose of this section: 1845 Wasp Blvd., Building 176, Honolulu, HI 96818; telephone: (808) 725–6100; facsimile: 808–725–6199; email: *pidvms@noaa.gov;* business hours: Monday through Friday, except Federal holidays, 8 a.m. to 4:30 p.m., Hawaii Standard Time.

(2) The contact information for the NOAA Office of Law Enforcement's VMS Helpdesk is telephone: (888) 219–9228; email: *ole.helpdesk@noaa.gov.* The business hours of the VMS Helpdesk are Monday through Friday, except Federal holidays, 7 a.m. to 11 p.m., Eastern Time.

(b) *Applicability.* This section applies to any U.S. commercial fishing vessel that is 24 meters or more in overall length and engaging in fishing activities for tuna or tuna-like species in the Convention Area, and for which either of the following permits is required: Pacific highly migratory species permit under § 660.707, or high seas fishing permit under § 300.13 of this part.

(c) *Provisions for Installation, Activation and Operation*—(1) *VMS Unit Installation.* The vessel owner or operator must obtain and have installed on the fishing vessel, in accordance with instructions provided by the SAC and the VMS unit manufacturer, a VMS unit that is type-approved by NOAA for fisheries in the IATTC Convention Area. The vessel owner or operator shall arrange for a NOAA-approved mobile communications service provider to receive and relay transmissions from the VMS unit to NOAA. The vessel owner or operator shall authorize NOAA OLE, the U.S. Coast Guard (USCG) and other authorized entities to receive and relay position reports. The owner or operator must authorize NOAA to set up the reporting interval of the VMS unit as once per hour. The NOAA OLE VMS Helpdesk is available to provide

instructions for VMS installation and a list of the current type-approved VMS units and mobile communication service providers.

(2) *VMS Unit Activation.* If the VMS unit has not yet been activated as described in this paragraph, or if the VMS unit has been newly installed or reinstalled, or if the mobile communications service provider has changed since the previous activation, or if directed by the SAC, the vessel owner or operator must, prior to leaving port:

(i) Turn on the VMS unit to make it operational;

(ii) Submit a written activation report to the SAC, via mail, facsimile or email, that includes the vessel's name; the vessel's official number; the VMS unit manufacturer and identification number; and telephone, facsimile or email contact information for the vessel owner or operator; and

(iii) Receive verbal or written confirmation from the SAC that the proper VMS unit transmissions are being received from the VMS unit.

(3) *VMS Unit Operation.* The vessel owner and operator shall continuously operate the VMS unit at all times, except that the VMS unit may be shut down while the vessel is in port or otherwise not at sea, or if, after the end of the fishing season, the vessel will no longer be engaging in fishing activities in the Convention Area for which either a Pacific highly migratory species permit or a high seas fishing permit is required, provided that the owner or operator:

(i) Prior to shutting down the VMS unit, reports to the SAC or the NOAA Office of Law Enforcement's VMS Helpdesk via facsimile, email, or web-form the following information: The intent to shut down the VMS unit; the vessel's name; the vessel's official number; an estimate for when the vessel's VMS may be turned back on; and telephone, facsimile or email contact information for the vessel owner or operator. In addition, the vessel owner or operator shall receive verbal or written confirmation from the SAC before shutting down the VMS unit after the end of the fishing season; and

(ii) When turning the VMS unit back on, report to the SAC or the NOAA Office of Law Enforcement's VMS Helpdesk, via mail, facsimile or email, the following information: That the VMS unit has been turned on; the vessel's name; the vessel's official number; and telephone, facsimile or email contact information for the vessel owner or operator; and

(iii) Prior to leaving port, receive verbal or written confirmation from the SAC that proper transmissions are being received from the VMS unit.

(4) *Failure of VMS unit.* If the VMS unit has become inoperable or transmission of automatic position reports from the VMS unit has been interrupted, or if notified by NOAA or the USCG that automatic position reports are not being received from the VMS unit or that an inspection of the VMS unit has revealed a problem with the performance of the VMS unit, the vessel owner or operator shall comply with the following requirements:

(i) If the vessel is at port: The vessel owner or operator shall repair or replace the VMS unit and ensure it is operable before the vessel leaves port.

(ii) If the vessel is at sea: The vessel owner, operator, or designee shall contact the SAC by telephone, facsimile, or email at the earliest opportunity during the SAC's business hours and identify the caller and vessel. The vessel operator shall follow the instructions provided by the SAC which could include, but are not limited to, ceasing fishing, stowing fishing gear, returning to port, and/or submitting periodic position reports at specified intervals by other means; and repair or replace the VMS unit and ensure it is operable before starting the next trip.

(5) *Related VMS Requirements.* Installing, carrying and operating a VMS unit in compliance with the requirements in 50 CFR 300.219, 50 CFR 660.712, 50 CFR 660.14, or 50 CFR 665.19 relating to the installation, carrying, and operation of VMS units shall be deemed to satisfy the requirements of paragraph (c) of this section, provided that the VMS unit is operated continuously and at all times while the vessel is at sea, unless the SAC authorizes a VMS unit to be shut down as described in paragraph (c)(3), the VMS unit and mobile communications service providers are type-approved by NOAA for fisheries in IATTC Convention Area, the owner or operator has authorized NOAA to receive and relay transmissions from the VMS unit, and the specific requirements of paragraph (c)(4) of this section are followed. If the VMS unit is owned by NOAA, the requirement under paragraph (c)(4) of this section to repair or replace the VMS unit will be the responsibility of NOAA, but the vessel owner and operator shall be responsible for ensuring that the VMS unit is operable before leaving port or starting the next trip.

(d) *Costs.* The vessel owner and operator shall be responsible for all costs associated with the purchase, installation and maintenance of the VMS unit and for all charges levied by the mobile communications service provider as necessary to ensure the transmission of automatic position reports to NOAA as required in paragraph (c) of this section. However, if NOAA is paying for the VMS-associated costs because the VMS unit is carried and operated under a requirement of 50 CFR 300.219, 50 CFR 660.712, or 50 CFR 665.19, the vessel owner and operator shall not be responsible to pay the costs.

(e) *Tampering.* The vessel owner and operator must ensure that the VMS unit is not tampered with, disabled, destroyed, damaged or maintained improperly, and that its operation is not impeded or interfered with.

(f) *Inspection.* The vessel owner and operator must make the VMS unit, including its antenna, connectors and antenna cable, available for inspection by authorized officers.

(g) *Access to data.* The vessel owner and operator must make the vessel's position data obtained from the VMS unit or other means immediately and always available for inspection by NOAA personnel, USCG personnel, and authorized officers.

[FR Doc. 2015–11991 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 150401329–5437–01]

RIN 0648–BF00

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Framework Adjustment 9

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

ACTION: Proposed rule, request for comments.

SUMMARY: Framework Adjustment 9 proposes management measures to further enhance catch monitoring and address discarding catch before it has been sampled by observers (known as slippage), in the Atlantic mackerel fishery. Framework 9 would implement slippage consequence measures, and a requirement that slippage events be reported via the vessel monitoring system. For allowable slippage events, due to safety, mechanical failure, or excess catch of spiny dogfish, vessels

must move 15 nm from the location of the slippage event. For non-allowable slippage events, due to reasons other than those listed previously, vessels must terminate their fishing trip. Slippage events have the potential to substantially affect analysis or extrapolations of incidental catch, including river herring and shad, these proposed measures are designed to address this issue.

DATES: Public comments must be received by June 18, 2015.

ADDRESSES: Copies of supporting documents used by the Mid-Atlantic Fishery Management Council, including the Environmental Assessment (EA) and Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA), are available from: Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901, telephone (302) 674–2331. The EA/RIR/IRFA is also accessible via the Internet at *http://www.greateratlantic.fisheries.noaa.gov.*

You may submit comments, identified by NOAA–NMFS–2015–0049, by any one of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0049,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Framework 9.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Carly Bari, Fishery Policy Analyst, (978) 281–9224, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

NMFS implemented measures to improve catch monitoring of the mackerel, squid, and butterfish fisheries through Amendment 14 to the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan (FMP) (79 FR 10029, February 24, 2014). The focus of Amendment 14 was to improve evaluation of the incidental catch of river herring (alewife and blueback herring) and shad (American shad and hickory shad), and to address incidental catch of river herring and shad. NMFS disapproved three measures that were initially included in Amendment 14 including: A dealer reporting requirement; a cap that, if achieved, would require vessels discarding catch before it had been sampled by observers (known as slippage) to return to port; and a recommendation of 100-percent observer coverage on midwater trawl vessels and 100-, 50-, and 25-percent observer coverage on bottom trawl mackerel vessels, with the industry contributing $325 per day toward observer costs.

Currently, slippage events are prohibited for vessels issued a limited access mackerel permit or a longfin squid/butterfish moratorium permit and carrying a NMFS-approved observer except in circumstances which allow slippage events including: Safety; mechanical failure; and excess catch of spiny dogfish. Additionally, following a slippage event, vessels are currently required to submit a Released Catch Affidavit within 48 hours of the end of the fishing trip. In response to the disapproval of the slippage measures in Amendment 14, the Mid-Atlantic Fishery Management Council developed Framework Adjustment 9 to the Atlantic Mackerel, Squid, and Butterfish FMP to further enhance catch monitoring and to address slippage in the Atlantic mackerel fishery. Framework 9 would add slippage consequence measures and slippage reporting requirements to build upon the current measures and to address monitoring the catch of river herring and shad.

Framework 9 would require Tier 1, 2, and 3 mackerel vessels on observed trips to move 15 nm following an excepted slippage event, which includes safety, mechanical failure, or excess catch of spiny dogfish. These vessels would also be required to terminate a fishing trip and immediately return to port following a non-excepted slippage event, which would be due to any reason other than those listed above. In addition to submitting a Released Catch Affidavit, vessels carrying an observer would also be required to report all slippage events through the vessel monitoring system daily catch report for mackerel and longfin squid.

Corrections

This proposed rule also contains an additional regulation change that was mistakenly omitted in the 2015–2017 Atlantic mackerel, squid, and butterfish specifications final rule (80 FR 14870, March 20, 2015). This regulation change would prohibit all vessels with a valid mackerel permit from fishing for, possessing, transferring, receiving, or selling more than 20,000 lb (9.07 mt) of mackerel per trip or per day after 95 percent of the river herring and shad catch cap has been harvested. This change in the regulations was identified, described, and made available for public comment in the proposed rule for the 2015–2017 Atlantic mackerel, squid, and butterfish specifications (79 FR 68202, November 14, 2014).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Atlantic Mackerel, Squid, and Butterfish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An IRFA was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A summary of the analysis follows.

Description of the Reasons Why Action by the Agency Is Being Considered

This action proposes management measures for the slippage consequences to better monitor catch of river herring and shad in the Atlantic mackerel fishery. The preamble to this proposed rule includes a complete description of the reasons why the Council and NMFS are considering this action and these are not repeated here.

Statement of the Objectives of, and Legal Basis for, This Proposed Rule

The purpose of this proposed action is to minimize slippage, which will improve observer data, and should in turn improve decision-making that uses observer data. Failure to implement the measures described in this proposed rule could result in biased observer data. The preamble to this proposed rule includes a complete description of the objectives of and legal basis for this action and these are not repeated here.

Description and Estimate of the Number of Small Entities to Which This Proposed Rule Would Apply

The proposed alternative applies to mackerel limited access permits. Based on permit data for 2013, 150 separate vessels hold mackerel limited access permits, 114 entities own those vessels, and, based on current Small Business Administration (SBA) definitions, 107 of these are small entities. Of the 107 small entities, 4 had no revenue in 2013 and those entities with no revenue are considered small entities for the purpose of this analysis. All of the entities that had revenue fell into the finfish or shellfish categories, and the SBA definitions for those categories for 2014 are $20.5 million for finfish fishing and $5.5 million for shellfish fishing. Of the entities with revenues, their average revenues in 2013 were $1,201,419. 70 had primary revenues from finfish fishing and 33 had their primary revenues from shellfish fishing.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

The proposed action contains collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval under Control Number 0648–0679.

Under the proposed action, all limited access mackerel vessels carrying an observer would be required to report all slippage events on the VMS mackerel and longfin squid daily catch report. This information collection is intended to improve monitoring the catch of river herring and shad in the Atlantic mackerel fishery. The burden estimates for these new requirements apply to all limited access mackerel vessels. In a given fishing year, NMFS estimates that these additionally reporting requirements will not cause any additional time or cost burden from that which was previously approved under OMB Control Number 0648–0679.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to the Regional Administrator (see **ADDRESSES**), and email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–5806.

Notwithstanding any other provisions of the law, no person is required 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 of information displays a currently valid OMB Control Number. All currently approved NOAA collections of information may be viewed at: *http://www.cio.noaa.gov/services_programs/prasubs.html.*

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

This action contains no other compliance costs. It does not duplicate, overlap, or conflict with any other Federal law.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statues and Which Minimize Any Significant Economic Impact on Small Entities

The proposed alternative should not have more than minimal impact on the affected small entities compared to recent operation of the fishery (2011–2013, and 2014 landings to date appear similar to 2013). First, the primary impact should only be that vessels will not slip catches before observers have a chance to observe/sample them, which should have almost no economic impact on vessels. Slippage for reasons besides safety, mechanical issues, and spiny dogfish are already prohibited, and this proposed action would require vessels to move 15 nm before fishing again if a slippage for those excepted reasons occurs (vessels could not fish within 15 nm of the slippage event for the remainder of the trip). Total small entity mackerel revenues over 2011–2013 averaged $2.0 million, for an average of approximately $19,000 per affected small entity (107), compared to their average revenues of $1,201,419 in 2013 as described above. Given the small relative value of mackerel for most affected entities, the infrequency of slippage, and given the consequence of excepted slippages is only to move 15 nm, it seems likely that the economic impacts should be minimal for affected small entities. This is especially true since only a small portion of trips are observed, and the measures only apply to observed trips.

If slippages have been masking higher river herring and shad landings, it is possible that prohibiting slippages could lead to the mackerel fishery closing earlier (because of the river herring and shad cap) than it otherwise would if more slippages were occurring. However, given the very low mackerel catches in recent years (less than 20 percent of the quota), it is more likely that catch increases might be limited rather than actually having decreased catches, so small entities should not be more than minimally impacted compared to recent fishery operations. In addition, if vessels are prohibited from targeting mackerel due to the cap, they will likely partially mitigate any foregone revenue by fishing for other species (*e.g.* squid, butterfish, herring, etc.).

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: May 13, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.11, paragraph (n)(3)(ii) is revised and paragraph (n)(3)(iii) is added to read as follows:

§ 648.11 At-sea sea sampler/observer coverage.

* * * * *

(n) * * *

(3) * * *

(ii) If fish are released prior to being brought on board the vessel due to any of the exceptions in paragraphs (n)(3)(i)(A)–(C) of this section, the vessel operator must move at least 15 nm from the location of release before fishing again, and must stay at least 15 nm from the slippage event location for the remainder of the fishing trip. The vessel operator must also complete and sign a Released Catch Affidavit detailing the vessel name and permit number; the VTR serial number; where, when, and for what reason the catch was released; the estimated weight of each species brought on board (if only part of the tow was released) or released on that tow. A completed affidavit must be submitted to NMFS within 48 hr of the end of the trip. The vessel operator must also report a slippage event on the VMS

mackerel and longfin squid daily catch report.

(iii) If fish are released prior to being brought on board the vessel due to any reason other than the exceptions in paragraphs (n)(3)(i)(A)–(C) of this section, the vessel operator must immediately terminate the trip and return to port. No fishing activity may occur during the return to port. The vessel operator must also complete and sign a Released Catch Affidavit detailing the vessel name and permit number; the VTR serial number; where, when, and for what reason the catch was released; the estimated weight of each species brought on board (if only part of the tow was released) or released on that tow. A completed affidavit must be submitted to NMFS within 48 hr of the end of the trip. The vessel operator must also report the slippage event on the VMS mackerel and longfin squid daily catch report.

* * * * *

■ 3. In § 648.14, paragraph (g)(2)(ii)(G) is added, paragraphs (g)(2)(vi) and (vii) are revised and paragraphs (g)(2)(viii), (ix), and (x) are added to read as follows:

§ 648.14 Prohibitions.

* * * * *

(g) * * *

(2) * * *

(ii) * * *

(G) Fish for, possess, transfer, receive, or sell; or attempt to fish for, possess, transfer, receive, or sell; more than 20,000 lb (9.07 mt) of mackerel per trip; or land, or attempt to land more than 20,000 lb (9.07 mt) of mackerel per day after 95 percent of the river herring and shad cap has been harvested, if the vessel holds a valid mackerel permit.

* * * * *

(vi) Release fish from codend of the net, transfer fish to another vessel that is not carrying a NMFS-approved observer, or otherwise discard fish at sea before bringing the fish aboard and making it available to the observer for sampling, unless subject to one of the exceptions defined at § 648.11(n)(3) if issued a Limited Access Atlantic mackerel permit, or a longfin squid/butterfish moratorium permit.

(vii) Fail to move 15 nm, as specified at § 648.11(n)(3)(ii).

(viii) Fail to immediately return to port as specified at § 648.11(n)(3)(iii).

(ix) Fail to complete, sign, and submit a Released Catch Affidavit if fish are released pursuant to the requirements at § 648.11(n)(3).

(x) Fail to report a slippage event on the VMS mackerel and longfin squid daily catch report.

* * * * *

[FR Doc. 2015–12060 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 80, No. 96

Tuesday, May 19, 2015

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–2015–0032]

Notice of Request for Extension of Approval of an Information Collection; Importation of Christmas Cactus and Easter Cactus in Growing Media From the Netherlands and Denmark

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with regulations for the importation of Christmas cactus and Easter cactus in growing media from the Netherlands and Denmark.

DATES: We will consider all comments that we receive on or before July 20, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0032.*
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2015–0032, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0032* 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.

FOR FURTHER INFORMATION CONTACT: For information on the importation of Christmas cactus and Easter cactus in growing media from the Netherlands and Denmark, contact Mr. William Aley, Senior Regulatory Specialist, PPP, RPM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2130. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

SUPPLEMENTARY INFORMATION:

Title: Importation of Christmas Cactus and Easter Cactus in Growing Media From the Netherlands and Denmark.

OMB Control Number: 0579–0266.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture is authorized to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. The Secretary has delegated this authority to the Animal and Plant Health Inspection Service (APHIS).

The regulations contained in ''Subpart—Plants for Planting'' (7 CFR 319.37 through 319.37–14) prohibit or restrict, among other things, the importation of living plants, plant parts, and seeds for propagation. These regulations are intended to ensure that imported plants for planting do not serve as a host for plant pests, such as insects or pathogens, that can cause damage to U.S. agricultural and environmental resources.

Under these regulations, Christmas cactus and Easter cactus in approved growing media may be imported into the United States from the Netherlands and Denmark under certain conditions, which require the use of a phytosanitary certificate and declaration stating the plants were grown in accordance with specific conditions, an agreement between APHIS and the plant protection service of the country where the plants are grown, and an agreement between the foreign plant protection service and the grower.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.57 hours per response.

Respondents: Foreign plant protection service officials and growers in the Netherlands and Denmark.

Estimated annual number of respondents: 20.

Estimated annual number of responses per respondent: 10.5.

Estimated annual number of responses: 210.

Estimated total annual burden on respondents: 120 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of May 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–12073 Filed 5–18–15; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Idaho Advisory Committee for Members of the Committee To Receive Member Orientation and Discuss Civil Rights Issues in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

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 (FACA) that a meeting of the Idaho Advisory Committee (Committee) to the Commission will be held on Friday, June 5, 2015, for the purpose of discussing project proposals on equity in school spending and state compliance with the Supreme Court Olmsted decision. The meeting will be held by teleconference.

DATES: Friday, June 5, 2015 from 3:30 p.m. to 4:30 p.m. MST.

FOR FURTHER INFORMATION CONTACT: Peter Minarik, DFO, at (213) 894–3437 or *pminarik@usccr.gov.*

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–437–9455 conference ID: 6159656. Any interested member of the public may call this number and listen to 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 charges for calls they initiate over wireless lines, and 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 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments. The comments must be received in the Western Regional Office of the Commission by July 6, 2015. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments may do so by sending them to Angelica Trevino, Civil Rights Analyst, Western Regional Office, at *atrevino@usccr.gov.* Persons who desire additional information should contact the Western Regional Office, at (213) 894–3437, (or for hearing impaired TDD 913–551–1414), or by email to *atrevino@usccr.gov.* Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=245* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Western Regional Office at the above email or street address.

Agenda:

Election of vice-chair
Discussion of proposal on equity in school district spending
Discussion of proposal on state compliance with Olmsted decision
Adjournment

Public Call Information:

Dial: 888–437–9445
Conference ID: 6159656

Dated: May 13, 2015.

David Mussatt,

Chief, Regional Programs Coordination Unit.

[FR Doc. 2015–12041 Filed 5–18–15; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Current Population Survey, Basic Demographic Items.

OMB Control Number: 0607–0049.

Form Number(s): There are no forms. We conduct all interviews on computers.

Type of Request: Regular.

Number of Respondents: 708,000.

Average Hours Per Response: 0.0273.

Burden Hours: 19,347.

Needs and Uses: The Census Bureau plans to request clearance from the Office of Management and Budget (OMB) for the collection of same sex marriage data as part of the basic demographic information on the Current Population Survey (CPS) beginning in June 2015. The current clearance expires July 31, 2017. The CPS has been the source of official government statistics on employment and unemployment for over 50 years. The Bureau of Labor Statistics (BLS) and the Census Bureau jointly sponsor the basic monthly survey. The Census Bureau also prepares and conducts all the field work. At the OMB's request, the Census Bureau and the BLS divide the clearance request in order to reflect the joint sponsorship and funding of the CPS program. The BLS submits a separate clearance request for the portion of the CPS that collects labor force information for the civilian noninstitutional population. Some of the information within that portion includes employment status, number of hours worked, job search activities, earnings, duration of unemployment, and the industry and occupation classification of the job held the previous week.

The justification that follows is in support of the demographic data. The demographic information collected in the CPS provides a unique set of data on selected characteristics for the civilian noninstitutional population. Some of the demographic information we collect are age, marital status, gender, Armed Forces status, education, race, origin, and family income. We use these data in conjunction with other data, particularly the monthly labor force data, as well as periodic supplement data. We also use these data independently for internal analytic research and for evaluation of other surveys. In addition, we use these data as a control to produce accurate estimates of other personal characteristics.

Affected Public: Individuals or Households.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Section 182; and Title 29, United States Code, Sections 1–9.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent

within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Dated: May 13, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–11979 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Second Amended Final Results of Administrative Review Pursuant to Court Decision

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

SUMMARY: On April 21, 2015, the United States Court of International Trade (''CIT'') issued its final judgment in *Home Meridian Int'l, Inc.* v. *United States,* Consol. Court No. 11–00325,[1] and sustained the Department of Commerce's (''the Department'') third remand redetermination.[2] Consistent with the decision of the United States Court of Appeals for the Federal Circuit (''CAFC'') in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (''*Timken*''), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (''*Diamond Sawblades''*), the Department is notifying the public that the final judgment in this case is not in harmony with the Department's *Amended Final Results.*[3] The Department is amending its *Amended Final Results* with regard to the calculation of the weighted average dumping margin applied to the mandatory respondent, Dalian Huafeng Furniture Group Co., Ltd. (''Huafeng''), and the two separate rate respondents included in this decision: Nanhai Baiyi Woodwork Co. Ltd. (''Nanhai'') and Dongguan Liaobushangdun Huada Furniture Factory and Great Rich (HK) Enterprise Co., Ltd. (''Dongguan'').

DATES: *Effective Date:* May 1, 2015.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor, AD/CVD Operations, Office IV, Enforcement and Compliance—International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC, 20230; telephone (202) 482–0989.

SUPPLEMENTARY INFORMATION:

Background

In the *Final Results,* the Department valued certain wood inputs used by the respondent, Huafeng, with surrogate values and used Insular Rattan and Native Products Corporation's (''Insular Rattan'') 2009 financial statements, among others, to calculate surrogate financial ratios.[4] The CIT twice remanded issues involving the *Final Results* to the Department, and, in its second redetermination, the Department valued certain wood inputs used by Huafeng with market economy purchase prices and revised the calculation of the surrogate financial ratios by excluding Insular Rattan's financial statements from the calculation.[5] On November 14, 2013, the CIT sustained the final results of the Department's second redetermination and, in accordance with *Timken,* the Department published a notice of *Amended Final Results.*[6] The American Furniture Manufacturers Committee for Legal Trade and Vaughan-Bassett Furniture Company, Inc. appealed the valuation of wood inputs, but not the issue of excluding Insular Rattan's financial statements, to the CAFC. On December 1, 2014, the CAFC reversed the CIT's decision and vacated the Department's redetermination results in which it used market economy purchase prices, rather than surrogate values, to value certain of Huafeng's wood inputs. The CAFC directed the CIT to reinstate the Department's wood valuation in the first redetermination (using surrogate values for Huafeng's wood inputs). On January 28, 2015, the CIT ordered the Department to file a redetermination with the Court in which it continued to exclude Insular Rattan's financial statements from its calculations and reinstated the wood valuation from the first redetermination. Pursuant to the CIT's order, the Department filed the final results of its third redetermination with the CIT on March 27, 2015 in which it valued Huafeng's wood inputs using surrogate values and continued to exclude Insular Rattan's financial statements from its calculations.[7] On April 21, 2015, the CIT sustained the Department's *Remand Redetermination III.*[8]

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (''the Act''), the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's April 21, 2015, judgment sustaining the Department's *Remand Redetermination III* in which it valued certain wood inputs using surrogate values, rather than market economy purchase prices, constitutes a final decision of that court that is not in harmony with the Department's *Amended Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal, or if appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final court decision with respect to this case, the Department is amending its *Amended Final Results* with respect to Huafeng's weighted-average dumping margin for the period January 1, 2009 through December 31, 2009. In addition, the Department has amended the *Amended Final Results* for Nanhai and Dongguan, the separate rate respondents included in this final court decision. The remaining weighted-average dumping margins from the *Final Results,* as subsequently amended,[9] remain unchanged.

Manufacturer/exporter	Weighted-average dumping margin (percent)
Dalian Huafeng Furniture Group Co., Ltd	45.83

[1] *See Home Meridian Int'l, Inc.* v. *United States,* Consol. Court No. 11–00325, Slip Op. 15–34 (April 21, 2015) (''*Home Meridian III*'').

[2] *See* Final Results of Third Redetermination Pursuant to Court Order,'' Court No. 14–1251, (March 27, 2015) (''*Remand Redetermination III*'') available at *http://enforcement.trade.gov/remands/cafc-1415-1251.pdf.*

[3] *See Wooden Bedroom Furniture From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Administrative Review Pursuant to Court Decision,* 78 FR 72862 (December 4, 2013) (''*Amended Final Results*'').

[4] *See Wooden Bedroom Furniture from the People's Republic of China: Final Results and Final Rescission in Part,* 76 FR 49729 (Aug. 11, 2011) (''*Final Results*'').

[5] *See* Second Redetermination Pursuant to Court Order, Court No. 11–00325, dated August 26, 2013 (''*Remand Redetermination II*'').

[6] *See Amended Final Results.*

[7] *See Remand Redetermination III.*

[8] *See Home Meridian III.*

[9] *See Wooden Bedroom Furniture From the People's Republic of China: Amended Final Results of Antidumping Duty Administrative Review,* 76 FR 57713 (September 16, 2011).

Manufacturer/exporter	Weighted-average dumping margin (percent)
Nanhai Baiyi Woodwork Co. Ltd	45.83
Dongguan Liaobushangdun Huada Furniture Factory	45.83
Great Rich (HK) Enterprise Co., Ltd.	

In the event the CIT's ruling is not appealed or, if appealed, upheld by the CAFC, the Department will instruct CBP to liquidate entries of subject merchandise based on the revised assessment rates calculated by the Department.

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: May 11, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–12084 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD741

Taking of Marine Mammals Incidental to Specified Activities; Anacortes Tie-Up Slips Dolphin and Wingwall Replacement

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

ACTION: Notice; issuance of an incidental take authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the Washington State Department of Transportation (WSDOT) to take, by harassment, small numbers of 11 species of marine mammals incidental to construction activities for a tie-up slips dolphin and wingwall replacement project in Anacortes, Washington State, between September 1, 2015, and August 31, 2016.

DATES: Effective September 1, 2015, through August 31, 2016.

ADDRESSES: Requests for information on the incidental take authorization should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. A copy of the application containing a list of the references used in this document, NMFS' Environmental Assessment (EA), Finding of No Significant Impact (FONSI), and the IHA may be obtained by writing to the address specified above or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/.* Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for a one-year authorization to incidentally take small numbers of marine mammals by harassment, provided that there is no potential for serious injury or mortality to result from the activity. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Summary of Request

On April 1, 2014, WSDOT submitted a request to NOAA requesting an IHA for the possible harassment of small numbers of 11 marine mammal species incidental to construction associated with the Anacortes Tie-up Slips Dolphin and Wingwall Replacement in the city of Anacortes, on Fidalgo Island, adjacent to Guemes Channel, Skagit County, Washington, between September 1, 2015, and February 15, 2016. NMFS determined that the IHA application was complete on July 1, 2014.

Description of the Specified Activity

A detailed description of the WSDOT's Anacortes tie-up slips dolphin and wingwall project is provided in the **Federal Register** notice for the proposed IHA (80 FR 11648; March 4, 2015). Since that time, no changes have been made to the proposed construction activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to WSDOT was published in the **Federal Register** on March 4, 2015. That notice described, in detail, WSDOT's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission). Specific comments and responses are provided below.

Comment 1: The Commission notes that the construction would be conducted in December and January, however, WSDOT's ambient noise measurements were conducted in March and showed that median ambient noise level at the proposed construction area is 123 dB re 1 μPa. The Commission states that the ambient noise levels would be lower in winter (December and January) than those were collected in March when vessel traffic is greater. Therefore, the Commission recommends that NMFS either (1) require WSDOT to measure ambient sound levels during winter and adjust the Level B harassment zones accordingly or (2) base the Level B harassment zones on the 120-dB re 1 μPa threshold and adjust

the zones to ensure adequate protection for southern resident killer whales.

Response: NMFS worked with WSDOT and its acoustic consultant regarding the ambient noise levels in the vicinity of the construction area. In general, doubling the number of boats would only increase the background sound levels by about 3 decibels so adding or subtracting one boat will not have a substantial effect on the overall background sound levels. The ferry vessels dominate the sound levels in the areas around the terminals where WSDOT's measurement was collected. It is only expected a slight increase in sound levels in the summer months due to more recreational boats in the area. Both NMFS and WSDOT's acoustic consultant considers that sound levels between about September to May should be consistent from month to month and representative of the work period.

Nevertheless, WSDOT agreed that modeled 120 dB isopleths to be used as the threshold for Level B takes for vibratory pile driving and pile removal activities and submitted a updated monitoring plan to encompass this larger zone of influence (ZOI). The updated monitoring measures are discussed in details below in the ''Mitigation Measure'' and ''Monitoring and Reporting'' sections.

In addition, WSDOT is considering getting new winter background data prior to the start of the project. If the measurement shows smaller ZOI, WSDOT will inform NMFS with another revised monitoring plan that reflects the updated ZOI based on onsite measurements.

The revised ZOI does not change the number of marine mammals takes, because all animals within the general vicinity of the project are being considered for potential takes.

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species under NMFS jurisdiction most likely to occur in the proposed construction area include Pacific harbor seal (*Phoca vitulina richardsi*), northern elephant seal (*Mirounga angustirostris*), California sea lion (*Zalophus californianus*), Steller sea lion (*Eumetopias jubatus*), killer whale (*Orcinus orca*) (transient and Southern Resident stocks), gray whale (*Eschrichtius robustus*), humpback whale (*Megaptera novaeangliae*), minke whale (*Balaenoptera acutorostrata*), harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*P. dali*), and Pacific white-sided dolphin (*Lagenorhynchus obliquidens*). A list of the species and their status are provided in Table 1.

TABLE 1—MARINE MAMMAL SPECIES POTENTIALLY PRESENT IN REGION OF ACTIVITY

Species	ESA status	MMPA status	Occurrence
Harbor Seal	Not listed	Non-depleted	Frequent.
California Sea Lion	Not listed	Non-depleted	Frequent.
Northern Elephant Seal	Not listed	Non-depleted	Occasional.
Steller Sea Lion (eastern DPS)	Not listed	Under review	Rare.
Harbor Porpoise	Not listed	Non-depleted	Frequent.
Dall's Porpoise	Not listed	Non-depleted	Occasional.
Pacific White-sided dolphin	Not listed	Non-depleted	Occasional.
Killer Whale	Endangered (S. Resident)	Depleted	Occasional.
Gray Whale	Delisted	Unclassified	Occasional.
Humpback Whale	Endangered	Depleted	Rare.
Minke Whale	Not listed	Non-depleted	Rare.

General information on the marine mammal species found in Washington coastal waters can be found in Caretta *et al.* (2014), which is available at the following URL: *http://www.nmfs.noaa.gov/pr/sars/pdf/po2013.pdf.* Refer to that document for information on these species. A list of marine mammals in the vicinity of the action and their status are provided in Table 3. Specific information concerning these species in the vicinity of the proposed action area is provided in detail in the WSDOT's IHA application.

Potential Effects of the Specified Activity on Marine Mammals

The effects of underwater noise from in-water pile removal and pile driving associated with the construction activities for a tie-up slips dolphin and wingwall replacement project in Anacortes has the potential to result in behavioral harassment of marine mammal species and stocks in the vicinity of the action area. The Notice of Proposed IHA included a discussion of the effects of anthropogenic noise on marine mammals, which is not repeated here. No instances of hearing threshold shifts, injury, serious injury, or mortality are expected as a result of WSDOT's activities given the strong likelihood that marine mammals would avoid the immediate vicinity of the pile driving area.

Potential Effects on Marine Mammal Habitat

The primary potential impacts to marine mammals and other marine species are associated with elevated sound levels, but the project may also result in additional effects to marine mammal prey species and short-term local water turbidity caused by in-water construction due to pile removal and pile driving. These potential effects are discussed in detail in the **Federal Register** notice for the proposed IHA and are not repeated here.

Mitigation Measures

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

For WSDOT's proposed Anacortes tie-up slips dolphin and wingwall replacement project, NMFS is requiring WSDOT to implement the following mitigation measures to minimize the potential impacts to marine mammals in the project vicinity as a result of the in-water construction activities.

No Impact Pile Driving

To avoid potential injury to marine mammals, only vibratory pile hammer will be used for pile removal and pile driving.

Time Restriction

Work would occur only during daylight hours, when visual monitoring

of marine mammals can be conducted. In addition, all in-water construction will be limited to the period between September 1, 2015, and February 15, 2016.

Establishment of Level B Harassment Zones of Influence

Because WSDOT will not use impact pile driving for the proposed construction work, no Level A exclusion zone exists for marine mammals. NMFS currently uses received level of 120 dB as the onset of Level B harassment from non-impulse sources such as vibratory pile driving and pile removal. Although ambient measurement during March at the vicinity of Anacortes Ferry Terminal showed that the median ambient noise level is at 123 dB re 1 μPa, WSDOT will use 120 dB re 1 μPa as the isopleths for modeling its Level B harassment zone. WSDOT is considering collecting ambient noise data before in-water construction and adjust the Level B behavioral harassment zone based on measurements.

The 120-dB Level B harassment ZOIs from in-water vibratory pile removal and pile driving are modeled based on in-water measurements at the WSDOT Port Townsend Ferry Terminal (Laughlin 2011) and Friday Harbor Ferry Terminal (Laughlin 2010) constructions. These modeled results are presented in Table 2 below.

TABLE 2—MODELED ZOI DISTANCES TO LEVEL B BEHAVIORAL HARASSMENT FROM THE PILE DRIVING AND PILE REMOVAL AT WSDOT'S ANACORTES PROJECT AREA

Vibratory pile type/method	Threshold	In-water ZOI (km)	In-air ZOI (m)
12-inch timber removal	120 dB_{RMS} re 1 μPa	2.3	.....
24-inch steel removal/driving	120 dB_{RMS} re 1 μPa	6.3	.....
30-inch steel driving	120 dB_{RMS} re 1 μPa	39.8	.....
36-inch steel driving	120 dB_{RMS} re 1 μPa	63.1	.....
All piles/in-air (harbor seals)	90 dB_{RMS} re 20 μPa	.....	30
All piles/in-air (other pinnipeds)	100 dB_{RMS} re 20 μPa	.....	10

Soft Start

WSDOT will implement ''soft start'' (or ramp up) to reduce potential startling behavioral responses from marine mammals. Soft start requires contractors to initiate noise from the vibratory hammer for 15 seconds at reduced energy followed by a 1-minute waiting period. The procedure will be repeated two additional times. Each day, WSDOT will use the soft-start technique at the beginning of pile driving, or if pile driving has ceased for more than one hour.

Shutdown Measures

WSDOT shall implement shutdown measures if southern resident killer whales are sighted within the vicinity of the project area and are approaching the Level B harassment zone (zone of influence, or ZOI) during in-water construction activities.

If a killer whale approaches the ZOI during pile driving or removal, and it is unknown whether it is a Southern Resident killer whale or a transient killer whale, it shall be assumed to be a Southern Resident killer whale and WSDOT shall implement the shutdown measure.

If a Southern Resident killer whale or an unidentified killer whale enters the ZOI undetected, in-water pile driving or pile removal shall be suspended until the whale exits the ZOI to avoid further level B harassment.

Further, WSDOT shall implement shutdown measures if the number of any allotted marine mammal takes reaches the limit under the IHA (if issued), if such marine mammals are sighted within the vicinity of the project area and are approaching the Level B harassment zone during in-water construction activities.

Coordination With Local Marine Mammal Research Network

Prior to the start of pile driving, the Orca Network and/or Center for Whale Research will be contacted to find out the location of the nearest marine mammal sightings. The Orca Sightings Network consists of a list of over 600 (and growing) residents, scientists, and government agency personnel in the U.S. and Canada. Sightings are called or emailed into the Orca Network and immediately distributed to other sighting networks including: the Northwest Fisheries Science Center of NOAA Fisheries, the Center for Whale Research, Cascadia Research, the Whale Museum Hotline and the British Columbia Sightings Network.

'Sightings' information collected by the Orca Network includes detection by hydrophone. The SeaSound Remote Sensing Network is a system of interconnected hydrophones installed in the marine environment of Haro Strait (west side of San Juan Island) to study orca communication, in-water noise, bottom fish ecology and local climatic conditions. A hydrophone at the Port Townsend Marine Science Center measures average in-water sound levels and automatically detects unusual sounds. These passive acoustic devices allow researchers to hear when different marine mammals come into the region. This acoustic network, combined with the volunteer (incidental) visual sighting network allows researchers to document presence and location of various marine mammal species.

With this level of coordination in the region of activity, WSDOT will be able to get real-time information on the presence or absence of whales before starting any pile driving.

Mitigation Conclusions

NMFS has carefully evaluated the mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals

wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of pile driving and pile removal or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(3) A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of pile driving and pile removal, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(4) A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of pile driving, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the prescribed mitigation measures, NMFS has determined the measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an incidental take authorization (ITA) for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth, ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. WSDOT submitted a marine mammal monitoring plan as part of the IHA application, and updated the plan based on comments received from the Commission. The updated monitoring plan can be found at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

(1) An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

(2) An increase in our understanding of how many marine mammals are likely to be exposed to levels of pile driving that we associate with specific adverse effects, such as behavioral harassment, TTS, or PTS;

(3) An increase in our understanding of how marine mammals respond to stimuli expected to result in take and how anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information);
- Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information);
- Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli;

(4) An increased knowledge of the affected species; and

(5) An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Monitoring Measures

WSDOT shall employ NMFS-approved protected species observers (PSOs) to conduct marine mammal monitoring for its Anacortes tie-up dolphins and wingwall replacement project. The PSOs will observe and collect data on marine mammals in and around the project area for 30 minutes before, during, and for 30 minutes after all pile removal and pile installation work. If a PSO observes a marine mammal within a ZOI that appears to be disturbed by the work activity, the PSO will notify the work crew to initiate shutdown measures.

Monitoring of marine mammals around the construction site shall be conducted using high-quality binoculars (*e.g.,* Zeiss, 10 × 42 power). Due to the different sizes of ZOIs from different pile sizes, two different ZOIs and monitoring protocols corresponding to a specific pile size will be established. Specifically, during vibratory timber removal, and 24″ steel vibratory pile driving and removal, one land-based PSO will monitor the area from the terminal work site, and one boat with a driver and a PSO will travel through the monitoring area. During 30/36″ vibratory pile driving, one land-based PSO will monitor the area from the terminal work site, and two boats with two drivers and two PSOs will travel through the monitoring area (see Figures 2 and 3 in WSDOT's updated Marine Mammal Monitoring Plan).

Data collection during marine mammal monitoring will consist of a count of all marine mammals by species, a description of behavior (if possible), location, direction of movement, type of construction that is occurring, time that pile replacement work begins and ends, any acoustic or visual disturbance, and time of the observation. Environmental conditions such as weather, visibility, temperature, tide level, current, and sea state would also be recorded.

Reporting Measures

WSDOT is required to submit a final monitoring report within 90 days after completion of the construction work or the expiration of the IHA (if issued), whichever comes earlier. This report shall detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed. NMFS shall have an opportunity to provide comments on the report, and if NMFS has comments, WSDOT shall address the comments and submit a final report to NMFS within 30 days.

In addition, NMFS requires WSDOT to notify NMFS' Office of Protected Resources and NMFS' Stranding Network within 48 hours of sighting an injured or dead marine mammal in the vicinity of the construction site. WSDOT shall provide NMFS with the species or description of the animal(s),

the condition of the animal(s) (including carcass condition, if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available).

In the event that WSDOT finds an injured or dead marine mammal that is not in the vicinity of the construction area, WSDOT would report the same information as listed above to NMFS as soon as operationally feasible.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

As discussed above, in-water pile removal and pile driving (vibratory and impact) generate loud noises that could potentially harass marine mammals in the vicinity of WSDOT's proposed Anacortes Ferry Terminal tie-up slip dolphin and wingwall replacement project.

As mentioned earlier in this document, currently NMFS uses 120 dB re 1 μPa and 160 dB re 1 μPa at the received levels for the onset of Level B harassment from non-impulse (vibratory pile driving and removal) and impulse sources (impact pile driving) underwater, respectively. Table 3 summarizes the current NMFS marine mammal take criteria.

TABLE 3—CURRENT ACOUSTIC EXPOSURE CRITERIA FOR NON-EXPLOSIVE SOUND UNDERWATER

Criterion	Criterion definition	Threshold
Level A Harassment (Injury)	Permanent Threshold Shift (PTS) (Any level above that which is known to cause TTS).	180 dB re 1 μPa (cetaceans). 190 dB re 1 μPa (pinnipeds) root mean square (rms).
Level B Harassment	Behavioral Disruption (for impulse noises)	160 dB re 1 μPa (rms).
Level B Harassment	Behavioral Disruption (for non-impulse noise)	120 dB re 1 μPa (rms).

As explained above, ZOIs will be established that encompass the areas where received underwater sound pressure levels (SPLs) exceed the applicable thresholds for Level B harassment. In the case of WSDOT's proposed Anacortes construction project, the Level B harassment ZOI for non-impulse noise sources will be at the received level at 120 dB. This level may be revised and the Level B ZOI reestablished if WSDOT conduct an ambient noise measurement during the time of construction. There will not be a zone for Level A harassment in this case, because source levels from vibratory hammer do not exceed the threshold for Level A harassment, and no impact hammer will be used in the proposed project.

Sound Levels From Proposed Construction Activity

As mentioned earlier, the revised 120-dB Level B harassment ZOIs are modeled based on in-water measurements at the WSDOT Port Townsend Ferry Terminal (Laughlin 2011) and Friday Harbor Ferry Terminal (Laughlin 2010) constructions (Table 2). Incidental take is calculated for each species by estimating the likelihood of a marine mammal being present within a ZOI during active pile removal/driving. Expected marine mammal presence is determined by past observations and general abundance near the Anacortes ferry terminal during the construction window. Ideally, potential take is estimated by multiplying the area of the ZOI by the local animal density. This provides an estimate of the number of animals that might occupy the ZOI at any given moment. However, there are no density estimates for any Puget Sound population of marine mammal.

As a result, the take requests were estimated using local marine mammal data sets, and information from state and federal agencies. All haulout and observation data available are summarized in Section 3 of WSDOT's IHA application. Project duration is presented in Section 2 of WSDOT's IHA application.

The calculation for marine mammal exposures is estimated by:

Exposure estimate = N (number of animals in the area) * Number of days of pile removal/driving activity.

Estimates include Level B acoustical harassment during vibratory pile removal and driving. All estimates are conservative, as pile removal/driving will not be continuous during the work day. Using this approach, a summary of estimated takes of marine mammals incidental to WSDOT's Anacortes Ferry Terminal tip-up dolphins and wingwall replacement work are provided in Table 4.

TABLE 4—ESTIMATED NUMBERS OF MARINE MAMMALS THAT MAY BE EXPOSED TO RECEIVED PILE REMOVAL LEVELS ABOVE 120 DB RE 1 μPA (RMS)

Species	Estimated marine mammal takes	Abundance	Percentage
Pacific harbor seal	900	14,612	6.0
California sea lion	180	296,750	0.06
Steller sea lion	360	52,847	0.7
Northern elephant seal	72	124,000	0.06
Harbor porpoise	612	10,682	5.7
Dall's porpoise	108	42,000	0.3
Killer whale, transient	70	354	20
Killer whale, Southern Resident	4	81	5.0
Pacific white-sided dolphin	360	25,233	1.4
Gray whale	36	18,017	0.2
Humpback whale	30	2,043	1.5

TABLE 4—ESTIMATED NUMBERS OF MARINE MAMMALS THAT MAY BE EXPOSED TO RECEIVED PILE REMOVAL LEVELS ABOVE 120 dB RE 1 μPA (RMS)—Continued

Species	Estimated marine mammal takes	Abundance	Percentage
Minke whale	10	202–600	1.7–5

Analysis and Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

WSDOT's Anacortes Ferry Terminal tie-up dolphins and wingwall replacement project would involve vibratory pile removal and pile driving activities. Elevated underwater noises are expected to be generated as a result of these activities; however, these noises are expected to result in no mortality or Level A harassment and limited Level B harassment of marine mammals. WSDOT will not use impact hammer for pile driving, thus eliminating the potential for injury (including PTS) and TTS from noise impact. For vibratory pile removal and pile driving, noise levels are not expected to reach the level that may cause TTS, injury (including PTS), or mortality to marine mammals. Therefore, NMFS does not expect that any animals would experience Level A harassment (including injury or PTS) or Level B harassment in the form of TTS from being exposed to in-water pile removal and pile driving associated with WSDOT's construction project.

Additionally, the sum of noise from WSDOT's proposed Anacortes Ferry Terminal tie-up dolphins and wingwall replacement construction activities is confined to a limited area by surrounding landmasses; therefore, the noise generated is not expected to contribute to increased ocean ambient noise. In addition, due to shallow water depths in the project area, underwater sound propagation of low-frequency sound (which is the major noise source from pile driving) is expected to be poor.

In addition, WSDOT's proposed activities are localized and of short duration. The entire project area is limited to WSDOT's Anacortes Ferry Terminal construction work. The entire project would involve the removal of 272 existing piles and installation of 81 piles. The duration for the construction would involve 68 hours in 9 days for pile removal and 27 hours in 27 days for pile installation. These low-intensity, localized, and short-term noise exposures may cause brief startle reactions or short-term behavioral modification by the animals. These reactions and behavioral changes are expected to subside quickly when the exposures cease. Moreover, the proposed mitigation and monitoring measures are expected to reduce potential exposures and behavioral modifications even further. Additionally, no important feeding and/or reproductive areas for marine mammals are known to be near the proposed action area. Therefore, the take resulting from the proposed Anacortes Ferry Terminal tie-up dolphins and wingwall replacement work is not reasonably expected to, and is not reasonably likely to, adversely affect the marine mammal species or stocks through effects on annual rates of recruitment or survival.

The project area is not a prime habitat for marine mammals, nor is it considered an area frequented by marine mammals. Therefore, behavioral disturbances that could result from anthropogenic noise associated with WSDOT's construction activities are expected to affect only a small number of marine mammals on an infrequent and limited basis.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat, as analyzed in detail in the ''Anticipated Effects on Marine Mammal Habitat'' section. The project activities would not modify existing marine mammal habitat. The activities may cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS finds that the total marine mammal take from WSDOT's Anacortes Ferry Terminal tie-up dolphins and wingwall replacement project will have a negligible impact on the affected marine mammal species or stocks.

Small Number

Based on analyses provided above, it is estimated that approximately 900 harbor seals, 180 California sea lions, 360 Steller sea lions, 72 northern elephant seals, 612 harbor porpoises, 108 Dall's porpoises, 70 transient killer whales, 4 Southern Resident killer whales, 360 Pacific white-sided dolphins, 36 gray whales, 30 humpback whales, and 10 minke whales could be exposed to received noise levels that could cause Level B behavioral harassment from the proposed construction work at the Anacortes Ferry Terminal in Washington State. These numbers represent approximately 0.06% to 20% of the populations of these species that could be affected by Level B behavioral harassment, respectively (see Table 5 above), which are small percentages relative to the total populations of the affected species or stocks.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, which are expected to reduce the number of marine mammals potentially affected by the proposed action, NMFS finds that small numbers of marine mammals will be taken relative to the

populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no subsistence uses of marine mammals in the proposed project area; and, thus, no subsistence uses impacted by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

The humpback whale and the Southern Resident stock of killer whale are the only marine mammal species currently listed under the ESA that could occur in the vicinity of WSDOT's proposed construction projects. Under section 7 of the ESA, the Federal Highway Administration (FHWA) and WSDOT have consulted with NMFS West Coast Regional Office (WCRO) on the proposed WSDOT Anacortes Ferry Terminal tie-up slip dolphins and wingwall replacement project. WCRO issued a Biological Opinion on July 15, 2014, which concludes that the proposed Anacortes Ferry Terminal tie-up slip dolphins and wingwall replacement project may affect, but is not likely to adversely affect the listed marine mammal species and stocks.

The issuance of an IHA to WSDOT constitutes an agency action that authorizes an activity that may affect ESA-listed species and, therefore, is subject to section 7 of the ESA. As the effects of the activities on listed marine mammals were analyzed during a formal consultation between the FHWA and NMFS, and as the underlying action has not changed from that considered in the consultation, the discussion of effects that are contained in the Biological Opinion and accompanying memo issued to the FHWA on July 15, 2014, pertains also to this action. Therefore, NMFS has determined that issuance of an IHA for this activity would not lead to any effects to listed marine mammal species apart from those that were considered in the consultation on FHWA's action.

National Environmental Policy Act (NEPA)

NMFS prepared an Environmental Assessment (EA) and analyzed the potential impacts to marine mammals that would result from WSDOT's Anacortes Ferry Terminal tie-up slip dolphins and wingwall replacement project. A Finding of No Significant Impact (FONSI) was signed in May 2015. A copy of the EA and FONSI is available upon request (see **ADDRESSES**).

Authorization

NMFS has issued an IHA to WSDOT for the potential harassment of small numbers of 11 marine mammal species incidental to the Anacortes Ferry Terminal tie-up slip dolphins and wingwall replacement construction in Washington State, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: May 12, 2015.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD807

Takes of Marine Mammals Incidental to Specified Activities; Construction Activities at the Children's Pool Lifeguard Station at La Jolla, California

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

ACTION: Notice; proposed Incidental Harassment Authorization (IHA); request for comments.

SUMMARY: NMFS has received an application from the City of San Diego for an IHA to take small numbers of marine mammals, by Level B harassment, incidental to construction activities at the Children's Pool Lifeguard Station in La Jolla, California. NMFS has reviewed the IHA application, including all supporting documents, and determined that it is adequate and complete. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to the City of San Diego to take, by Level B harassment only, three species of marine mammals during the specified activities.

DATES: Comments and information must be received no later than June 18, 2015.

ADDRESSES: Comments on the IHA application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.Goldstein@noaa.gov.* Please include 0648–XD807 in the subject line. NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 25-megabyte size.

All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental/* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

An electronic copy of the IHA application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/.* Documents cited in this notice, including the IHA application, may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Howard Goldstein or Jolie Harrison, Office of Protected Resources, NMFS, 301–427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*), directs the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals, by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for the incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring, and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified

activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) of the MMPA establishes a 45-day time limit for NMFS's review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the public comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On February 25, 2015, NMFS received an application from the City of San Diego, Engineering and Capital Projects Department, requesting an IHA for the taking of marine mammals incidental to construction activities. NMFS determined that the IHA application was adequate and complete on April 9, 2015.

The City of San Diego would undertake the proposed construction activities between June 2015 and June 2016 at the Children's Pool Lifeguard Station in La Jolla, California. In-air noise generated from equipment used during the construction activities is likely to result in the take of marine mammals. The requested IHA would authorize the take, by Level B (behavioral) harassment, of small numbers of Pacific harbor seals (*Phoca vitulina richardii*), California sea lions (*Zalophus californianus*), and northern elephant seals (*Mirounga angustirostris*) incidental to construction activities of the Children's Pool Lifeguard Station at La Jolla, CA. Because the proposed construction activities were subject to delays and cannot be completed by June 27, 2015, the City of San Diego has requested a renewal of the 2014 to 2015 IHA for an additional year. The construction activities are planned to take place during June 2015 to June 2016 in La Jolla, CA. Regarding the previous IHA, NMFS published a notice in the **Federal Register** (79 FR 8160) on February 11, 2014, making preliminary determinations and proposing to issue an IHA. The notice initiated a 30-day public comment period. On June 6, 2014, NMFS published a notice in the **Federal Register** (79 FR 32699) announcing the issuance of an IHA. Additional information on the construction activities at the Children's Pool Lifeguard Station is contained in the IHA application, which is available upon request (see **ADDRESSES**).

Also, NMFS issued the City of San Diego an IHA in 2013 (78 FR 40705, July 8, 2013) for demolition and construction activities at the Children's Pool Lifeguard Station that were scheduled to be completed in 2013. Because the construction activities were subject to delays (*e.g.,* nesting migratory birds, unexpected drainage pipes, unexpected demolition and construction planning, etc.) and could not be completed by December 15, 2013, the City of San Diego requested a renewal of the 2013 IHA for an additional year. Additional information on the construction activities at the Children's Pool Lifeguard Station is contained in the IHA application, which is available upon request (see **ADDRESSES**).

Description of the Proposed Specified Activity

Overview

The City of San Diego plans to conduct construction activities at the Children's Pool Lifeguard Station in La Jolla, CA in order to meet the needs of the lifeguards at Children's Pool and the demand for lifeguard services. The overall project includes the demolition of the existing lifeguard station and construction of a new, three-story, lifeguard station on the same site. Demolition of the existing lifeguard station was completed in 2013 to 2014 and construction of the new lifeguard station is expected to be completed in 2015 to 2016. Because the previously existing lifeguard station was demolished and closed to entry, a temporary lifeguard tower was moved onto the bluff near the previous lifeguard station.

Proposed Dates and Duration

The City of San Diego is planning to begin/resume the project at the Children's Pool in La Jolla, CA on June 1, 2015, (see page 30 to 31 of the Negative Declaration in the IHA application) with completion of the new lifeguard station to be completed by December 15, 2015. The City of San Diego and NMFS are requiring a moratorium on all construction activities during harbor seal pupping and weaning (*i.e.,* December 15th to May 30th; see page 5 of the Mitigated Negative Declaration in the IHA application). Therefore, work on this project can only be performed between June 1st and December 14th of any year.

Proposed construction activities would generally occur Monday through Friday (no work will occur on holidays) during daylight hours only, as stipulated in the ''Mitigated Negative Declaration'' included in the IHA application and local ordinances. As a modification to the original IHA, the City of San Diego has requested that planned construction activities be allowed on weekends (*i.e.,* Saturday and Sunday to ensure completion of the project during 2015. The exact dates of the proposed activities depend on logistics and scheduling. The IHA is valid through June 2016 to allow for construction delays.

Proposed Specific Geographic Region

The La Jolla Children's Pool Lifeguard Station is located at 827 ½ Coast Boulevard, La Jolla, CA 92037 (32° 50′ 50.02″ North, 117° 16′ 42.8″ West). The locations and distances (in ft) from the construction site to the Children's Pool haul-out area, breakwater ledge/rocks haul-out area, reef haul-out area, and Casa Beach haul-out area can be found in the City of San Diego's IHA application.

Detailed Description of the Proposed Specified Activities

The Children's Pool was created in 1931 by building a breakwater wall which created a protected pool for swimming. Although partially filled with sand, the Children's Pool still has open water for swimming and a beach for sunbathing and beachcombing. The Children's Pool and nearby shore areas (*i.e.,* shoreline, beaches, and reefs of La Jolla) are used by swimmers, sunbathers, SCUBA divers and snorkelers, shore/surf fishermen, school classes, tide pool explorers, kayakers, surfers, boogie and skim boarders, seal, sea lion, bird and nature watchers, and for other activities by the general public. Over the last three years (2010 through 2012), an average of 1,556,184 people have visited the Children's Pool annually, and lifeguards have taken an average of 8,147 preventive actions and 86 water rescues annually (CASA, 2010; 2011; 2012).

The previous lifeguard facility at Children's Pool, built in 1967, was old, deteriorating from saltwater intrusion, and no longer served the needs of the lifeguard staff or the beach-going public. The structure was condemned on February 22, 2008 due to its deteriorated condition and lack of structural integrity. Because the existing building was no longer viable, a temporary lifeguard tower was moved in. However, a new lifeguard station is required to meet the needs of the lifeguards and the demand for lifeguard services.

The overall project includes the demolition of the existing lifeguard station and construction of a new, three-story, lifeguard station on the same site. Demolition and removal of the existing lifeguard station was completed in 2013 to 2014 and construction of the new lifeguard station is expected to be completed in 2015 to 2016. The building contractor utilized excavators, backhoes, concrete saws, and jackhammers for demolishing the previous structure and has hauled the waste materials to an offsite landfill where it was separated into recycled content and waste. During the second year of construction (2014 to 2015) and in the same footprint as the old lifeguard station, the new lifeguard station is being constructed within and adjacent to the previous facility. Rough plumbing and electrical have been laid; the foundation has been poured and some of the steel structure has been erected. The new lifeguard facility is in an optimal location to provide lifeguard service to the community. The new, three-story, building will contain a lower level with beach access level public restrooms and showers, lifeguard lockers, and sewage pump room; a second level with two work stations, ready/observation room, kitchenette, restroom, and first aid station; and a third ''observation'' level (with a 270° view of the beach and nearby reef areas) with a single occupancy observation space, radio storage closet, and exterior catwalk. Interior stairs will link the floors. The existing below grade retaining walls will remain in place and new retaining walls will be constructed for a ramp from street level to the lower level for emergency vehicle beach access and pedestrian access to the lower level restrooms and showers. A 5.6 m (18. 5 ft) wall will be located along the north end of the lower level. The walls will be designed for a minimum design life of 50 years and will not be undermined from ongoing coastal erosion. The walls will not be readily viewed from Coast Boulevard, the public sidewalks or the surrounding community. Enhanced paving, seating and viewing space, drinking fountains, adapted landscaping, and water efficient irrigation will also be included.

The City of San Diego has divided the demolition and construction activities are divided into phases:

(1.) Mobilization and temporary facilities;

(2.) Demolition and site clearing;

(3.) Site preparation and utilities;

(4.) Building foundation;

(5.) Building shell;

(6.) Building exterior;

(7.) Building interior;

(8.) Site improvements; and

(9.) Final inspection and demobilization.

Demolition and construction of the new lifeguard station was initially estimated to take approximately 7 months (148 actual demolition and construction days) and be completed by December 15, 2013; however, demolition and construction did not start until later than previously planned in June 2013 and June 2014 due to the presence of nesting migratory birds (*i.e.,* Western seagulls [*Larus occidentalis*] and eggs/chicks). There were additional unexpected delays in the demolition due to unforeseen underground structures at the site making it impossible to finish the project by December 15, 2013 or 2014. The City of San Diego completed phases 1 to 4 during 2013 and 2014. During the 2013 to 2014 construction window, the temporary on-site tower was removed and two temporary towers were installed nearby (one about 500 m [1,640.4 ft] south of the construction site and another about 1,000 m [3,280.8 ft] east of the construction site to serve citizens utilizing the beaches and ocean waters nearby. Construction of phases 5 to 9 would commence in June 2015, thereby necessitating a renewal of the previous IHA.

The notice of the final IHA for the City of San Diego's demolition and construction activities that was published in the **Federal Register** on July 8, 2013 (78 FR 40705) provides a detailed summary on phases 1 to 4 (*i.e.,* mobilization and temporary facilities, demolition and site clearing, site preparation and utilities, and building foundation). Phases 5 to 9 include (phases overlap in time):

(5.) *Building shell:*

Pre-cast concrete panel walls, panel walls, rough carpentry and roof framing, wall board, cable railing, metal flashing, and roofing.

Equipment—crane, truck, fork lift, and hand/power tools.

Timeframe—Approximately 35 days.

This phase will be completed in 2015 and has a maximum source level of 100 dB.

(6.) *Building exterior:*

Doors and windows, siding paint, light fixtures, and plumbing fixtures.

Equipment—truck, hand/power tools, and chop saw.

Timeframe—Approximately 4 weeks.

This phase will be completed in 2015 and has a maximum source level of 100 dB.

(7.) *Building interiors:*

Walls, sewage lift station, rough and finish mechanical electrical plumbing structural (MEPS), wall board, door frames, doors and paint.

Equipment—truck, hand/power tools, and chop saw.

Timeframe—Approximately 37 days.

This phase will be completed in 2015 and has a maximum source level of 100 dB.

(8.) *Site improvements:*

Modify storm drain, concrete seat walls, curbs, and planters, fine grade, irrigation, hardscape, landscape, hand rails, plaques, and benches.

Equipment—backhoe, truck, hand/power tools, concrete pump/truck, and fork lift.

Timeframe—Approximately 37 days.

This phase will be completed in 2015 and has a maximum source level of 110 dB.

(9.) *Final inspection and demobilization:*

System testing, remove construction equipment, inspection, and corrections.

Equipment—truck, and hand/power tools.

Timeframe—Approximately 41 days.

This phase will be completed in 2015 and has a maximum source level of 100 dB.

The exact dates of the planned activities depend on logistics and scheduling.

Sound levels during all phases of the project would not exceed 110 dB re 20 μPa at five feet from the sound sources. The 110 dB estimate is based on equipment manufacturers' estimates obtained by the construction contractor. The City of San Diego utilized published or manufacturers' measurement data based on the proposed equipment (*i.e.,* a backhoe, dump truck, cement pump, air compressor, electric screw guns, jackhammers, concrete saw, chop saw, and hand tools) to be utilized on the project site. Operation of the equipment is the primary activity within the range of construction activities that is likely to affect marine mammals by potentially exposing them to in-air (*i.e.,* airborne or sub-aerial) noise. During the working day, the City of San Diego estimates

there would be sound source levels above 90 dB re 20 μPa, including 65 days of 100 to 110 dB re 20 μPa at the construction site.

On average, pinnipeds will be about 30.5 meters (m) (100 feet [ft]) or more from the construction site with a potential minimum of about 15.2 m (50 ft). During 2013 and 2014, measured sound levels from the demolition equipment reaching the pinnipeds did not exceed approximately 90 dB re 20 μPa at the haul-out area closest to the demolition and construction and a peak of about 83 dB re 20 μPa at the mean hauling-out distance (30.5 m). The City of San Diego used the formula and online calculator on the Web site: *http://sengpielaudio.com/calculator-distance.htm* and measured distances from the sound source to determine the area of potential impacts from in-air sound. Table 1 of the City of San Diego's monitoring report provides mean sound and mean distance from sound sources by the type of equipment and monitoring location. The City of San Diego intends to continue to measure in-air background noise levels in the days immediately prior to, during, and after the construction activities.

Additional details regarding the proposed construction activities of the Children's Pool Lifeguard Station can be found in the City of San Diego's IHA application. The IHA application can also be found online at: *http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.*

Description of Marine Mammals in the Specified Geographic Area of the Proposed Specified Activity

Three species of pinnipeds are known to or could occur in the Children's Pool proposed action area and off the Pacific coastline (see Table 1 below). Pacific harbor seals, California sea lions, and northern elephant seals are the three species of marine mammals that occur and are likely to be found within the immediate vicinity of the activity area. Therefore, these three species are likely to be exposed to effects of the proposed specified activities. A variety of other marine mammals have on occasion been reported in the coastal waters off southern California. These include gray whales, killer whales, bottlenose dolphins, Steller sea lions, northern fur seals, and Guadalupe fur seals. However, none of these species have been reported to occur in the immediate proposed action area of the Children's Pool beach. Therefore, NMFS does not expect, and is not authorizing, incidental take of other marine mammal species from the proposed specified activities. Table 1 below identifies the cetacean and pinnipeds species, their habitat, and conservation status in the nearshore area of the general region of the proposed project area.

TABLE 1—THE HABITAT, ABUNDANCE, AND CONSERVATION STATUS OF MARINE MAMMALS INHABITING THE GENERAL REGION OF THE ACTION AREA IN THE PACIFIC OCEAN OFF THE SOUTHERN COAST OF CALIFORNIA

Species	Habitat	Occurrence	Range	Best population estimate (minimum) [1]	ESA [2]	MMPA [3]
Mysticetes						
Gray whale (*Eschrichtius robustus*).	Coastal and shelf.	Transient during season migrations.	North Pacific Ocean, Gulf of California to Arctic—Eastern North Pacific stock.	20,990 (20,125).	DL—Eastern Pacific stock. EN—Western Pacific stock.	NC—Eastern North Pacific stock D—Western North Pacific stock.
Odontocetes						
Killer whale (*Orcinus orca*).	Widely distributed.	Varies on inter-annual basis.	Cosmopolitan	354 (354)—West Coast Transient stock.	NL EN—Southern resident population.	NC D—Southern Resident and AT1 Transient populations.
Bottlenose dolphin (*Tursiops truncatus*).	Offshore, inshore, coastal, estuaries.	Limited, small population within 1 km of shore.	Tropical and temperate waters between 45° North and South.	323 (290)—California Coastal stock.	NL	NC.
Long-beaked common dolphin (*Delphinus capensis*).	Inshore	Common, more inshore distribution, year-round presence.	Nearshore and tropical waters.	107,016 (76,224)—California stock.	NL	NC.
Pinnipeds						
Pacific harbor seal (*Phoca vitulina richardii*).	Coastal	Common	Coastal temperate to polar regions in Northern Hemisphere.	30,968 (27,348)—California stock.	NL	NC.
Northern elephant seal (*Mirounga angustirostris*).	Coastal, pelagic when not migrating.	Common	Eastern and Central North Pacific—Alaska to Mexico.	179,000 (81,368)—California breeding stock.	NL	NC.
California sea lion (*Zalophus californianus*).	Coastal, shelf	Common	Eastern North Pacific Ocean—Alaska to Mexico.	296,750 (153,337)—U.S. stock.	NL	NC.

TABLE 1—THE HABITAT, ABUNDANCE, AND CONSERVATION STATUS OF MARINE MAMMALS INHABITING THE GENERAL REGION OF THE ACTION AREA IN THE PACIFIC OCEAN OFF THE SOUTHERN COAST OF CALIFORNIA—Continued

Species	Habitat	Occurrence	Range	Best population estimate (minimum) [1]	ESA [2]	MMPA [3]
Steller sea lion (*Eumetopias jubatus*).	Coastal, shelf ..	Rare	North Pacific Ocean—Central California to Korea.	72,223 (52,847)—Eastern U.S. stock.	DL—Eastern U.S. stock. EN—Western U.S. stock.	D.
Northern fur seal (*Callorhinus ursinus*).	Pelagic, off-shore.	Rare	North Pacific Ocean—Mexico to Japan.	12,844 (6,722)—California stock.	NL	NC—California stock.
Guadalupe fur seal (*Arctocephalus townsendi*).	Coastal, shelf ..	Rare	California to Baja California, Mexico.	7,408 (3,028)—Mexico to California.	T	D.

NA = Not available or not assessed.
[1] NMFS Marine Mammal Stock Assessment Reports
[2] U.S. Endangered Species Act: EN = Endangered, T = Threatened, DL = Delisted, and NL = Not listed.
[3] U.S. Marine Mammal Protection Act: D = Depleted, S = Strategic, and NC = Not classified.

The rocks and beaches at or near the Children's Pool in La Jolla, CA, are almost exclusively Pacific harbor seal hauling-out sites. On infrequent occasions, one or two California sea lions or a single juvenile northern elephant seal have been observed on the sand or rocks at or near the Children's Pool (*i.e.,* breakwater ledge/rocks haul-out area, reef haul-out area, and Casa Beach haul-out area). These sites are not usual haul-out locations for California sea lions and/or northern elephant seals. The City of San Diego commissioned two studies of harbor seal abundance trends at the Children's Pool. Both studies reported that appearances of California sea lions and northern elephant seals are infrequent, but not rare at Children's Pool (Yochem and Stewart, 1998; Hanan, 2004; Hanan & Associates, 2011). During 2013, the City of San Diego observed one juvenile and three adult California sea lions and two juvenile northern elephant seals at the Children's Pool. During 2014, the City of San Diego observed 22 California sea lions (during 19 days) and 30 juvenile elephant seals (during 29 days) at the Children's Pool. Adult sea lions were also observed hauling out on rocks and cliffs near the Children's Pool.

Pacific Harbor Seal

Harbor seals are widely distributed in the North Atlantic and North Pacific. Two subspecies exist in the Pacific Ocean: *P.* v. *stejnegeri* in the western North Pacific near Japan, and *P.* v. *richardii* in the eastern North Pacific. The subspecies in the eastern North Pacific Ocean inhabits near-shore coastal and estuarine areas from Baja California, Mexico, to the Pribilof Islands in Alaska. These seals do not make extensive pelagic migrations, but do travel 300 to 500 kilometers (km) (162 to 270 nautical miles [nmi]) on occasion to find food or suitable breeding areas (Herder, 1986; Harvey and Goley, 2011). Previous assessments of the status of harbor seals have recognized three stocks along the west coast of the continental U.S.: (1) California, (2) Oregon and Washington outer coast waters, and (3) inland waters of Washington. An unknown number of harbor seals also occur along the west coast of Baja California, at least as far south as Isla Asuncion, which is about 100 miles south of Punta Eugenia. Animals along Baja California are not considered to be a part of the California stock because it is not known if there is any demographically significant movement of harbor seals between California and Mexico and there is no international agreement for joint management of harbor seals. Harbor seal presence at haul-out sites is seasonal with peaks in abundance during their pupping and molting periods. Pupping and molting periods are first observed to the south and progress northward up the coast with time (*e.g.,* January to May near San Diego, April to June in Oregon and Washington) (Jeffries, 1984; Jeffries, 1985; Huber *et al.,* 2001; Hanan, 2004; Hanan & Associates, 2011).

In California, approximately 400 to 600 harbor seal haul-out sites are distributed along the mainland coast and on offshore islands, including intertidal sandbars and ledges, rocky shores and islets, and beaches (Harvey *et al.,* 1995; Hanan, 1996; Lowry *et al.,* 2008). Preferred haul-out sites are those that are protected from the wind and waves, and allow access to deep water for foraging (Perrin *et al.,* 2008). Of the known haul-out sites, 14 locations are rookeries (2 locations have multiple sites, for a total of 17 sites) on or near the mainland of California. The population of harbor seals has grown off the U.S. west coast and has led to new haul-out sites being used in California (Hanan, 1996). Harbor seals are one of the most common and frequently observed marine mammals along the coastal environment.

Harbor seals have been observed hauling-out and documented giving birth at the Children's Pool since the 1990's (Yochem and Stewart, 1998; Hanan & Associates, 2004). Pacific harbor seals haul-out year-round on beaches and rocks (*i.e.,* breakwater ledge/rocks haul-out area, reef haul-out area, and Casa Beach haul-out area) below the lifeguard tower at Children's Pool. According to Yochem (2005), the Children's Pool beach site is used by harbor seals at all hours of the day and at all tides with the exception of occasional high tide/high swell events in which the entire beach is awash. It is one of the three known haul-out sites for this species in San Diego County. These animals have been observed in this area moving to/from the Children's Pool, exchanging with the rocky reef directly west of and adjacent to the breakwater and with Seal Rock, which is about 150 m (492 ft) west of the Children's Pool. Harbor seals have also been reported on the sandy beach just southwest of the Children's Pool. At low tide, additional space for hauling-out is available on the rocky reef areas outside the retaining wall and on beaches immediately southward. Haul-out times vary by time of year, from less than an hour to many

hours. There have been no foraging studies at this site, but harbor seals have been observed in nearshore waters and kelp beds nearby, including La Jolla Cove.

The Children's Pool area is the only rookery in San Diego County and the only mainland rookery on the U.S. west coast between the border of Mexico and Point Mugu in Ventura County, CA (321.9 km [200 miles]). The number of harbor seals in this area has increased since 1979, and seals are documented to give birth on these beaches during December through May (Hanan, 2004; Hanan & Associates, 2011). The official start to pupping season is December 15. Females in an advanced stage of pregnancy begin to show up on the Children's Pool beach by late October to early November. Several studies have identified harbor seal behavior and estimated harbor seal numbers including patterns of daily and seasonal area use (Yochem and Stewart, 1998; Hanan & Associates, 2011; Linder, 2011). Males, females, and pups (in season) of all ages and stages of development are observed at the Children's Pool and adjacent areas.

In southern California, a considerable amount of information is known about the movements and ecology of harbor seals, but population structure in the region is not as well known (Stewart and Yochem, 1994, 2000; Keper *et al.,* 2005; Hanan & Associates, 2011). Linder (2011) suggests that this population moves along the California coast and the beach at Children's Pool is part of a ''regional network of interconnected'' haul-out and pupping sites. Harbor seals often haul-out in protected bays, inlets, and beaches (Reeves *et al.,* 1992). At and near the Children's Pool, harbor seals haul-out on the sand, rocks, and breakwater base in numbers of 0 to 15 harbor seals to a maximum of about 150 to 250 harbor seals depending on the time of day, season, and weather conditions (Hanan, 2004, Hanan & Associates, 2011; Linder, 2011). Because space is limited behind the breakwater at the Children's Pool, Linder (2011) predicted that it is unlikely that numbers will exceed 250 harbor seals. Based on monitoring from a camera, Western Alliance for Nature (WAN) reported that during the month of May 2013 up to 302 harbor seals were documented resting on the Children's Pool beach at any given time, with additional harbor seals on the rocks and in the water (Wan, personal communication). Almost every day, except for weekends, over 250 individual harbor seals were present on the beach. During the months of September 2012 to January 2013, the average number of harbor seals on the beach varied from 83 to 120 animals before people entered the beach or when people were behind the rope. During this same period, when people were on the beach and/or across the rope, the average number of harbor seals varied from 7 to 27. The City of San Diego observed 12 counts totaling more than 200 and a maximum of 238 animals during the 2014 to 2015 construction window. The weather (*i.e.,* wind and/or rain) and the proximity of humans to the beach likely affect the presence of harbor seals on the beach.

Radio-tagging and photographic studies have revealed that only a portion of seals utilizing a hauling-out site are present at any specific moment or day (Hanan, 1996, 2005; Gilbert *et al.,* 2005; Harvey and Goley, 2011; and Linder, 2011). These radio-tagging studies indicate that harbor seals in Santa Barbara County haul-out about 70 to 90% of the days annually (Hanan, 1996). The City of San Diego expects harbor seals to behave similarly at the Children's Pool. Tagged and branded harbor seals from other haul-out sites have been observed by Dr. Hanan at the Children's Pool. For example, harbor seals with red-stained heads and coats, which are typical of some harbor seals in San Francisco Bay have been observed at Children's Pool, indicating that seals tagged at other locations and haul-out sites visit the site. A few seals have been tagged at the Children's Pool and there are no reports of these tagged animals at other sites (probably because of very low re-sighting efforts and a small sample size [10 individuals radio-tagged]), which may indicate a degree of site-fidelity (Yochem and Stewart, 1998). These studies further indicate that seals are constantly moving along the coast including to/from the offshore islands and that there may be as many as 600 individual harbor seals using Children's Pool during a year, but certainly not all at one time.

The City of San Diego has fitted a polynomial curve to the number of expected harbor seals hauling-out at the Children's Pool by month (see Figure 1 of the IHA application and Figure 2 below) based on counts at the Children's Pool by Hanan (2004), Hanan & Associates (2011), Yochem and Stewart (1998), and the Children's Pool docents (Hanan, 2004). A three percent annual growth rate of the population was applied to Yochem and Stewart (1998) counts to normalize them to Hanan & Associates and docent counts in 2003 to 2004. Based on monitoring during 2013 to 2014, Dr. Hanan estimates that similar numbers of harbor seals hauling-out at Children's Pool during 2011 and would expect similar numbers in 2015 to 2016.

A complete count of all harbor seals in California is impossible because some are always away from the haul-out sites. A complete pup count (as is done for other pinnipeds in California) is also not possible because harbor seals are precocial, with pups entering the water almost immediately after birth. Population size is estimated by counting the number of seals ashore during the peak haul-out period (May to July) and by multiplying this count by a correction factor equal to the inverse of the estimated fraction of seals on land. Based on the most recent harbor seal counts (2009) and including a revised correction factor, the estimated population of harbor seals in California is 30,196 individuals (NMFS, 2011), with an estimated minimum population of 26,667 for the California stock of harbor seals. Counts of harbor seals in California increased from 1981 to 2004. The harbor seal is not listed under the ESA and the California stock is not considered depleted or strategic under the MMPA (Carretta *et al.,* 2010).

California Sea Lion

The California sea lion is a full species, separate from the Galapagos sea lion (*Zalophus wollebaeki*) and the extinct Japanese sea lion (*Zalophus japonicus*) (Brunner, 2003; Wolf *et al.,* 2007; Schramm *et al.,* 2009). This species of sea lion is found from southern Mexico to southwestern Canada. The breeding areas of the California sea lion are on islands located in southern California, western Baja California, and the Gulf of California. A genetic analysis of California sea lions identified five genetically distinct geographic populations: (1) Pacific Temperate, (2) Pacific Subtropical, (3) Southern Gulf of California, (4) Central Gulf of California, and (5) Northern Gulf of California (Schramm *et al.,* 2009). In that study, the Pacific Temperate population included rookeries within U.S. waters and the Coronados Islands just south of U.S./Mexico border. Animals from the Pacific Temperate population range north into Canadian waters, and movement of animals between U.S. waters and Baja California waters has been documented, though the distance between the major U.S. and Baja California rookeries is at least 740.8 km (400 nmi). Males from western Baja California rookeries may spend most of the year in the United States.

The entire California sea lion population cannot be counted because all age and sex classes are never ashore at the same time. In lieu of counting all sea lions, pups are counted during the

breeding season (because this is the only age class that is ashore in its entirety), and the numbers of births is estimated from the pup count. The size of the population is then estimated from the number of births and the proportion of pups in the population. Censuses are conducted in July after all pups have been born. There are no rookeries at or near the Children's Pool, although in the past two years births have been reported at La Jolla Cove (about 0.75 km [0.47 miles] east of Children's Pool). Population estimates for the U.S. stock of California sea lions range from a minimum of 153,337 to an average estimate of 296,750 animals. They are considered to be at carrying capacity of the environment. The California sea lion is not listed under the ESA and the U.S. stock is not considered depleted or strategic under the MMPA.

Northern Elephant Seal

Northern elephant seals breed and give birth in California (U.S.) and Baja California (Mexico), primarily on offshore islands (Stewart *et al.,* 1994) from December to March (Stewart and Huber, 1993). Spatial segregation in foraging areas between males and females is evident from satellite tag data (Le Beouf *et al.,* 2000). Males migrate to the Gulf of Alaska and western Aleutian Islands along the continental shelf to feed on benthic prey, while females migrate to pelagic areas in the Gulf of Alaska and the central North Pacific to feed on pelagic prey (Le Beouf *et al.,* 2000). Adults return to land between March and August to molt, with males returning later than females. Adults return to their feeding areas again between their spring/summer molting and their winter breeding seasons.

Populations of northern elephant seals in the U.S. and Mexico have recovered after being nearly hunted to extinction (Stewart *et al.,* 1994). Northern elephant seals underwent a severe population bottleneck and loss of genetic diversity when the population was reduced to an estimated 10 to 30 individuals (Hoelzel *et al.,* 2002). However, movement and genetic exchange continues between rookeries when they start breeding (Huber *et al.,* 1991). The California breeding population is now demographically isolated from the Baja California population. The California breeding population is considered in NMFS's stock assessment report to be a separate stock.

A complete population count of elephant seals is not possible because all age classes are not ashore simultaneously. Elephant seal population size is typically estimated by counting the number of pups produced and multiplying by the inverse of the expected ratio of pups to total animals (McCann, 1985). Based on counts of elephant seals at U.S. rookeries in 2010, Lowry *et al.* (2014) reported that 40,684 pups were born. Lowry *et al.* (2014) applied a multiplier of 4.4 to extrapolate from total pup counts to a population estimate of approximately 179,000 elephant seals. This multiplier is derived from life tables based on published elephant seal fecundity and survival rates, and reflects a population with approximately 23% pups (Cooper and Stewart, 1983; Le Boeuf and Reiter, 1988; Hindell 1991; Huber *et al.,* 1991; Reiter and Le Boeuf, 1991; Clinton and Le Boeuf, 1993; Le Boeuf *et al.,* 1994; Pistorius and Bester, 2002; McMahon et al., 2003; Pistorius *et al.,* 2004; Condit *et al.,* 2014). The minimum population size for northern elephant seals in 2010 can be estimated very conservatively as 81,368, which is equal to twice the observed pup count (to account for the pups and their mothers). The population is reported to have grown at 3.8% annually since 1988 (Lowry *et al.,* 2014). Northern elephant seals are not listed under the ESA and are not considered as depleted or a strategic stock under the MMPA.

Further information on the biology and local distribution of these marine mammal species and others in the region can be found in the City of San Diego's IHA application, which is available upon request (see **ADDRESSES**), and the NMFS Marine Mammal Stock Assessment Reports, which are available online at: *http://www.nmfs.noaa.gov/pr/sars/.*

Potential Effects of the Proposed Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that the types of stressors associated with the proposed specified activity (*e.g.,* construction equipment and activities) have been observed to impact marine mammals. This discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of take (for example, with acoustics), we may include a discussion of studies that showed animals not reacting at all to sound or exhibiting barely measureable avoidance). This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented, or how either of those will shape the anticipated impacts from this specific activity. The ''Estimated Take by Incidental Harassment'' section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis'' section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, the ''Proposed Mitigation'' section, and the ''Anticipated Effects on Marine Mammal Habitat'' section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been derived using auditory evoked potentials, anatomical modeling, and other data, Southall *et al.* (2007) designate ''functional hearing groups'' for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- Low-frequency cetaceans (13 species of mysticetes): functional hearing is estimated to occur between approximately 7 Hz and 30 kHz;
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (eight species of true porpoises, six species of river dolphins, *Kogia* spp., the franciscana (*Pontoporia blainvillei*), and four species of cephalorhynchids): functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and
- Phocid pinnipeds in water: functional hearing is estimated to occur between approximately 75 Hz and 100 kHz;
- Otariid pinnipeds in water: functional hearing is estimated to occur between approximately 100 Hz and 40 kHz.

As mentioned previously in this document, 3 marine mammal species (0

cetacean and 3 pinniped species) are likely to occur in the proposed action area. Of the 3 pinniped species likely to occur in the City of San Diego's proposed action area, 2 are classified as phocid pinnipeds (*i.e.,* Pacific harbor seal and northern elephant seal) and, 1 is classified as an otariid pinniped (*i.e.,* California sea lion) (Southall *et al.,* 2007). The City of San Diego requests authorization for Level B harassment of these 3 species of marine mammals (*i.e.,* Pacific harbor seals, California sea lions, and northern elephant seals) incidental to the use of equipment and its propagation of in-air noise from various acoustic mechanisms associated with the construction activities of the Children's Pool Lifeguard Station at La Jolla, CA discussed above. NMFS considers a species' functional hearing group when we analyze the effects of exposure to sound on marine mammals.

The notice of the proposed IHA (79 FR 8160, February 11, 2014) included a discussion of the effects of in-air sounds from construction activities on pinnipeds, which included tolerance, behavioral disturbance, and hearing impairment. NMFS refers readers to the City of San Diego's IHA application and NMFS's EA for additional information on the behavioral reactions (or lack thereof) by all types of marine mammals to high levels of in-air sounds.

The potential effects to marine mammals described in this section of the document generally do not take into consideration the monitoring and mitigation measures described later in this document (see the ''Proposed Mitigation'' and ''Proposed Monitoring and Reporting'' sections), which are designed to effect the least practicable impact on affected marine mammal species or stocks.

Anticipated Effects on Marine Mammal Habitat

The rocks and beaches at or near the Children's Pool in La Jolla, CA, are almost exclusively Pacific harbor seal hauling-out sites. Harbor seals have been observed hauling-out and documented giving birth at the Children's Pool since the 1990's (Yochem and Stewart, 1998; Hanan & Associates, 2004). It is one of the three known haul-out sites for this species in San Diego County and is the only rookery in San Diego County and the only mainland rookery on the U.S. west coast between the border of Mexico and Point Mugu in Ventura County, CA. More information on this population of Pacific harbor seals can be found in the ''Description of Marine Mammals in the Specified Geographic Area of the Proposed Specified Activity.''

The primary anticipated adverse impacts upon habitat consist of temporary changes to the in-air acoustic environment, as detailed in the notice of the proposed IHA (79 FR 8160, February 11, 2014). These changes are minor, temporary, and limited in duration to the period of the construction activities. The temporary impacts on the acoustic environment are not expected to have any permanent effects on the species or stock populations of marine mammals occurring at the Children's Pool.

All proposed construction activities are beyond or outside the habitat areas where harbor seals and other pinnipeds are found. Visual barriers would be erected to shield construction activities from the visual perception and potentially dampen acoustic effects on pinnipeds. Because the public occasionally harasses the harbor seals with various activities, the NMFS-qualified PSO monitoring the site would make observations and attempt to distinguish and attribute any observed harassment to the public or to the proposed construction activities and give all details in the observation report. If any short-term, temporary impacts to habitat due to sounds or visual presence of equipment and workers did occur, the City of San Diego would expect pinniped behavior to return to pre-construction conditions soon after the activities are completed, which is anticipated to occur before the next pupping season (Hanan & Associates, 2011).

The area of habitat affected is small and the effects are localized and temporary; thus there is no reason to expect any significant reduction in habitat available for foraging and other habitat uses. No aspect of the project is anticipated to have any permanent effect on the location or use of pinniped haul-outs or related habitat features in the area (Hanan & Associates, 2011). Further, the site is already very disturbed by member of the public who come to the area during the day and night to view the pinnipeds. The City of San Diego and NMFS do not project any loss or modification of physical habitat for these species. Any potential temporary loss or modification of habitat due to in-air noise or visual presence of equipment and workers during the proposed construction activities is expected by the City of San Diego and NMFS to be quickly restored after construction activities end and all equipment and barriers are removed.

For these reasons, NMFS anticipates that the proposed action would result in no impacts to marine mammal habitat beyond rendering the areas immediately around the Children's Pool less desirable during construction activities.

Proposed Mitigation

In order to issue an Incidental Take Authorization (ITA) under section 101(a)(5)(D) of the MMPA, NMFS must prescribe, where applicable, the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

The City of San Diego has established the Children's Pool as a shared beach for pinnipeds and people (except during pupping season when the beach has been closed to the public). In the past, during the pupping season, a rope was placed along the upper part of the beach with signage to inform and designate how close people can come to the haul-out area and the pinnipeds. The timeframe for the rope has been extended so that it is now present year-round. The construction activities are planned to occur outside the harbor seal pupping and weaning periods.

The City of San Diego would implement the following proposed mitigation measures to help ensure the least practicable impact on marine mammals:

(1) Prohibition of construction during pupping season;

(2) Daily construction timing;

(3) Construction of visual and acoustic barriers;

(4) Use of Protected Species Observers;

(5) Establishment of buffer zones; and

(6) Potential abandonment survey.

Visual and acoustic barriers were constructed in 2013 to mitigate the effects of the construction activities. The visual and acoustic barriers were constructed of plywood, 1.2 to 2.4 m (4 to 8 ft) tall stood on end and held up by wood posts. The sheets of plywood were stood upright and held up with two wooden two by fours hinged to the top of the frame, so they could be collapsed and moved depending on the location and need for access by demolition and construction equipment. The barriers were placed at the site with input from NMFS Southwest Regional Office (SWRO) personnel so that they will hide as advantageously as possible the construction activities that may be seen by pinnipeds. The barriers appear to dampen the acoustic sound sources, but do not prevent sound from permeating the environment. The

barriers also appear to hide and reduce visual cues that may stimulate behavioral reactions from the pinnipeds on the beach below. As the site is a beach with construction along the cliff and on flat areas above the cliff, a complete barrier cannot be constructed to hide all construction activities for the project. Once the walls of the lifeguard station's building are in place, much of the construction activities will take place above the Children's Pool beach (*i.e.,* out of sight) as well as inside the building (*i.e.,* a visual and partial sound barrier). There would be no activities in the ocean or closer to the water's edge and since harbor seals mate underwater in the ocean, there will be no impacts on mating activities. California sea lions and northern elephant seals are such infrequent users of this area and their rookeries are so far away (at least 104.6 km [65 miles] at offshore islands) that there will be no adverse impact on these species.

As part of the public comment process for the issuance of the previous 2013 IHA, NMFS modified several of the monitoring and mitigation measures included in the proposed IHA (78 FR 25958, May 3, 2013) for practicability reasons, and also included several additional measures in the final IHA (78 FR 40705, July 8, 2013). These included changing the pupping season from December 15th to May 15th and prohibiting construction activities during this time; extending construction activities from 7:00 a.m. to 7:00 p.m. to help assure that more work would be completed during the 2013 construction window; continuing monitoring for 60 days following the end of construction activities; and triggering a shut-down of construction activities in the unexpected event of abandonment of the Children's Pool site. The mitigation measure on scheduling the heaviest construction activities (with the highest sound levels) during the annual period of lowest haul-out occurrence (October to November) was originally included in the City of San Diego's Mitigated Negative Declaration when it was anticipated that the City of San Diego would obtain an IHA in the summer of 2012 and begin demolition and construction activities in the fall of 2012. This requirement has been removed because it is no longer practicable due to logistics, scheduling and to allow the planned activities to be completed before the next pupping season.

The activities proposed by the applicant includes a variety of measures calculated to minimize potential impacts on marine mammals, including:

Prohibition of Construction During Pupping Season

Construction shall be prohibited during the Pacific harbor seal pupping season (December 15th to May 15th) and for an additional two weeks thereafter to accommodate lactation and weaning of late season pups. Thus, construction shall be prohibited from December 15th to June 1st.

Daily Construction Timing

Construction activities shall be scheduled, to the maximum extent practicable, during the daily period of lowest haul-out occurrence, from approximately 8:30 a.m. to 3:30 p.m. However, construction activities may be extended from 7 a.m. to 7 p.m. to help assure that the project can be completed during the 2015 construction window. Harbor seals typically have the highest daily or hourly haul-out period during the afternoon from 3 p.m. to 6 p.m.

Construction of Visual and Acoustic Barriers

A visual and acoustic barrier would be erected and maintained for the duration of the project to shield construction activities from beach view. The temporary barrier shall consist of ½ to ¾ inch (1.3 to 1.9 centimeters [cm]) plywood constructed 1.8 to 2.4 m (6 to 8 ft) high depending on the location. The City of San Diego does not believe that a complete barrier can be constructed to hide all of the proposed construction activities. Once the walls of the lifeguard station building are in place, much of the proposed construction activities would take place on the bluff above the beach (thus out of sight) and inside the building, which would provide a visual and partial sound barrier.

Protected Species Observers

Trained PSOs would be used to detect, document, and minimize impacts (*i.e.,* possible shut-down of noise-generating operations [turning off the equipment so that in-air sounds associated with construction no longer exceed levels that are potentially harmful to marine mammals]) to marine mammals. More information about this measure is contained in the ''Proposed Monitoring'' section (below).

Establishment of Buffer Zones

The City of San Diego shall establish buffer zones (*i.e.,* where sound pressure levels are at or above 90 dB re 20 μPa for harbor seals and/or at or above 100 dB re 20 μPa for all pinniped species except harbor seals [for in-air noise]) around the construction activities so that in-air sounds associated with the construction activities no longer exceed levels that are potentially harmful to marine mammals.

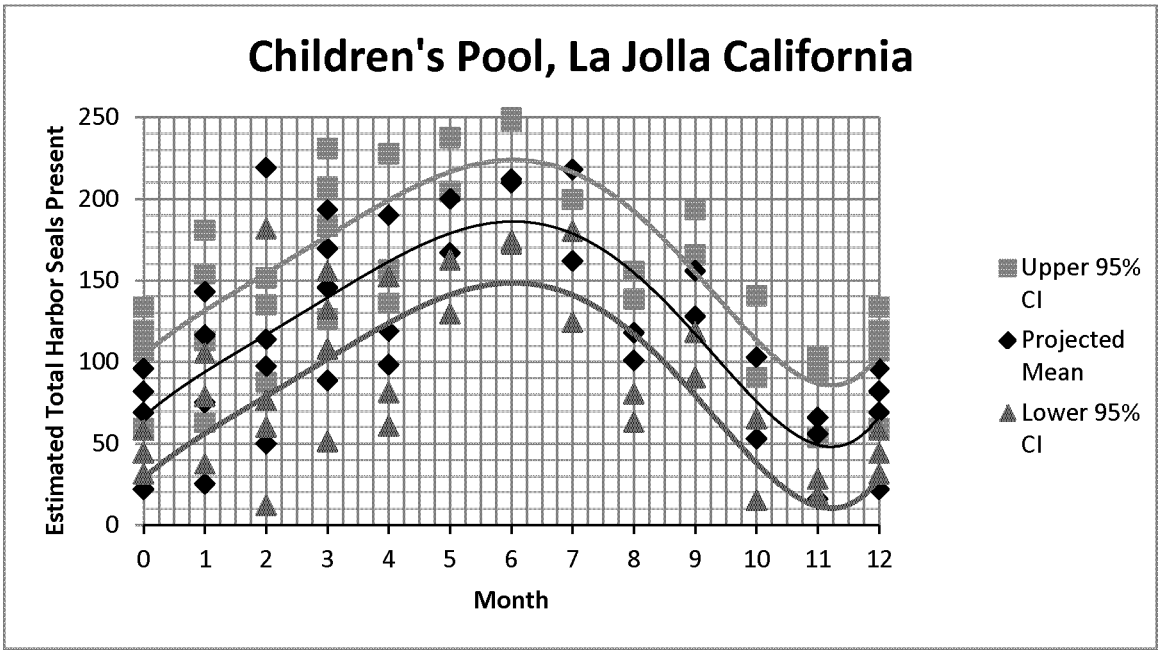
Timing Constraints for In-Air Noise

To minimize in-air noise impacts on marine mammals, construction activities shall be limited to the period when the species of concern would be least likely to be in the project area. The construction window for construction activities shall be from June 1 to December 15, 2015. The IHA may extend to June 1 through June 27, 2016 to finish the construction activities if needed. Avoiding periods when the highest number of marine mammal individuals are in the action area is another mitigation measure to protect marine mammals from the proposed construction activities.

Potential Abandonment Survey

After the first two months of monitoring during construction activities, the City of San Diego will take the mean number of observed harbor seals at the Children's Pool in a 24-hour period across that two months and compare it to the mean of the lower 95 percent confidence interval in Figure 1 (see below). If the observed mean is lower, the City of San Diego would shut-down construction activities and work with NMFS and other harbor seal experts (*e.g.,* Mark Lowry, Dr. Sarah Allen, Dr. Pamela Yochem, and/or Dr. Brent Stewart) to develop and implement a revised mitigation plan to further reduce the number of takes and potential impacts. Once a week every week thereafter, the City of San Diego will take the same mean of observed harbor seals across the previous three tide cycles (a tide cycle is approximately 2 weeks) and compare it to the 95% lower confidence interval in Figure 1 for the same time period. If the observed mean is lower, the City of San Diego would shut-down and take the action described above. If abandonment of the site is likely, monitoring would be expanded away from the Children's Pool to determine if animals have been temporarily displaced to known haul-out sites in the southern California area (*e.g.,* north end of Torrey Pines, cave on the exposed ocean side of Point Loma, etc.). For the purpose of this action, NMFS will consider the Children's Pool site to possibly be abandoned if zero harbor seals are present each day during the daytime and nighttime hours for at least three tide cycles (a tide cycle is approximately 2 weeks), but this cannot be confirmed until observations continue to be zero during a full pupping and molting season.

Figure 1. Estimated total harbor seals by month based on counts at the site by Hanan & Associates, Yochem and Stewart, and Children's Pool docents. The polynomial curve fits to counts by months, which includes the projected mean as well as the upper 95% and lower 95% confidence intervals, was used to estimate harbor seals expected to be hauled-out by day.



More information regarding the City of San Diego's monitoring and mitigation measures for the proposed construction activities at the Children's Pool Lifeguard Station can be found in the IHA application.

Proposed Mitigation Conclusions

NMFS has carefully evaluated the applicant's mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. NMFS's evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the activity.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels from construction equipment, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(3) A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels from construction equipment, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(4) A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels from construction equipment, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).

(5) Avoidance of minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on NMFS's evaluation of the applicant's proposed measures, as well as other measures considered by NMFS or recommended by the public, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104 (a)(13) require that requests for ITAs include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

(1) An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

(2) An increase in our understanding of how many marine mammals are likely to be exposed to levels from construction equipment that we associate with specific adverse effects, such as behavioral harassment, TTS or PTS;

(3) An increase in our understanding of how marine mammals respond to stimuli expected to result in take and how anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information);
- Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict receive level, distance from the source, and other pertinent information);
- Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli;

(4) An increased knowledge of the affected species; and

(5) An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Proposed Monitoring

The City of San Diego has developed a monitoring plan (see Appendix I, Mitigated Negative Declaration in the IHA application) based on discussions between the project biologist, Dr. Doyle Hanan, and NMFS biologists. The plan has been vetted by City of San Diego planners and reviewers. The plan has been formally presented to the public for review and comment. The City of San Diego has responded in writing and in public testimony (see City of San Diego Council Hearing, December 14, 2011) to all public concerns.

The monitoring plan involves surveying prior to construction activities, monitoring during construction activities by NMFS-approved PSOs with high-resolution binoculars and handheld digital sound level meters (measuring devices in the 30 to 130 dB re 20 μPa range), and post-construction monitoring. The City of San Diego would include sound measurements at and near the construction site in their initial survey prior to the activities as a background and baseline for the project. While no specific acoustic study is planned, the City of San Diego's Mitigated Negative Declaration states that marine mammal monitoring shall be conducted for three to five days prior to construction and shall include hourly systematic counts of pinnipeds using the beach, Seal Rock, and associated reef areas. Monitoring three to five days prior to construction will provide baseline data regarding recent haul-out behavior and patterns as well as background noise levels near the time of the proposed construction activities.

During the proposed construction activities, monitoring shall assess behavior and potential behavioral responses to construction noise and activities. PSOs would observe the proposed construction activities from a station along the breakwater wall and from the base of the cliff below the construction area. PSOs would be on site approximately 30 minutes before the start of proposed construction activities and would remain on site until 30 minutes after activities have ceased. Visual digital recordings and photographs shall be used to document individuals and behavioral responses to construction. The City of San Diego (*i.e.,* PSOs) plans to make hourly counts of the number of pinnipeds present and record sound or visual events that result in behavioral responses and changes, whether during construction or from public stimuli. During these events, pictures and video will also be taken when possible. The ''Mitigated Negative Declaration'' states ''monitoring shall assess behavior and potential behavioral responses to construction noise and activities. Visual digital recordings and photographs shall be used to document individuals and behavioral responses to construction.''

Monitors would have authority to stop construction as necessary depending on sound levels, pinniped presence, and distance from sound sources. Daily monitoring reports would be maintained for periodic summary reports to the City of San Diego and to NMFS. Observations would be entered into and maintained on Hanan & Associates computers. The City of San Diego plans to follow the reporting requirements in the Mitigated Negative Declaration, which states that ''the biologist shall document field activity via the Consultant Site Visit Record. The Consultant Site Visit Record shall be either emailed or faxed to the City of San Diego's Mitigation Monitoring Coordination process (MMC) on the 1st day of monitoring, the 1st week of each month, the last day of monitoring, and immediately in the case of any undocumented discovery. The project biologist shall submit a final construction monitoring report to MMC within 30 days of construction completion.'' The MMC ''coordinates the monitoring of development projects and requires that changes are approved and implemented to be in conformance with the permit requirements and to minimize any damage to the environment.'' These documents will also be sent to NMFS. Finally, the City of San Diego has modified its monitoring program to include 60 days of monitoring post-construction activities. Following construction, the City of San Diego would have a program of onsite PSOs that would randomly select a day per week to monitor.

NMFS notes that the WAN's La Jolla Harbor Seal Webcam was attached to the old (now demolished) lifeguard station and is no longer available online (*http://www.wanconservancy.org/la_jolla_harbor_seal_earthcam.htm). The City of San Diego has stated that there is no suitable place to mount the camera at the construction site.* Therefore, the City of San Diego cannot do periodic checks using the webcam for monitoring purposes as required by the 2013 IHA.

However, the camera was not expected to replace NMFS-qualified PSOs at the site making accurate counts, measuring sound levels and observing the public and the construction, as well as the harbor seals. In the old camera view, a person may have been able to see visual evidence of Level B harassment but probably would not have been able to distinguish between harassment from construction activities and harassment from the public since the camera had a limited scope and only showed the Children's Pool beach and pinnipeds (usually a specific portion of the beach, but not the reef nor nearby beaches).

Consistent with NMFS procedures, the following marine mammal monitoring and reporting shall be performed for the proposed action:

(1) The PSO shall be approved by NMFS prior to construction activities.

(2) The NMFS-approved PSO shall attend the project site prior to, during, and after construction activities cease each day throughout the construction window.

(3) The PSO shall search for marine mammals within the Children's Pool area.

(4) The PSO shall be present during construction activities to observe for the presence of marine mammals in the vicinity of the specified activity. All such activity would occur during daylight hours (*i.e.,* 30 minutes after sunrise and 30 minutes before sunset). If inclement weather limits visibility within the area of effect, the PSO would perform visual scans to the extent conditions allow.

(5) If marine mammals are sighted by the PSO within the acoustic threshold areas, the PSO shall record the number of marine mammals within the area of effect and the duration of their presence while the noise-generating activity is occurring. The PSO would also note whether the marine mammals appeared to respond to the noise and, if so, the nature of that response. The PSO shall record the following information: Date and time of initial sighting, tidal stage, weather conditions, Beaufort sea state, species, behavior (activity, group cohesiveness, direction and speed of travel, etc.), number, group composition, distance to sound source, number of animals impacted, construction activities occurring at time of sighting, and monitoring and mitigation measures implemented (or not implemented). The observations would be reported to NMFS.

(6) A final report would be submitted summarizing all in-air acoustic effects from construction activities and marine mammal monitoring during the time of the authorization, and any long term impacts from the project.

A written log of dates and times of monitoring activity will be kept. The log shall report the following information:

- Time of observer arrival on site;
- Time of the commencement of in-air noise generating activities, and description of the activities;
- Distances to all marine mammals relative to the sound source;
- Distances from the sound meter to each sound-producing activity when conducting sound measurements;
- For harbor seal observations, notes on seal behavior during noise-generating activity, as described above, and on the number and distribution of seals observed in the project vicinity;
- For observations of all marine mammals other than harbor seals, the time and duration of each animal's presence in the project vicinity; the number of animals observed; the behavior of each animal, including any response to noise-generating activities;
- Time of the cessation of in-air noise generating activities; and
- Time of observer departure from site.

All monitoring data collected during construction would be included in the biological monitoring notes to be submitted. A final report summarizing the construction monitoring and any general trends observed would also be submitted to NMFS within 90 days after monitoring has ended during the period of the lifeguard station construction.

Proposed Reporting

The City of San Diego would notify NMFS Headquarters and the NMFS Southwest Regional Office prior to initiation of the construction activities. A draft final report must be submitted to NMFS within 90 days after the conclusion of the construction activities of the Children's Pool Lifeguard Station. The report would include a summary of the information gathered pursuant to the monitoring requirements set forth in the IHA, including dates and times of operations and all marine mammal sightings (dates, times, locations, species, behavioral observations [activity, group cohesiveness, direction and speed of travel, etc.], tidal stage, weather conditions, Beaufort sea state and wind force, associated construction activities). A final report must be submitted to the Regional Administrator within 30 days after receiving comments from NMFS on the draft final report. If no comments are received from NMFS, the draft final report would be considered to be the final report.

While the IHA does not authorize injury (*i.e.,* Level A harassment), serious injury, or mortality, should the applicant, contractor, monitor or any other individual associated with the construction project observe an injured or dead marine mammal, the incident (regardless of cause) will be reported to NMFS as soon as practicable. The report should include species or description of animal, condition of animal, location, time first found, observed behaviors (if alive) and photo or video, if available.

In the unanticipated event that the City of San Diego discovers a live stranded marine mammal (sick and/or injured) at Children's Pool, they shall immediately contact Sea World's stranded animal hotline at 1–800–541–7235. Sea World shall also be notified if a dead stranded pinniped is found so that a necropsy can be performed. In all cases, NMFS shall be notified as well, but for immediate response purposes, Sea World shall be contacted first.

Reporting Prohibited Take—In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury, or mortality, the City of San Diego shall immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov, Howard.Goldstein@noaa.gov,* and the West Coast Regional Stranding Coordinator (562–980–3230). The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- The type of activity involved;
- Description of the circumstances during and leading up to the incident;
- Status of all sound source use in the 24 hours preceding the incident; water depth; environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of marine mammal observations in the 24 hours preceding the incident; species identification or description of the animal(s) involved;
- The fate of the animal(s); and photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with the City of San Diego to determine the action necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The City of San Diego may not resume its activities until notified by NMFS via letter, email, or telephone.

Reporting an Injured or Dead Marine Mammal with an Unknown Cause of Death—In the event that the City of San Diego discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), the City of San Diego would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov, Howard.Goldstein@noaa.gov,* and the NMFS West Coast Regional Office (1–866–767–6114), and/or to the West Coast Regional Stranding Coordinator (562–980–3230). The report must include the same information identified above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS would work with the City of San Diego to determine whether modification of the activities is appropriate.

Reporting an Injured or Dead Marine Mammal Not Related to the Activities—In the event that the City of San Diego discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the City of San Diego shall report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov, Howard.Goldstein@noaa.gov,* and the NMFS West Coast Regional Office (1–866–767–6114) and/or to the West Coast Regional Stranding Coordinator (562–980–3230) within 24 hours of the discovery. The City of San Diego shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Activities may continue while NMFS reviews the circumstances of the incident.

Monitoring Results From Previously Authorized Activities

2013 to 2014

Hanan & Associates, Inc., on behalf of the City of San Diego, conducted marine mammal and in-air sound monitoring at six locations during demolition and construction activities at the Children's Pool Lifeguard Station in La Jolla, California from June 3, 2013 to February 12, 2014. Demolition and construction activities began on July 10, 2013 and were halted for the Pacific harbor seal pupping season (December 15, 2013 to June 1, 2014). During 115 days of visual and acoustic observations, Hanan & Associates counted a total of 61,631 Pacific harbor seals and 26,037 people. During the 2013 demolition and construction activities, Hanan & Associates observed a total of 15,673 takes by Level B harassment (*i.e.,* alerts, movements, and flushes) that could be attributed to demolition and construction activities (5,095 takes), the general public (8,639 takes), and other sources (1,939 takes). As of April 15, 2014, at least 60 harbor seal pups (including 2 still births) have been born at the Children's Pool and there has been no indication of abandonment. In addition to the Pacific harbor seal sightings, PSOs recorded 11 sightings of cetaceans (gray whales and bottlenose dolphins), 4 sightings of California sea lions (1 juvenile, 3 adult), and 2 northern elephant seals (both juveniles) at the Children's Pool.

Hanan & Associates recorded mean in-air sound levels of 69.2 dB re 20 μPa (range of 55.6 to 93.7 dB re 20 μPa) during non-demolition and construction activities and 70.3 dB re 20 μPa (range of 50.7 to 103.1 dB re 20 μPa) during demolition and construction activities. During 2013, measured sound levels from the demolition equipment reaching the pinnipeds did not exceed approximately 90 dB re 20 μPa at the haul-out area closest to the demolition and construction activities, nor did they exceed a peak of about 83 dB re 20 μPa at the mean hauling-out distance (30.5 m).

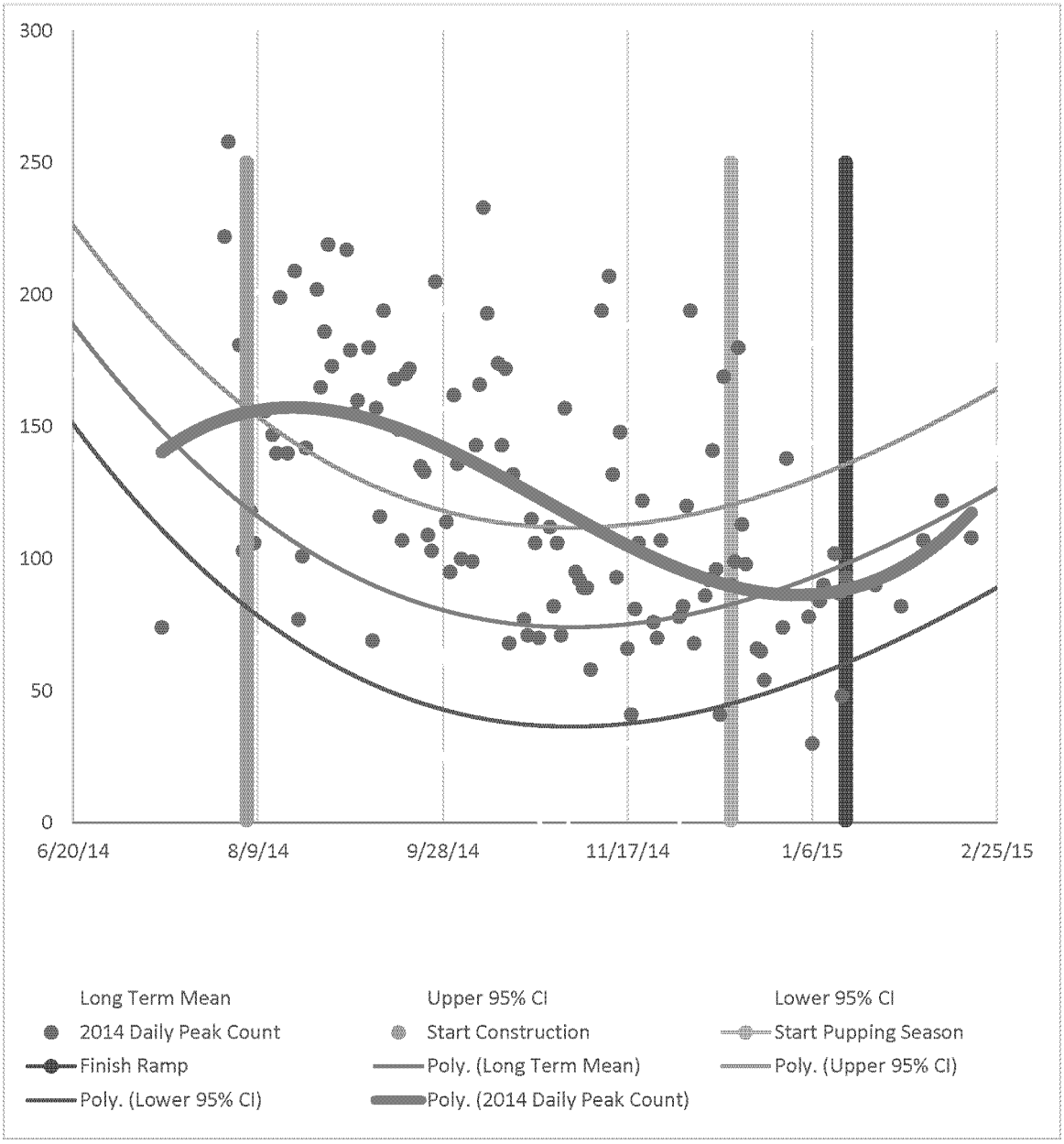
2014 to 2015

Hanan & Associates, Inc., on behalf of the City of San Diego, conducted marine mammal and in-air sound monitoring at seven locations during demolition and construction activities at the Children's Pool Lifeguard Station in La Jolla, California from August 6, 2014 to March 15, 2015. Construction activities began on August 6, 2014 and were halted for the Pacific harbor seal pupping season (December 15, 2014 to June 1, 2015). During 127 days of visual and acoustic observations, Hanan & Associates counted a total of 63,598 Pacific harbor seals and 27,844 people. During the 2014 demolition and construction activities, Hanan & Associates observed a total of 20,259 takes by Level B harassment (*i.e.,* alerts, movements, and flushes) that could be attributed to demolition and construction activities (7,424 takes), the general public (10,000 takes), and other sources (2,835 takes). As of March 13, 2015, at least 60 harbor seal pups (including 6 still or premature births) have been born at the Children's Pool and there has been no indication of abandonment. In addition to the Pacific harbor seal sightings, PSOs recorded 24 sightings of cetaceans (gray whales, common and bottlenose dolphins), 366 sightings of California sea lions (at Seal Rock, Children's Pool beach, South Casa Beach, and on the reef), and 1 northern elephant seals (1 juvenile on Children's Pool beach) at the Children's Pool. One dead adult and one dead juvenile California sea lion were sighted on the Children's Pool beach after the start of the beach closure and after the construction activities stopped for the pupping season. These strandings were reported to NMFS.

Hanan & Associates recorded mean in-air sound levels of 68.9 dB re 20 μPa (range of 51.5 to 97.2 dB re 20 μPa) during non-construction activities and 71.3 dB re 20 μPa (range of 49.4 to 102.7 dB re 20 μPa) during construction activities. During 2014, measured sound levels from the construction equipment reaching the pinnipeds did not exceed approximately 90 dB re 20 μPa at the haul-out area closest to the construction activities.

More information on the monitoring results from the City of San Diego's previous demolition and construction activities at the La Jolla Children's Pool Lifeguard Station can be found in the final monitoring reports. The 2013 to 2014 and 2014 to 2015 monitoring reports can be found online at: *http://www.nmfs.noaa.gov/pr/permits/incidental/construction.htm#childrenspool.*

Figure 2. Daily peak counts and long-term trends with a 95% confidence interval of Pacific harbor seals at Children's Pool from June 2014 to February 2015 based on monitoring at the site by Hanan & Associates.



Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

TABLE 2—NMFS'S CURRENT UNDERWATER AND IN-AIR ACOUSTIC EXPOSURE CRITERIA

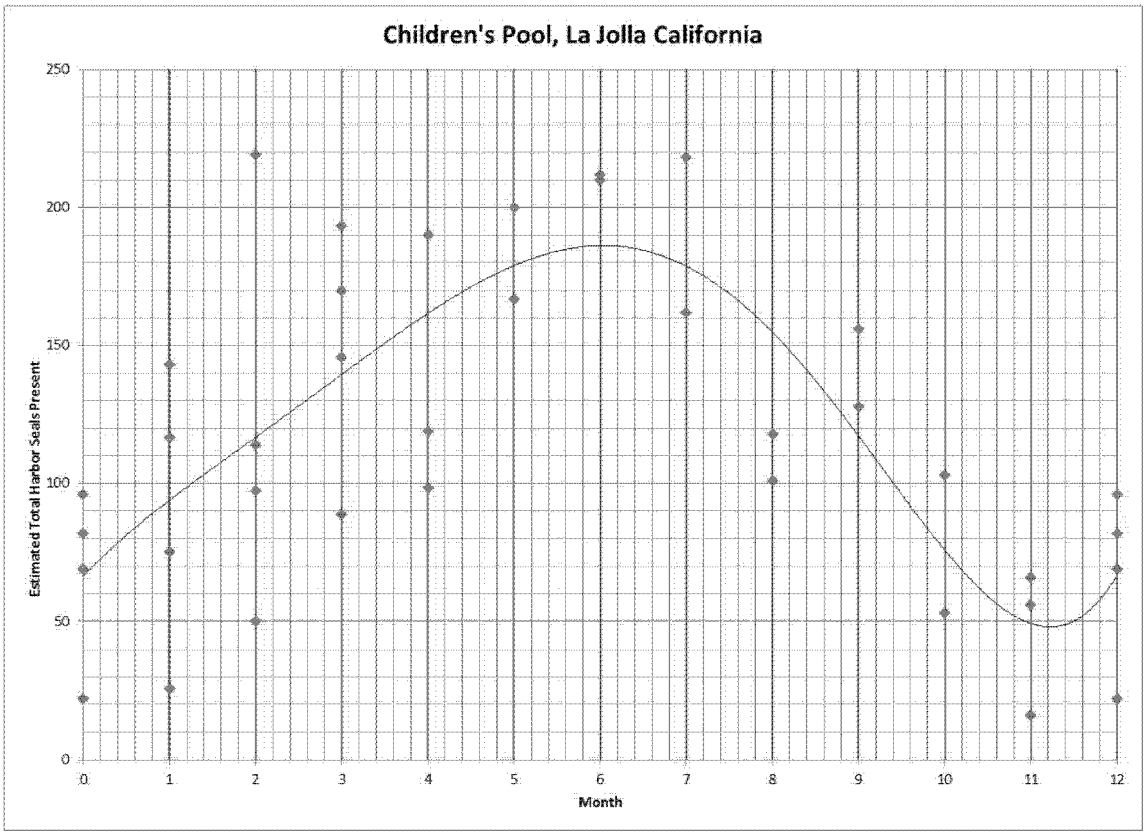
Criterion	Criterion definition	Threshold
Underwater Impulsive (Non-Explosive) Sound		
Level A harassment (injury)	Permanent threshold shift (PTS) (Any level above that which is known to cause TTS).	180 dB re 1 μPa-m (root means square [rms]) (cetaceans). 190 dB re 1 μPa-m (rms) (pinnipeds).
Level B harassment	Behavioral disruption (for impulsive noise)	160 dB re 1 μPa-m (rms).
Level B harassment	Behavioral disruption (for continuous noise)	120 dB re 1 μPa-m (rms).
In-Air Sound		
Level A harassment	NA	NA.
Level B harassment	Behavioral disruption	90 dB re 20 μPa (harbor seals). 100 dB re 20 μPa (all other pinniped species). NA (cetaceans).

NA = Not available or not assessed.

The City of San Diego and NMFS anticipate takes of Pacific harbor seals, California sea lions, and northern elephant seals by Level B (behavioral) harassment only incidental to the construction project at the Children's Pool. No takes by injury (Level A harassment), serious injury, or mortality are expected. NMFS will consider pinnipeds behaviorally reacting to the construction activities by flushing into the water, moving more than 1 m (3.3 ft), but not into the water; becoming alert and moving, but not moving more than 1 m; and changing direction of current movements by individuals as behavioral criteria for take by Level B harassment.

With proposed construction activities scheduled to begin in June 2015, the City of San Diego expects a range of 0 to 190 harbor seals to be present daily during June and a seasonal decline through November to about 0 to 50 harbor seals present daily. If all of the estimated harbor seals present are taken by incidental harassment each day, there could be a maximum of 10,000 takes (*i.e.,* approximately 2,947 adult males and 2,211 juvenile males, 2,842 adult females and 2,000 juvenile females based on age and sex ratios presented in Harkonen *et al.,* 1999) over the entire duration of the activities. An unknown portion of the incidental takes will be from repeated exposures as harbor seals leave and return to the Children's Pool area. A polynomial curve fit to counts by month was used by the City of San Diego to estimate the number of harbor seals expected to be hauled-out by day (see below and Figure 2 of the IHA application).

Figure 3. Estimated total harbor seals by month based on counts at the site by Hanan & Associates, Yochem and Stewart, and Children's Pool docents. The polynomial curve fits to counts by months was used to estimate harbor seals expected to be hauled-out by day.



Assuming the total seals predicted to haul-out daily at the Children's Pool are exposed to sound levels that are considered Level B harassment during days where sound is predicted to exceed 90 dB at the construction site (65 days), there could be a maximum of approximately 10,000 incidental takes (*i.e.,* exposures) of approximately up to 600 individual Pacific harbor seals over the duration of the activities. The estimated 600 individual Pacific harbor seals would be taken by Level B harassment multiple times during the proposed construction activities.

Very few California sea lions and/or northern elephant seals are ever observed at the Children's Pool (*i.e.,* one or two individuals). The City of San Diego requests the authority to incidentally take (*i.e.,* exposures) 10,000 Pacific harbor seals, 100 California sea lions, and 25 northern elephant seals, which will equate to 600, 2, and 1 individuals, respectively, being exposed multiple times. More information on the number of takes authorized, and the approximate percentage of the stock for the three species in the proposed action area can be found in Table 3 (below).

TABLE 3—SUMMARY OF THE AUTHORIZED INCIDENTAL TAKE BY LEVEL B HARASSMENT OF PINNIPEDS FOR THE CITY OF SAN DIEGO'S PROPOSED CONSTRUCTION ACTIVITIES GENERATING IN-AIR NOISE AT THE CHILDREN'S POOL LIFEGUARD STATION IN LA JOLLA, CA

Species	Take authorization (number of exposures)	Estimated number of individuals taken	Abundance	Approximate percentage of estimated stock (individuals)	Population trend
Pacific harbor seal	10,000	600	30,968—California stock	1.93	Increased in California 1981 to 2004.
California sea lion	100	2	296,750—U.S. stock	<0.01	Increasing.
Northern elephant seal	25	1	179,000—California breeding stock.	<0.01	Increasing 3.8% annually since 1988.

Encouraging and Coordinating Research

Each construction phase and potential harassment activity will be evaluated as to observed sound levels and any pinniped reaction by type of sound source. Flushing would be documented by sex and age class. These data will provide information for IHA permitting in future projects. Potential additional mitigation (other than what is already required) will be discussed and suggested in the final report. NMFS has encouraged the City of San Diego to review and analyze any available data to determine baseline information as well as evaluate the impacts from the construction activities on the pinnipeds at the Children's Pool.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) of the MMPA requires NMFS to determine that the authorization will not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. There are not relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for subsistence purposes.

Analysis and Preliminary Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

In making a negligible impact determination, NMFS evaluated factors such as:

(1) The number of anticipated injuries, serious injuries, or mortalities;

(2) The number, nature, and intensity, and duration of Level B harassment; and

(3) The context in which the takes occur (*i.e.,* impacts to areas of significance, impacts to local populations, and cumulative impacts when taking into account successive/contemporaneous actions when added to baseline data);

(4) The status of the stock or species of marine mammals (*i.e.,* depleted, not depleted, decreasing, increasing, stable, impact relative to the size of the population);

(5) Impacts on habitat affecting rates of recruitment/survival; and

(6) The effectiveness of monitoring and mitigation measures.

No injuries (Level A harassment), serious injuries, or mortalities are anticipated to occur as a result of the City of San Diego's construction activities, and none are authorized by NMFS. The proposed activities are not expected to result in the alteration of reproductive behaviors, and the potentially affected species would be subjected to only temporary and minor behavioral impacts.

Behavioral disturbance may potentially occur incidental to the visual presence of humans and construction activities; however, pinnipeds at this site have likely adapted or become acclimated to human presence at this site. These ''urbanized'' harbor seals do not exhibit sensitivity at a level similar to that noted in harbor seals in some other regions affected by human disturbance (Allen *et al.,* 1984; Suryan and Harvey, 1999; Henry and Hammil, 2001; Johnson and Acevedo-Gutierrez, 2007; Jansen *et al.,* 2006; Hanan & Associates, 2011). Therefore, there is a high likelihood that many of the harbor seals present during the proposed construction activities would not be flushed off of the beach or rocks, as pinnipeds at this site are conditioned to human presence and loud noises (Hanan, 2004; Hanan & Associates, 2011) (see *http://www.youtube.com/watch?v=4IRUYVTULsg*).

As discussed in detail above, the proposed project scheduling avoids sensitive life stages for Pacific harbor seals. Proposed project activities producing in-air noise will commence in June and end by December 15. The commencement date occurs after the end of the pupping season, affords additional time to accommodate lactation and weaning of season pups, and takes into account periods of lowest haul-out occurrence. The end date falls approximately two weeks prior to January 1, the time after which most births occur, providing protection for pregnant and nursing harbor seals that may give birth before January 1.

Table 3 of this document outlines the number of Level B harassment takes that are anticipated as a result of these proposed activities. Due to the nature, degree, and context of Level B (behavioral) harassment anticipated and described (see ''Potential Effects on Marine Mammals'' section above) in this notice, this activity is not expected to impact rates of annual recruitment or survival for the affected species or stock (*i.e.,* California stock of Pacific harbor seals, U.S. stock of California sea lions, and California breeding stock of northern elephant seals), particularly given the proposed mitigation, monitoring, and reporting measures that would be implemented to minimize impacts to marine mammals.

The Children's Pool is one of the three known haul-out sites for Pacific harbor seal in San Diego County and the only rookery in San Diego County and the only mainland rookery on the U.S. west coast for this species between the border of Mexico and Point Mugu in Ventura County, CA. For the other marine mammal species that may occur within the action area (*i.e.,* California sea lions and northern elephant seals), there are no known designated or important feeding and/or reproductive areas. Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (*i.e.,* 24 hour cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). However, Pacific harbor seals have been hauling-out at Children's Pool during the year for many years (including during pupping season and while females are pregnant) while being exposed to anthropogenic sound sources such as vehicle traffic, human voices, etc. and other stimuli from human presence. While studies have shown the types of sound sources used during the construction activities have the potential to displace marine mammals from breeding areas for a prolonged period (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007), based on the best available information, this does not seem to be the case for the Pacific harbor seals at the Children's Pool. The Pacific harbor seals have repeatedly hauled-out to pup over many years and the NMFS Stock Assessment Reports

(NMFS, 2011) for this stock have shown that the population is increasing and is considered stable. Additionally, the proposed construction activities would increase sound levels in the environment in a relatively small area surrounding the lifeguard station (compared to the range of the animals), and some animals may only be exposed to and harassed by sound for less than a day.

NMFS's practice has been to apply the 90 dB re 20 μPa and 100 dB re 20 μPa received level threshold for in-air sound levels to determine whether take by Level B harassment occurs. Southall *et al.* (2007) provide a severity scale for ranking observed behavioral responses of both free-ranging marine mammals and laboratory subjects to various types of anthropogenic sound (see Table 4 in Southall *et al.* [2007]). NMFS has not established a threshold for Level A harassment (injury) for marine mammals exposed to in-air noise, however, Southall *et al.* (2007) recommends 149 dB re 20 μPa (peak flat) as the potential threshold for injury from in-air noise for all pinnipeds. No in-air sounds from proposed construction activities would exceed 110 dB at the source and no measured sounds approached that sound level in 2013.

Of the 3 marine mammal species under NMFS jurisdiction that may or are known to likely occur in the action area, none are listed as threatened or endangered under the ESA. No incidental take has been requested to be authorized for ESA-listed species as none are expected to be within the action area. To protect these animals (and other marine mammals in the action area), the City of San Diego shall schedule construction activities with highest sound levels during the daily period of lowest haul-out occurrence; limit activities to the hours of daylight; erect a temporary visual and acoustic barrier; use PSOs and prohibit construction activities during harbor seal pupping season. No injury, serious injury, or mortality is expected to occur and due to the nature, degree, and context of the Level B harassment anticipated, the proposed activity is not expected to impact rates of recruitment or survival.

Although behavioral modifications, including temporarily vacating the area during the proposed construction activities, may be made by these species to avoid the resultant acoustic disturbance, the availability of alternate areas within these areas for species and the short and sporadic duration of the activities, have led NMFS to determine that the taking by Level B harassment from the specified activity would have a negligible impact on the affected species in the specified geographic region. NMFS believes that the time period of the proposed construction activities, the requirement to implement mitigation measures (*e.g.,* prohibiting construction activities during pupping season, scheduling operations to periods of the lowest haul-out occurrence, visual and acoustic barriers, and the addition of a new measure that helps protect against unexpected abandonment of the site), and the inclusion of the monitoring and reporting measures, will reduce the amount and severity of the potential impacts from the activity to the degree that will have a negligible impact on the species or stocks in the action area.

Based on the analysis contained herein of the likely effects of the proposed specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS finds that the total marine mammal take from the City of San Diego's activities would have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

As mentioned previously, NMFS estimates that 3 species of marine mammals under its jurisdiction could be potentially affected by Level B harassment over the course of the IHA. It is estimated that up to 600 individual Pacific harbor seals, 2 individual California sea lions, and 1 northern elephant seal would be taken (multiple times) by Level B harassment, which would be approximately 1.93, less than 0.01, and less than 0.01% of the respective California, U.S., and California breeding stocks. The population estimates for the marine mammal species that may be taken by Level B harassment were provided in Table 2 of this document.

NMFS has determined, provided that the aforementioned proposed mitigation and monitoring measures are implemented, that the impact of the proposed construction activities at the Children's Pool Lifeguard Station in La Jolla, CA, June 2015 to June 2016, may result, at worst, in a temporary modification in behavior and/or low-level physiological effects (Level B harassment) of small numbers of certain species of marine mammals. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed mitigation and monitoring measures, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks. See Table 2 for the proposed authorized take numbers of marine mammals.

Endangered Species Act

NMFS (Permits and Conservation Division) has determined that an ESA section 7 consultation for the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity is not necessary for any ESA-listed marine mammal species under its jurisdiction, as the proposed action would not affect ESA-listed species.

National Environmental Policy Act

To meet NMFS's National Environmental Policy Act (NEPA; 42 U.S. C. 4321 *et seq.*) requirements for the issuance of an IHA to the City of San Diego, NMFS prepared an Environmental Assessment (EA) in 2013 for a similar activity titled *Environmental Assessment on the Issuance of an Incidental Harassment Authorization to the City of San Diego to Take Marine Mammals by Harassment Incidental to Demolition and Construction Activities at the Children's Pool Lifeguard Station in La Jolla, California* to comply with the Council of Environmental Quality (CEQ) regulations and NOAA Administrative Order (NAO) 216–6. NMFS will evaluate the proposed action to determine whether the 2013 EA supports the City of San Diego's 2015 IHA request.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposed to issue an IHA to the City of San Diego for conducting construction activities at the Children's Pool Lifeguard Station in La Jolla, CA, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The duration of the IHA would not exceed one year from the date of its issuance. The proposed IHA language is provided below:

The City of San Diego, Public Works Department, Engineering and Capital Projects Branch, Architectural Engineering and Parks Division, 525 B Street, Suite 750, MS 908A, San Diego, California 92101, is hereby authorized under section 101(a)(5)(D) of the Marine Mammal Protection Act (16 U.S.C. 1371(a)(5)(D)), to harass small numbers of marine mammals incidental to the construction activities at the Children's Pool Lifeguard Station, June 2015 through June 2016, contingent upon the following conditions:

1. Effective Dates

This Authorization is valid from June 28, 2015 through June 27, 2016.

2. Specified Geographic Region

This Authorization is valid only for the construction activities at the Children's Pool Lifeguard Station that shall occur in the following specified geographic area:

The La Jolla Children's Pool Lifeguard Station at 827 ½ Coast Boulevard, La Jolla, California 92037 (32° 50′50.02″ North, 117°16′42.8″ West), as specified in the City of San Diego's IHA application.

3. Species Authorized and Level of Takes

(a) The incidental taking of marine mammals, by Level B harassment only, is limited to the following species in the La Jolla, California area:

(i) *Pinnipeds*—see Table 2 (above) for authorized species and take numbers.

(ii) If any marine mammal species are encountered during construction activities that are not listed in Table 3 (above) for authorized taking and are likely to be exposed to sound pressure levels (SPLs) at or above 90 decibels (dB) re 20 μPa for harbor seals and/or at or above 100 dB re 20 μPa for all pinniped species except harbor seals (for in-air noise), then the City of San Diego must shut-down operations to avoid take.

(b) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in Condition 3(a) above, or the taking of any kind of any other species of marine mammal, is prohibited and may result in the modification, suspension or revocation of this Authorization.

4. The methods authorized for taking by Level B harassment are limited to acoustic-generating equipment sources (*e.g.,* backhoe, dump truck, cement truck, air compressor, electric screw guns, jackhammer, concrete saw, chop saw, and hand tools) without an amendment to this Authorization:

5. Prohibited Take

The taking of any marine mammal in a manner prohibited under this Authorization must be reported immediately to the Office of Protected Resources, National Marine Fisheries Service (NMFS), at 301–427–8401.

6. Mitigation and Monitoring Requirements

The City of San Diego is required to implement the following mitigation and monitoring requirements when conducting the specified activities in order to achieve the least practicable adverse impact on affected marine mammal species or stocks:

Construction Prohibited During Pupping Season

(a) The construction activities shall be prohibited during the Pacific harbor seal pupping season at Children's Pool (December 15th to May 15th) and for an additional two weeks to accommodate lactation and weaning of late season pups. Thus, construction shall be prohibited from December 15th to June 1st.

Daily Construction Timing

(b) The construction activities shall be scheduled Monday through Friday; however, they may continue on weekends to ensure completion of the project in 2015. To the maximum extent practicable, the construction activities shall be conducted from approximately 8:30 a.m. to 3:30 p.m., during the daily period of lowest haul-out occurrence; however, construction activities may be extended from 7 a.m. to 7 p.m. (*i.e.,* daylight hours) to help assure that the project is completed during the 2015 construction window. Harbor seals typically have the highest daily or hourly haul-out period during the afternoon from 3 p.m. to 6 p.m.

Visual and Acoustic Barriers

(c) A visual and acoustic barrier will be erected and maintained for the duration of the project to shield construction activities from beach view. The temporary barrier shall consist of 1.3 to 1.9 centimeter (½ to ¾ inch) plywood constructed 1.2 to 2.4 meters (4 to 8 feet) high depending on the location. The barriers will be placed at the site with input from NMFS West Coast Regional Office personnel so that they will hide as advantageously as possible the construction activities that may be seen by pinnipeds.

Protected Species Observers

(d) A NMFS-qualified, trained Protected Species Observer (PSO) shall be used to detect, document, and minimize potential impacts from construction activities. The PSO shall attend the project site 30 minutes prior until 30 minutes after construction activities cease each day throughout the construction window. The PSO shall be approved by NMFS prior to construction activities. The PSO shall search for marine mammals using binoculars and/or the naked eye within the Level B (behavioral) harassment zones, which may vary upon the type of in-air sound being produced by the construction activities. The PSO will observe from a station along the breakwater wall as well as the base of the cliff below the construction area. If inclement weather limits visibility within the area of effect, the PSO will perform visual scans to the extent conditions allow. The PSO will not have to monitor on days or portions of days when there will be little chance of disturbance from construction activities (*e.g.,* nothing visual, sound levels at source less than 90 dB re 20 μPa, or all work activities inside the building).

(e) The PSO shall visually scan the action area for the presence of marine mammals at least 30 minutes prior to the start-up and continuously throughout periods of in-air noise-generating activities. Visual scans shall continue for at least 30 minutes after each noise-generating episode has ceased.

(f) The PSO shall use visual digital recordings and photographs to document individuals and behavioral responses to the construction activities. The PSO shall make hourly counts of the number of pinnipeds present and record sound or visual events that result in behavioral responses and changes, whether during construction activities or from public stimuli. During these events, pictures and videos will be taken when possible to document individuals and behavioral responses.

(g) A PSO shall record the following information when a marine mammal is sighted:

(i) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), distribution, bearing and distance relative to the sound source(s), group cohesiveness, duration of presence, apparent reaction to the construction activities (*e.g.,* none, avoidance, approach, etc.), direction and speed of travel, duration of presence, and if there are other causes of potential disturbance occurring;

(ii) Date, time, location, activity of construction operations, monitoring and mitigation measures implemented (or not implemented), tidal stage, weather conditions, Beaufort sea state, wind speed, visibility, and sun glare; and

(iii) The data listed under Condition 6(g)(ii) shall also be recorded at the start and end of each observation watch and during a watch whenever there is a change in one or more variables.

(h) A PSO shall also record the time of arrival and departure on site, commencement and cessation of in-air noise construction activities, and presence of humans on the beach. Whenever possible, the PSO should determine as to whether or not the harassment or pinnipeds is attributable

to the construction activities and/or the presence of the public on the beach and around the Children's Pool area. A PSO shall record the number of people on the beach and surrounding areas as well as their location relative to the animals.

Buffer Zones

(i) Buffer zones shall be established (*i.e.,* where sound pressure levels [SPLs] are at or above 90 decibels (dB) re 20 μPa for harbor seals and/or at or above 100 dB re 20 μPa for all pinniped species except harbor seals [for in-air noise]) around the construction activities so that in-air sounds associated with the construction activities no longer exceed levels that are potentially harmful to marine mammals.

In-Air Noise Monitoring

(j) In-air noise monitoring and reporting shall be performed during the construction activities at and near the Children's Pool Lifeguard Station. The PSO shall have access to handheld digital sound level measuring devices. The study will characterize in-air sound levels in the area related to (*e.g.,* construction equipment including backhoe, dump truck, cement truck, air compressor, electric screw guns, jackhammer, concrete saw, chop saw, and hand tools) and in the absence (as a background and baseline [*i.e.,* ambient] for the project) of all construction activities, and confirm or identify harassment isopleths for all types of and construction activities conducted. To better assess in-air sound propagation and source levels, the distance from the sound meter to each sound-producing activity when conducting sound measurements shall be noted. Monitoring shall be conducted three to five days prior to construction activities and shall include hourly systematic counts of pinnipeds using the beach, Seal Rock, and associated reef areas to provide baseline data regarding recent haul-out behavior and patterns as well as background noise levels near the time and construction activities. Monitoring shall continue for 60 days following the end of demolition and construction activities. Following construction, the City of San Diego will have a program where a PSO that will randomly select a day per week to visit the Children's Pool.

Potential Abandonment Survey

(k) After the first two months of monitoring during construction activities, the City of San Diego shall take the mean number of observed harbor seals at the Children's Pool in a 24-hour period across the two months and compare it to the mean of the lower 95 percent confidence interval in Figure 3 (see above). If the observed mean is lower, the City of San Diego shall shut-down construction activities and work with NMFS and other harbor seal experts (*e.g.,* Mark Lowry, Dr. Sarah Allen, Dr. Pamela Yochem, and/or Dr. Brent Stewart) to develop and implement a revised mitigation plan to further reduce the number of takes and potential impacts. Once a week every week thereafter, the City of San Diego shall take the same mean of observed harbor seals across the previous three tide cycles (a tide cycle is approximately 2 weeks) and compare it to the 95% lower confidence interval in Figure 3 for the same time period. If the observed mean is lower, the City of San Diego shall shut-down and take the action described above. If abandonment of the site is likely, monitoring shall be expanded away from the Children's Pool to determine if animals have been temporarily displaced to haul-out sites in the southern California area (*e.g.,* Torrey Pines, Point Loma, etc.).

7. Reporting Requirements

The City of San Diego is required to:

(a) Submit a draft report on all activities and monitoring results to the Office of Protected Resources, NMFS, within 90 days of the completion of the construction activities at the Children's Pool Lifeguard Station. This report must contain and summarize the following information:

(i) Dates, times, locations, weather, sea conditions (including Beaufort sea state and wind speed), and associated activities during all construction activities and marine mammal sightings;

(ii) Species, number, location, distance from the PSO, and behavior of any marine mammals, as well as associated construction activities, observed throughout all monitoring activities.

(iii) An estimate of the number (by species) of marine mammals that: (A) are known to have been exposed to the construction activities (based on visual observation) at received levels greater than or equal 90 dB re 20 μPa for harbor seals and 100 dB re 20 μPa for all other pinniped species for in-air noise with a discussion of any specific behaviors those individuals exhibited; and (B) may have been exposed (based on reported values and modeling measurements for the construction equipment) to the construction activities in-air noise at received levels greater than or equal 90 dB re 20 μPa for harbor seals and 100 dB re 20 μPa for all other pinniped species with a discussion of the nature of the probable consequences of that exposure on the individuals that have been exposed. NMFS will consider pinnipeds flushing into the water; moving more than 1 m (3.3 ft), but not into the water; becoming alert and moving, but not moving more than 1 m; and changing direction of current movement by individuals as behavioral criteria for take by Level B harassment.

(iii) A description of the implementation and effectiveness of the: monitoring and mitigation measures of the IHA.

(b) Submit a final report to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, within 30 days after receiving comments from NMFS on the draft report. If NMFS decides that the draft report needs no comments, the draft report shall be considered to be the final report.

8. In the unanticipated event that the City of San Diego discovers a live stranded marine mammal (sick and/or injured) at Children's Pool, they shall immediately contact Sea World's stranded animal hotline at 1–800–541–7235. Sea World shall also be notified for dead stranded pinnipeds so that a necropsy can be performed. In all cases, NMFS shall be notified as well, but for immediate responses purposes, Sea World shall be contacted first.

Reporting Prohibited Take

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this Authorization, such as an injury (Level A harassment), serious injury or mortality, the City of San Diego shall immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov* and the West Coast Regional Stranding Coordinator (562–980–3230). The report must include the following information:

(a) Time, date, and location (latitude/longitude) of the incident; the type of activity involved; description of the circumstances during and leading up to the incident; status of all sound source use in the 24 hours preceding the incident; water depth; environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility); description of marine mammal observations in the 24 hours preceding the incident; species identification or description of the animal(s) involved; the fate of the animal(s); and photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with the City of San Diego to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The City of San Diego may not resume their activities until notified by NMFS via letter or email, or via telephone.

Reporting an Injured or Dead Marine Mammal with an Unknown Cause of Death

In the event that the City of San Diego discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), the City of San Diego will immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov,* and the NMFS West Coast Regional Office (1–866–767–6114) and/or the West Coast Regional Stranding Coordinator (562–980–3230). The report must include the same information identified in the Condition 8(a) above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with the City of San Diego to determine whether modifications in the activities are appropriate.

Reporting an Injured or Dead Marine Mammal Not Related to the Activities

In the event that the City of San Diego discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in Condition 2 to 4 of this Authorization (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the City of San Diego shall report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov,* and the NMFS West Coast Regional Office (1–866–767–6114) and/or the West Coast Regional Stranding Coordinator (562–980–3230), within 24 hours of the discovery. The City of San Diego shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Activities may continue while NMFS reviews the circumstances of the incident.

9. A copy of this Authorization must be in the possession of all contractors and PSOs operating under the authority of this IHA.

Request for Public Comments

NMFS requests comment on our analysis, the draft authorization, and any other aspect of the preliminary determinations and notice of the proposed IHA for the City of San Diego's construction activities at the La Jolla Children's Pool Lifeguard Station. Please include with your comments any supporting data or literature citations to help inform our final decision on the City of San Diego's request for an MMPA authorization. Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this IHA application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 11, 2015.

Perry F. Gayaldo,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–11994 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD943

Fishing Capacity Reduction Program for the Southeast Alaska Purse Seine Salmon Fishery

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

ACTION: Notice of fee rate adjustment.

SUMMARY: NMFS issues this notice to decrease the fee rate to repay the $13,133,030 reduction loan for the fishing capacity reduction program in the Southeast Alaska purse seine salmon fishery.

DATES: The fee rate decrease is effective June 1, 2015.

ADDRESSES: Send questions about this notice to Paul Marx, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Paul Marx, (301) 427–8771.

SUPPLEMENTARY INFORMATION:

I. Background

NMFS' authority to make the loan resides in sections 1111 and 1112 of the Merchant Marine Act, 1936 (46 App. U.S.C. 1279(f) and 1279(g)(MMA)(title XI)).

The Program was authorized in the Consolidated Appropriations Act of 2005 (Section 209 of Title II of Division B of Pub. L. 108–447) and waives all of the fishing capacity reduction program requirements of the Magnuson-Stevens Act (Sections 312(b)–(e)) codified at 16 U.S.C. 1801 *et seq.* except for Sections (b)(1)(C) and (d) which state: (1) It must be cost-effective; and (2) it is subject to a referendum approved by a majority of permit holders.

NMFS published proposed program regulations on May 23, 2011 (76 FR 29707), and final program regulations on October 6, 2011 (76 FR 61985), to implement the reduction program. Subsequently, the Southeast Revitalization Association submitted a capacity reduction plan to NMFS. NMFS approved the plan on February 24, 2012. NMFS published the list of eligible voters on March 1, 2012 (77 FR 12568) and the notice of referendum period on March 29, 2012 (77 FR 19004). Interested persons should review these for further program details.

NMFS conducted a referendum where the majority of permit holders voted to repay a fishing capacity reduction loan to purchase the permits identified in the reduction plan.

On May 7, 2012, NMFS published another **Federal Register** document (77 FR 26744) advising the public that NMFS would tender the program's reduction payments to the 64 selected bidders who would permanently stop fishing with the permits they had relinquished in return for reduction payments. Subsequently, NMFS disbursed $13,133,030 in reduction payments to the 64 selected bidders.

NMFS published a **Federal Register** notice on July 16, 2012 (77 FR 41754) informing the public that fee collection would begin on July 22, 2012. Since then all harvesters of Southeast Alaska purse seine salmon must pay the fee and all fish buyers of Southeast Alaska purse seine salmon must collect the fee in accordance with the applicable regulations.

NMFS published a notice in the **Federal Register** on June 5, 2013 (78 FR 33810) to decrease the fee rate from 3.0% of landed value and any subsequent bonus payments to 1.5%, effective June 1, 2013.

II. Purpose

The purpose of this notice is to adjust the fee rate for the reduction fishery in

accordance with the framework rule's § 600.1013(b). Section 600.1013(b) directs NMFS to recalculate the fee to a rate that will be reasonably necessary to ensure reduction loan repayment within the specified 40-year term.

The initial fee applicable to the Southeast Alaska purse seine salmon program's reduction fishery was 3.0% of landed value and any subsequent bonus payments, which was decreased in June 2013 to 1.5%. NMFS has determined this fee rate is more than is needed to service the loan. Therefore, NMFS is decreasing the fee rate to 1.0% of landed value and any subsequent bonus payments which NMFS has determined is sufficient to ensure timely loan repayment. Fish buyers may continue to use *Pay.gov* to disburse collected fee deposits at: *http://www.pay.gov/paygov/*. Please visit the NMFS Web site for additional information at: *http://www.nmfs.noaa.gov/mb/financial_services/buyback.htm.*

III. Notice

The new fee rate for the Southeast Alaska purse seine salmon fishery is effective June 1, 2015.

Fish sellers and fish buyers must pay and collect the fee in the manner set out in 50 CFR 600.1107 and the framework rule. Consequently, all harvesters and fish buyers should read subpart L to 50 CFR 600.1013 to understand how fish harvesters must pay and fish buyers must collect the fee.

Dated: May 14, 2015.

Basil Brown,

Acting Director, Office of Management and Budget, National Marine Fisheries Service.

[FR Doc. 2015–12092 Filed 5–18–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2015–HA–0009]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 18, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: TRICARE Young Adult Application; DD Form 2947; OMB Control Number 0720–0049.

Type of Request: Reinstatement.

Number of Respondents: 16,000.

Responses per Respondent: 2.

Annual Responses: 32,000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 8,000.

Needs and Uses: The information collection requirement is necessary to evaluate eligibility and qualifications of former young adult dependents applying for extended dependent coverage under the TRICARE Young Adult program.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Meredith DeDona.

Written comments and recommendations on the proposed information collection should be sent to Ms. Meredith DeDona at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: May 14, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–12093 Filed 5–18–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Environmental Research and Development Program, Scientific Advisory Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce an open meeting of the Strategic Environmental Research and Development Program, Scientific Advisory Board (SAB). This meeting will be open to the public.

DATES: Tuesday, June 16, 2015, from 8:00 a.m. to 4:50 p.m.

ADDRESSES: Renaissance Portsmouth-Norfolk Waterfront Hotel, 425 Water Street, Portsmouth, Virginia 23704.

FOR FURTHER INFORMATION CONTACT: Dr. Anne Andrews, SERDP Office, 4800 Mark Center Drive, Suite 17D08, Alexandria, VA 22350–3605; or by telephone at (571) 372–6565.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. This notice is published in accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463).

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

The purpose of the June 16, 2015 meeting is to review research and development projects requesting Strategic Environmental Research and Development Program funds as required by the SERDP Statute, U.S. Code - Title 10, Subtitle A, Part IV, Chapter 172, § 2904. The full agenda follows:

8:00 a.m. Convene/Opening Remarks, Approval of October 2014 Minutes; Dr. Joseph Hughes, Chair.

8:05 a.m. Program Update; Dr. Anne Andrews, Acting Executive Director.

8:20 a.m. Munitions Response Overview; Dr. Herb Nelson, Munitions Response, Program Manager.

8:30 a.m. 15 MR01–039 (MR–2545): Sediment Volume Search Sonar Development, (FY15 New Start); Mr. Daniel Brown, Applied Research Laboratory, The

Pennsylvania State University, State College, PA.

9:15 a.m. Break

9:30 a.m. Resource Conservation and Climate Change Overview; Dr. John Hall, Resource Conservation and Climate Change, Program Manager.

9:50 a.m. RC–2245: Defense Coastal/Estuarine Research Program (DCERP) Overview, (FY16 Continuing); Dr. Patricia Cunningham, RTI International, Research Triangle Park, NC.

10:05 a.m. RC–2245: CB–4 Title: Predicting Sustainability of Coastal Military Training Environments; Dr. Jesse McNinch, ERDC Coastal Hydraulics Lab, Duck, NC.

10:35 a.m. RC–2245: CC–1 Title: Development of Uniform Historical and Projected Climate to Support Integrated Coastal Ecosystem Research; Dr. Ryan Boyles, North Carolina State University, Raleigh, NC.

11:20 a.m. RC–2245: Development of Empirical Carbon Budget; Dr. Craig Tobias, University of Connecticut, Groton, CT.

12:05 p.m. Lunch

1:05 p.m. RC–2245: Translating Science into Practice; Dr. Mike Piehler, University of North Carolina, Morehead City, NC.

1:35 p.m. RC–2245: TAC Comments and Project Management; Dr. Patricia Cunningham, RTI International, Research Triangle Park, NC.

2:20 p.m. FY16 Statements of Need—Summaries in Preparation of New Start Projects to be Presented in September and October; SERDP Program Managers.

3:25 p.m. Break

3:40 p.m. FY17 SON—Board Input; All.

4:05 p.m. Scenarios for Sea Level Rise and Extreme Water Levels: Building on SERDP Research; Dr. John Hall, Resource Conservation and Climate Change, Program Manager.

4:50 p.m. Public Discussion/Adjourn

Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Strategic Environmental Research and Development Program, Scientific Advisory Board. Written statements may be submitted to the committee at any time or in response to an approved meeting agenda.

All written statements shall be submitted to the Designated Federal Officer (DFO) for the Strategic Environmental Research and Development Program, Scientific Advisory Board. The DFO will ensure that the written statements are provided to the membership for their consideration. Contact information for the DFO can be obtained from the GSA's FACA Database at *http://www.facadatabase.gov/.* Time is allotted at the close of the meeting day for the public to make comments. Oral comments are limited to 5 minutes per person.

Dated: May 14, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–12098 Filed 5–18–15; 8:45 am]

BILLING CODE 5001–06–P

DELAWARE RIVER BASIN COMMISSION

Notice of Public Hearing and Business Meeting

June 9–10, 2015.

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Tuesday, June 9, 2015. A business meeting will be held the following day on Wednesday, June 10, 2015. The hearing and business meeting are open to the public and will be held at the Washington Crossing Historic Park Visitor Center, 1112 River Road, Washington Crossing, Pennsylvania.

Public Hearing. The public hearing on June 9, 2015 will begin at 1:30 p.m. Hearing items will include: Draft dockets for the withdrawals, discharges and other water-related projects subject to the Commission's review; a resolution apportioning among the signatory parties the amounts required for support of the current expense and capital budgets for the fiscal year ending June 30, 2016; a resolution approving the annual current expense and capital budgets for the fiscal year ending June 30, 2016; and a proposed rule, published elsewhere in this issue of the **Federal Register**, amending DRBC's *Administrative Manual Part III—Rules of Practice and Procedure* to provide for the One Process/One Permit Program.

The list of projects scheduled for hearing, including project descriptions, will be posted on the Commission's Web site, *www.drbc.net,* in a long form of this notice at least ten days before the hearing date. Draft resolutions scheduled for hearing also will be posted at *www.drbc.net* ten or more days prior to the hearing. Additional information related to the proposed rule to provide for the One Process/One Permit Program can be found in separate notices of proposed rulemaking in the **Federal Register**, the register publications of each of the Commission's member states, and at *www.drbc.net.*

Written comments on draft dockets and resolutions scheduled for hearing on June 9 will be accepted through the close of the hearing that day. After the hearing on all scheduled matters has been completed, and as time allows, an opportunity for public dialogue will also be provided.

The public is advised to check the Commission's Web site periodically prior to the hearing date, as items scheduled for hearing may be postponed if additional time is deemed necessary to complete the Commission's review, and items may be added up to ten days prior to the hearing date. In reviewing docket descriptions, the public is also asked to be aware that project details commonly change in the course of the Commission's review, which is ongoing.

Public Meeting. The public business meeting on June 10, 2015 will begin at 1:30 p.m. and will include: Adoption of the Minutes of the Commission's March 11, 2015 business meeting, announcements of upcoming meetings and events, a report on hydrologic conditions, reports by the Executive Director and the Commission's General Counsel, and consideration of any items for which a hearing has been completed or is not required.

There will be no opportunity for additional public comment at the June 10 business meeting on items for which a hearing was completed on June 9 or a previous date. Commission consideration on June 10 of items for which the public hearing is closed may result in either approval of the item (by docket or resolution) as proposed, approval with changes, denial, or deferral. When the Commissioners defer an action, they may announce an additional period for written comment on the item, with or without an additional hearing date, or they may take additional time to consider the input they have already received without requesting further public input. Any deferred items will be considered for action at a public meeting of the Commission on a future date. Items heard during the March 10, 2015 Public Hearing on which the Commission has not yet acted include draft dockets D–2014–008–1 for the Columbia Gas Transmission Corporation, and D–2014–022–1 for the Trancontinental Pipeline Company, LLC.

Advance Sign-Up for Oral Comment. Individuals who wish to comment for the record at the public hearing on June

9 or to address the Commissioners informally during the public dialogue portion of the meeting that day as time allows, are asked to sign up in advance by contacting Ms. Paula Schmitt of the Commission staff, at *paula.schmitt@drbc.state.nj.us* or by phoning Ms. Schmitt at 609–883–9500 ext. 224.

Addresses for Written Comment. Written comment on items scheduled for hearing may be delivered by hand at the public hearing or in advance of the hearing, either: By hand, U.S. Mail or private carrier to: Commission Secretary, P.O. Box 7360, 25 State Police Drive, West Trenton, NJ 08628; by fax to Commission Secretary, DRBC at 609–883–9522; or by email (preferred) to *paula.schmitt@drbc.state.nj.us.* If submitted by email in advance of the hearing date, written comments on a docket should also be sent to Mr. William Muszynski, Manager, Water Resources Management at *william.muszynski@drbc.state.nj.us.*

Accommodations for Special Needs. Individuals in need of an accommodation as provided for in the Americans with Disabilities Act who wish to attend the informational meeting, conference session or hearings should contact the Commission Secretary directly at 609–883–9500 ext. 203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how we can accommodate your needs.

Updates. Items scheduled for hearing are occasionally postponed to allow more time for the Commission to consider them. Other meeting items also are subject to change. Please check the Commission's Web site, *www.drbc.net,* closer to the meeting date for changes that may be made after the deadline for filing this notice.

Additional Information, Contacts. The list of projects scheduled for hearing, with descriptions, will be posted on the Commission's Web site, *www.drbc.net,* in a long form of this notice at least ten days before the hearing date. Draft dockets and resolutions for hearing items will be available as hyperlinks from the posted notice. Additional public records relating to hearing items may be examined at the Commission's offices by appointment by contacting Carol Adamovic, 609–883–9500, ext. 249. For other questions concerning hearing items, please contact Project Review Section assistant Victoria Lawson at 609–883–9500, ext. 216.

Dated: May 13, 2015.

Pamela M. Bush,

Commission Secretary and Assistant General Counsel.

[FR Doc. 2015–12077 Filed 5–18–15; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0065]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2015–16 National Postsecondary Student Aid Study (NPSAS:16) Full Scale Institution Contacting And Enrollment List Collection

AGENCY: Institute of Education Sciences/National Center for Education Statistics (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 18, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0065 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 note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* 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, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411.

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: 2015–16—National Postsecondary Student Aid Study (NPSAS:16) Full Scale Institution Contacting And Enrollment List Collection.

OMB Control Number: 1850–0666.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 4,478.

Total Estimated Number of Annual Burden Hours: 4,081.

Abstract: The National Postsecondary Student Aid Study (NPSAS), a nationally representative study of how students and their families finance postsecondary education, was first implemented by the National Center for Education Statistics (NCES) in 1987 and has been fielded every 3 to 4 years since. The next major data collection will occur in 2016 following a field test collection in 2015. This submission is for the ninth cycle in the series, NPSAS:16, which will also serve as the base year study for the 2016 Baccalaureate and Beyond Longitudinal Study (B&B) which provides data on the various paths of recent college graduates into employment and additional education. The NPSAS:16 sample will include about 2,000 institutions and about 128,000 students. Institution contacting will begin in October 2015 and student data collection will be conducted from January through September 2016. A separate package to request clearance for student data collection (interviews and institution record data) will be submitted in the fall 2015. This submission includes contacting materials and collection of enrollment lists from institutions

selected to participate in the full-scale study.

Dated: May 13, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–12040 Filed 5–18–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0066]

Agency Information Collection Activities; Comment Request; Graduate Assistance in Areas of National Need (GAANN) Performance Report

AGENCY: Department of Education (ED), Office of Postsecondary Education (OPE).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 20, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0066 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 note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* 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, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Ell, (202) 502–7779.

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: Graduate Assistance in Areas of National Need (GAANN) Performance Report.

OMB Control Number: 1840–0748.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Private Sector, State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 291.

Total Estimated Number of Annual Burden Hours: 3,273.

Abstract: Graduate Assistance in Areas of National Need (GAANN) grantees must submit a performance report annually. The reports are used to evaluate grantee performance. Further, the data from the reports will be aggregated to evaluate the accomplishments and impact of the GAANN Program as a whole. Results will be reported to the Secretary in order to respond to GPRA requirements.

Dated: May 14, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–12074 Filed 5–18–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Wednesday, June 10, 2015, 8:30 a.m.–5:00 p.m.

Thursday, June 11, 2015, 9:00 a.m.–12:00 p.m.

ADDRESSES: Red Lion Hanford House, 802 George Washington Way, Richland, WA 99352.

FOR FURTHER INFORMATION CONTACT: Kristen Skopeck, Federal Coordinator, Department of Energy Richland Operations Office, 825 Jadwin Avenue, P.O. Box 550, A7–75, Richland, WA 99352; Phone: (509) 376–5803; or Email: *kristen.skopeck@rl.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.

Tentative Agenda:

- Potential Draft Advice
  - Budget Priorities
- Discussion Topics
  - Tank Vapor Implementation Plan
  - Phoenix Tool—Tank Farm Application
  - Tri-Party Agreement Agencies' Updates
  - Hanford Advisory Board Committee Reports
  - Board Business

Public Participation: The meeting is open to the public. The EM SSAB, Hanford, welcomes the attendance of the public at its advisory committee meetings 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 Kristen Skopeck at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Kristen Skopeck 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 Kristen Skopeck's office at the address or phone number listed above. Minutes will also be available at the following Web site: *http://www.hanford.gov/page.cfm/hab.*

Issued at Washington, DC, on May 13, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–12075 Filed 5–18–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL15–65–000]

Southline Transmission, L.L.C., SU FERC, L.L.C.; Notice of Petition for Declaratory Order

Take notice that on May 11, 2015, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2014), Southline Transmission, L.L.C. (Southline) and SU FERC, L.L.C. (SU FERC), filed a petition for declaratory order requesting that the Commission: (1) Find that Southline Transmission is a passive entity and therefore not a public utility within the meaning of the Federal Power Act or an electric utility company under the Public Utility Holding Company Act of 2005, (2) grant SU FERC negotiated rate authority, (3) approve SU FERC's capacity allocation methodology, and (4) grant certain waivers of FERC's regulations.

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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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 Web site 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 June 10, 2015.

Dated: May 13, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12080 Filed 5–18–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2015–0283; FRL–9927–88–OARM]

Public Availability of Environmental Protection Agency FY 2014 Service Contract Inventory

AGENCY: Environmental Protection Agency

ACTION: Notice.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the Environmental Protection Agency is publishing this notice to advise the public of the availability of the FY 2014 Service Contract Inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2014. The information is organized by function to show how contracted resources are distributed throughout the Agency. The inventory has been developed in accordance with guidance issued by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP), *Service Contract Inventories (December 19, 2011).* The Environmental Protection Agency has posted its inventory and a summary of the inventory on the EPA's homepage at the following link: *http://www.epa.gov/oam/inventory/inventory.htm.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Linear Cherry in the Office of Acquisition Management, Policy, Training, and Oversight Division (3802R), Financial Analysis and Oversight Service Center, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4403; email address: *cherry.linear@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

How can I get copies of this docket and other related information?

1. The EPA has established a docket for this action under Docket ID No. EPA–HQ–OARM–2015–0283. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the FY 2014 Service Contract Inventory Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center 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 FY 2014 Service Contract Inventory Docket is (202) 566–1752.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

Dated: May 14, 2015.

John R. Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2015–12102 Filed 5–18–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update listing of financial institutions in liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as ''of record'' notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: May 11, 2015.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10514	Edgebrook Bank	Chicago	IL	5/8/2015

[FR Doc. 2015–12069 Filed 5–18–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, May 21, 2015 At 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes for March 19, 2015

Audit Division Recommendation Memorandum on the Oakland County Democratic Party (OCDP) (A12–02)

Audit Division Recommendation Memorandum on Kevin McCarthy for Congress (KMFC) (A13–02)

Audit Division Recommendation Memorandum on New American City, Inc. (NAC)

Presentation by the FEC Staff on Enhanced Engagement with the Public and Stakeholders

Notice to Respondents of Information Sharing by the Commission

Proposed Statement of Policy Regarding the Public Disclosure of Closed Enforcement Files

Motion to Open a Rulemaking in Response to Comments and Testimony on the *McCutcheon* v. *FEC* ANPRM

Proposed Directive 74 on the Timely Resolution of Enforcement Matters

Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2015–12159 Filed 5–15–15; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 11, 2015.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *United Community Banks, Inc., Blairsville, Georgia;* to merge with Palmetto Bancshares, Inc., and thereby acquire The Palmetto Bank, both of Greenville, South Carolina.

Board of Governors of the Federal Reserve System, May 13, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–12033 Filed 5–18–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 2, 2015.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *David L. Johnson and Sandra L. Castetter,* both of Kansas City, Missouri; each individually to acquire over 10 percent; and David L. Johnson and Sandra L. Castetter, together with Park GP, LLC, North Kansas City, Missouri, acting in concert to acquire up to 24.99 percent of the voting shares CCSB Financial Corp., parent of Clay County Savings Bank, both of Liberty, Missouri.

Board of Governors of the Federal Reserve System, May 13, 2015.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2015–12034 Filed 5–18–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Building Local Community Health Leadership for Action on Preventing Chronic Disease, SIP 15–006, initial review.

SUMMARY: This document corrects a notice that was published in the **Federal Register** on May 5, 2015, Volume 80, Number 86, Page 25692. The time and date should have read as follows:

TIME AND DATE: 11:00 a.m.–6:00 p.m., May 28, 2015 (Closed).

FOR FURTHER INFORMATION CONTACT: Brenda Colley Gilbert, Ph.D., M.S.P.H., Director, Extramural Research Program Operations and Services, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–6295, *BJC4@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12054 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) PS15–1505, Enhancing HIV Prevention Communication and Mobilization Efforts through Strategic Partnerships.

Time and Date: 10:00 a.m.–1:00 p.m., EDT, Panels 1–5; June 9, 2015 (CLOSED).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Enhancing HIV Prevention Communication and Mobilization Efforts through Strategic Partnerships'' FOA PS15–1505.

Contact Person for more Information: Lisa R. Williams, Public Health Analyst, CDC, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333, Telephone: (404) 639–1877.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12056 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15AIS; Docket No. CDC–2015–0037]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on the proposed information collection entitled *CDC Burden of Canine Brucellosis Information Collection.* This information collection will help to estimate canine brucellosis disease burden in dogs, which will aid in the determination of the public health importance of human *B. canis* infections, and the potential for zoonotic transmission.

DATES: Written comments must be received on or before July 20, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0037 by any of the following methods:

- *Federal eRulemaking Portal:* Regulation.gov. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and

instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed 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 proposed 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

CDC Burden of Canine Brucellosis Information Collection—New—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Canine brucellosis is a bacterial infection caused by the organism *Brucella canis.* Few seroprevalence studies have been done to estimate the prevalence of canine brucellosis, most of which were conducted over 25 years ago. Two recent reports from Oklahoma and Wisconsin describe increasing prevalence in dogs; however, the national burden is not known. *B. canis* is also pathogenic to humans, although human infections are thought to be rare in the United States.

Unlike *Brucella abortus, B. melitensis,* and *B. suis, B. canis* is not classified as a select agent. As a result, laboratory identification of the organism in humans does not require reporting to the Laboratory Response Network. *Brucella* species-specific data are not collected in the Nationally Notifiable Disease Surveillance System at CDC, and there are no validated *Brucella canis* serological tests to diagnose disease in humans. For these reasons, there are no national estimates of *B. canis* prevalence in humans or canines.

Additionally, canine infections with other *Brucella* species have been reported in the literature. Zoonotic transmission is a concern with all *Brucella* species pathogenic to humans, and at least one human infection with *B. suis* related to canine contact has been reported. Neither the prevalence of canine brucellosis nor the potential risk of zoonotic spread to humans is known.

There has been interest in human brucellosis caused by *B. canis* among the public health community. However, the degree of public health importance of human *B. canis* infections has not yet been ascertained. The Council of State and Territorial Epidemiologists approved a position statement in 2012 that recommends increased focus on *B. canis,* and urges CDC to support the development of a human diagnostic assay.

The purpose of this information collection request is to estimate the burden of canine brucellosis in the United States, which will aid in the determination of the level of public health importance of human *B. canis* infections, and the potential for transmission of brucellosis from dogs. An estimate of disease burden in dogs will provide an idea of potential transmission between dogs and humans, and determine the need for future human public health studies, which is critical during this time of scarce resources.

Veterinary diagnostic laboratories throughout the United States will be solicited to provide information on the quantity of test requests and positive results for *Brucella spp.* in canines, outsourcing of clinical testing, state-wide policies for reporting of positive results, and policies for human exposure to clinical specimens or isolates.

The laboratories were identified through multiple sources: A review of the Animal and Plant Health Inspection Service-approved *Brucella* diagnostic laboratories, the National Animal Health Laboratory Network laboratories, the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and an Internet search.

The outcomes of this information collection are to assess the burden of disease in the animal host (dogs, in this case), as well as evaluate the knowledge and practices of occupational exposures to the organism. The information collected will be used to guide a longer term strategy for identification of human cases, understanding risk factors and activities associated with zoonotic transmission, and eventually validation of a human diagnostic assay. These strategies will be implemented using other mechanisms.

The total annual burden is 129 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Veterinary diagnostic laboratory staff	Burden of Canine Brucellosis Information Collection.	119	1	1	119
Other laboratories	Burden of Canine Brucellosis Information Collection.	10	1	1	10

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Total					129

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–12094 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 11:00 a.m.–2:00 p.m. EDT, Tuesday, June 9, 2015.

Place: Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1–866–659–0537 and the pass code is 9933701.

Status: Open to the public. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, most recently, August 3, 2013, and will expire on August 3, 2015.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters for Discussion: The agenda for the conference call includes: NIOSH evaluation of SEC Petition for Westinghouse Electric Corp. facility in Bloomfield, New Jersey (January 1, 1950–March 1, 2011); Work Group and Subcommittee Reports; SEC Petitions Update for the July 2015 Advisory Board Meeting; Plans for the July 2015 Advisory Board Meeting; and Advisory Board Correspondence.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore M. Katz, M.P.A., Designated Federal Officer, NIOSH, CDC, 1600 Clifton Rd. NE., Mailstop: E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1–800–CDC–INFO, Email *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12059 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

World Trade Center Health Program Scientific/Technical Advisory Committee: Notice of Charter Renewal

This gives notice under Public Law 111–347 (The James Zadroga 9/11 Health and Compensation Act of 2010) and the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the World Trade Center Health Program Scientific/Technical Advisory Committee, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through May 12, 2017.

For information, contact person for more information: Paul J. Middendorf, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, 2400 Century Parkway NE., Mail Stop E–20, Atlanta, Georgia 30345, telephone 1 (888) 982–4748; email: *wtc-stac@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12058 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA), RFA–CE–15–001, Research Grants for Preventing Violence and Violence related Injury (R01).

Times and Dates: 08:30 a.m.–5:00 p.m., EDT, June 17–18, 2015 (Closed).

Place: Georgian Terrace, 659 Peachtree Road NE., Room 4, Atlanta, Georgia 30308. This meeting will also be held by teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Research Grants for Preventing Violence and Violence Related Injury (R01)'', FOA Number: CE–15–001.

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Hwy., NE., Mailstop E63, Atlanta, Georgia 30341–3724, Telephone: 770–488–4334.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12055 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0822; Docket No. CDC–2015–0035]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed revision to the approved information collection project entitled ''*The National Intimate Partner and Sexual Violence Survey (NISVS)''.* This project collects information about individual's experiences of sexual violence, stalking and intimate partner violence.

DATES: Written comments must be received on or before July 20, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0035 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov.*

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed 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 proposed 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

National Intimate Partner and Sexual Violence Survey (NISVS)—Revision—(OMB Control No. 0920–0822, Expiration—6/30/2016), National Center for Injury Prevention and Control

(NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2010, the National Intimate Partner and Sexual Violence Surveillance System (NISVSS) reported that approximately 6.9 million women and 5.6 million men experienced rape, physical violence and/or stalking by an intimate partner within the last year. The health care costs of Intimate Partner Violence (IPV) exceed $5.8 billion each year, nearly $3.9 billion of which is for direct medical and mental health care services.

In order to address this important public health problem, CDC implemented, beginning in 2010, the National Intimate Partner and Sexual Violence Surveillance System that produces national and state level estimates of Intimate Partner Violence (IPV), Sexual Violence (SV) and stalking on an annual basis.

This revision request is multi-faceted. CDC is requesting a continuation of data collection among non-institutionalized adult men and women aged 18 years or older in the United States assessing lifetime experiences of IPV, SV and stalking with a new and improved data collection tool. The revisions to the survey are aimed at reducing the time and complexity of the instrument, thus reducing the burden on the respondent. The simplified structure of the instrument will also reduce the complexity of the data set, making it more assessable for public use. Additionally, in collaboration with the Department of Defense (DoD), NISVS will collect information regarding the experiences of IPV, SV and stalking among active duty women and men in the military and wives of active duty men. This data collection will take place during the first three months of data collection.

To comply with OMB requirements, CDC is in the process of developing an expert panel to address methodological issues with the NISVS survey. The panel will meet multiple times over the course of the next year. The members of this panel will provide guidance on how to improve both survey design (methods, sampling frame, recruitment, mode of administration) and content/question wording with the goals of increasing response rates, reducing non-response bias, and maximizing the opportunities across Federal surveys for covering populations of interest. This change request also encompasses the implementation of the panel's recommendations to improve the survey.

In the bi-annual data collection periods, total of 170,000 households will be screened. After determining eligibility and consent, 25,000 will complete the survey. The average burden per screened respondent remains at three minutes (total burden in hours equals 8,500) while the average burden per surveyed respondent is 25 minutes (total burden in hours equals 10,417). The survey will be conducted among English or Spanish speaking male and female adults (18 years and older) living in the United States.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Non-Participating Individuals (Screened).	NISVS Survey Instrument	170,000	1	3/60	8,500
Eligible Individuals (Surveyed)	NISVS Survey Instrument	25,000	1	25/60	10,417
Total					18,917

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–12095 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Times and Dates:

8:00 a.m.–5:00 p.m., June 16, 2015 (Closed)
8:00 a.m.–5:00 p.m., June 17, 2015 (Closed)

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314, Telephone: 703–684–5900, Fax: 703–684–0653.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters for Dicussion: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications.

These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, CDC, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345, Telephone: (404) 498–2511, Fax: (404) 498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for

both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12057 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Integrating Self-Management Education with Cancer Survivorship Care Planning, SIP 15–001, and Using Cancer Registry Data to Promote Proactive Tobacco Cessation among Adult Cancer Survivors, SIP 15–003, initial review.

SUMMARY: This document corrects a notice that was published in the **Federal Register** on April 14, 2015 Volume 80, Number 86, Page 19990. The time and date should have read as follows:

DATES: *Time and Date:* 11:00 a.m.–6:00 p.m., May 12, 2015 (Closed).

FOR FURTHER INFORMATION CONTACT: Brenda Colley Gilbert, Ph.D., M.S.P.H., Director, Extramural Research Program Operations and Services, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–6295, *BJC4@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–12053 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Assets for Independence Program Performance Progress Report.

OMB No.: New.

Description

The Assets for Independence (AFI) Act (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, Pub. L. 105–285, [42 U.S.C. 604 note]) requires that organizations operating AFI projects submit annual progress reports.

This request is to create an AFI program specific Performance Progress Report (PPR) to replace the semiannual standard form performance progress report (SF–PPR) and the annual data report. The AFI PPR will collect data on project activities and attributes similar to the reports that it is replacing. The Office of Community Services (OCS) in the Administration for Children and Families (ACF) will use the data collected in the AFI PPR to prepare the annual AFI Report to Congress, to evaluate and monitor the performance of the AFI program overall and of individual projects, and to inform and support technical assistance efforts. The AFI PPR would fulfill AFI Act reporting requirements and program purposes.

The AFI PPR will be submitted quarterly: Three times per year using an abbreviated short form and one time using a long form. Both draft data collection instruments are available for review online at *https://idaresources.acf.hhs.gov/AFIPPR.*

Note: This request does not affect financial reporting requirements for AFI grantees. The SF–425 will still be required semiannually throughout the grant project period with a final report due 90 days after the grant project period ends.

Respondents: Assets for Independence (AFI) program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFI PPR Short Form	300	3	0.5	450
AFI PPR Long Form	300	1	4	1200

Estimated Total Annual Burden Hours: 1,650.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper,

Reports Clearance Officer.

[FR Doc. 2015–12096 Filed 5–18–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0998]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 08, 2015, the Agency submitted a proposed collection of information entitled, ''Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0409. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12078 Filed 5–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0802]

Exploring Naloxone Uptake and Use; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, in collaboration with the National Institutes on Drug Abuse, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration, will hold a public meeting to discuss increasing the use of naloxone to reduce the incidence of opioid drug overdose fatalities. During the meeting, academic and government experts, industry representatives, and patient advocates will discuss which populations are at-risk for opioid drug overdose and how we can work together to encourage the use of naloxone to reduce the risk of overdose from opioid drugs.

Date and Time: The public meeting will be held on July 1, 2015, from 8 a.m. to 5 p.m. and on July 2, 2015, from 8 a.m. to 3 p.m. The open public hearing will be held between 1 p.m. and 2 p.m. on July 1, 2015, and between 1 p.m. and 2 p.m. on July 2, 2015, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony may be limited by time constraints. Those wishing to participate in the open public hearing should limit their remarks to issues related to the uptake of naloxone both in conventional medical settings and outside of those settings to reduce the incidence of opioid drug overdose fatalities.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

Contact Person: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3519, *Mary.Gross@fda.hhs.gov;* or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3515, *Georgiann.Ienzi@fda.hhs.gov.*

Registration: If you wish to attend the public meeting or provide testimony during the open public hearing, please email your registration to *NaloxoneWorkshop@fda.hhs.gov* by June 22, 2015. Those without email access may register by contacting one of the contact persons (see *Contact Persons*). When registering, please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted for the public meeting. Onsite registration on the day of the public meeting will be permitted based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the public meeting at: *http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm.*

Comments: Submit either electronic or written comments by September 1, 2015. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi (see *Contact Persons*) at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Introduction

The number of prescriptions filled for opioid drugs has increased drastically in recent years. In 2009 nearly 257 million prescriptions were written for opioid drugs in the United States. This number rose to nearly 260 million in 2012. The increased availability of opioid drugs appears to be contributing significantly to abuse and overdose in the United States. In 2013 there were approximately 16,235 deaths from overdose involving opioid drugs. That same year, there were 8,257 deaths from overdose involving heroin.

Naloxone, a mu-opioid antagonist, is a medication that can rapidly reverse the overdose of both prescription opioid

drugs (*e.g.,* OxyContin) and illicit opioid drugs (*e.g.,* heroin). It is currently the standard treatment for those experiencing overdose and is commonly used by trained medical personnel in emergency departments and on ambulances. Its use among nonmedical personnel has also increased in recent years. The purpose of the public meeting is to explore issues surrounding the uptake of naloxone to treat opioid drug overdose. The meeting agenda will include topics on the clinical, regulatory, and legal implications of making naloxone more widely available. FDA will post the agenda and additional public meeting material approximately 2 days before the workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm.*

II. Transcripts

A transcript will be made available approximately 45 days after the public meeting. It will be accessible at *http://www.regulations.gov* and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12061 Filed 5–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA) intends to develop a list of bulk drug substances that may be used by outsourcing facilities registered under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs, in accordance with FDA's draft guidance for industry #230, ''Compounding Animal Drugs from Bulk Drug Substances.'' You may nominate specific bulk drug substances for this list. This notice describes the information that should be provided to the Agency in support of each nomination.

DATES: To ensure that FDA considers your nominations for the initial version of the bulk drug substances list, submit either electronic or written nominations for the bulk drug substances list by August 17, 2015.

After the comment period is closed, nominations to add or remove bulk drug substances from the list may be submitted to FDA by citizen petition under § 10.30 (21 CFR 10.30).

ADDRESSES: You may submit nominations by any of the following methods.

Electronic Submissions

Submit electronic nominations in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2013–N–1524. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or nominations received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV–210), 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, *neal.bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the FD&C Act do not apply to the compounding of animal drugs. The FD&C Act does not distinguish between compounding animal drugs from bulk drug substances [1] and any other manufacturing or processing of animal drugs. Except with respect to the limited exemption provided by the FD&C Act described in this document, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to compounded animal drugs.

Section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) provide a limited exemption from certain requirements for use for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extra-label use and the FD&C Act provides that a compounded drug is exempt from the approval requirements and requirements of section 502(f)(1) (21 U.S.C. 352(f)(1)) of the FD&C Act, if it meets the conditions set out in the statute and the extra-label use regulations at 21 CFR part 530.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances'' (GFI #230).[2] The draft guidance describes conditions under which FDA does not generally intend to initiate enforcement action against State-licensed pharmacies, licensed veterinarians, and facilities registered as outsourcing facilities under section 503B of the FD&C Act (outsourcing facilities) that compound animal drugs from bulk drug substances.

For pharmacies, these conditions include receipt of a valid prescription for a compounded drug from a licensed veterinarian for an individually identified animal patient before the

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[1] FDA regulations define ''bulk drug substance'' as ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.'' 21 CFR 207.3(a)(4). ''Active ingredient'' is defined as ''any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.'' 21 CFR 210.3(b)(7). Any component other than an active ingredient is an ''inactive ingredient.'' See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[2] GFI #230 can be found at *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm.*

facility compounds the drug (with some limited compounding of an animal drug product in advance of receipt of a prescription in quantities based on a history of receipt of patient-specific prescriptions for that drug product). FDA recognizes that there may be some limited circumstances in which a drug compounded from one or more bulk drug substances should be available to a veterinarian for office use and is developing a list of such animal drug products and the bulk drug substances needed to make them applicable to drugs compounded by facilities registered as outsourcing facilities under section 503B of the FD&C Act. The draft guidance proposes that outsourcing facilities compound animal drugs only from bulk drug substances that will be listed in Appendix A of the final guidance, either pursuant to a veterinarian's order or pursuant to a patient-specific prescription. When a facility registered as an outsourcing facility under section 503B of the FD&C Act uses the listed bulk drug substances to make the specified drug products pursuant to an order from a licensed veterinarian without a prescription for an individually identified animal, FDA does not intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 502(f), and 501(a)(2)(B) as long as such compounding is done in accordance with any associated conditions described in GFI #230. Although an outsourcing facility may fill a veterinarian's order for compounded animal drugs using bulk drug substances listed on Appendix A without obtaining prescriptions for individually identified animal patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(f) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a compounded drug to the owner or caretaker of an animal patient without a prescription for that individually identified animal patient.

This list only applies to outsourcing facilities. This list does not limit what bulk drug substances State-licensed pharmacies or licensed veterinarians can use in compounding drugs in accordance with the conditions set forth in the draft guidance, including the condition pertaining to obtaining a patient-specific prescription.

FDA intends to include a bulk drug substance on Appendix A only when all of the following criteria are met:

- There is no marketed approved, conditionally approved, or index-listed animal drug that can be used as labeled to treat the condition;
- there is no marketed approved animal or human drug that could be used under section 512(a)(4) or (a)(5) of the FD&C Act and part 530 (addressing extra-label use of approved animal and human drugs) to treat the condition;
- the drug cannot be compounded from an approved animal or human drug;
- immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
- FDA has not identified a significant safety concern specific to the use of the bulk drug substance to compound animal drugs (under the listed conditions and limitations).

Inactive ingredients need not appear on Appendix A to be used in compounding animal drug products.

II. Request for Nominations

A. Active Ingredients

You may nominate specific bulk drug substances for inclusion on the list in Appendix A. Nominations will only be evaluated if they are for specific ingredients that meet the definition of a bulk drug substance in § 207.3(a)(4) (21 CFR 207.3(a)(4)). Nominated substances that do not meet this definition will not be included on the list.

To determine if a bulk drug substance should be included in Appendix A, FDA needs the following information about the bulk drug substance being nominated and the animal drug product(s) that will be compounded using such substance:

1. Confirmation That the Nominated Substance Is a Bulk Drug Substance

A statement that the nominated substance is an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4), and an explanation of why the substance is considered an active ingredient when it is used in the identified compounded drug product(s), citing to specific sources that describe the active properties of the substance.

2. General Background on the Bulk Drug Substance

- Ingredient name;
- chemical name;
- common name(s); and
- identifying codes, as available, from FDA's Unique Ingredient Identifiers used in the FDA/U.S. Pharmacopeial Convention (USP) Substance Registration System, available at *http://fdasis.nlm.nih.gov/srs/*. Because substance names can vary, this code, where available, will be used by the Agency to confirm the exact substance nominated and to identify multiple nominations of the same substance so the information can be reviewed together.
- Chemical grade of the ingredient;
- description of the strength, quality, stability, and purity of the ingredient;
- information about how the ingredient is supplied (*e.g.,* powder, liquid); and
- information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development.

B. Information on the Animal Drug Products That Will Be Compounded With the Bulk Drug Substance

- Information about the dosage form(s) into which the bulk drug substance will be compounded;
- information about the strength(s) of the compounded product(s); and
- information about the anticipated route(s) of administration of the compounded product(s).

C. Need for the Animal Drug Products That Will Be Compounded With the Bulk Drug Substance

For FDA to be able to meaningfully evaluate a substance, the information provided must be specific to the particular substance nominated and animal drug product to be compounded. A ''boilerplate'' or general explanation of need for compounding with bulk drug substances will not enable FDA to conduct an adequate review. Unless adequate supporting data are submitted for a bulk drug substance, FDA will be unable to consider it for inclusion in Appendix A.

Prescribers of compounded animal drug products may be in the best position to explain why a particular bulk drug substance meets the criteria for including a bulk drug substance on Appendix A and are encouraged to provide data in support of a nomination. The following information about need is necessary to provide adequate support for nominations to the Appendix A list:

- A statement identifying the species and condition(s) that the drug product to be compounded with the nominated bulk drug substance is intended to treat;
- a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available,[3] including any relevant peer-reviewed veterinary literature;
- a list of animal drug products, if any, that are approved, conditionally approved, or index listed for the

[3] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support a new animal drug application.

condition(s) in the species that the drug compounded with the nominated substance is intended to address;

• if there are FDA-approved or index listed drug products that address the same conditions in the same species, an explanation, supported by relevant veterinary literature, of why a compounded drug product is necessary (*i.e.,* why the approved drug product is not suitable for a particular patient population);

• a review of the veterinary literature to determine whether there are FDA-approved animal or human drugs that could be prescribed as an extra-label use under section 512(a)(4) and (a)(5) of the FD&C Act and part 530 to treat the condition(s) in the species that the drug compounded with the nominated substance is intended to address;

• if the bulk drug substance is an active ingredient in an approved animal or human drug, an explanation, supported by appropriate scientific data, of why the animal drug product cannot be compounded from the approved drug under 21 CFR 530.13(b);

• an explanation, supported by relevant veterinary literature, of why the animal drug product to be compounded with the nominated bulk drug substance must be available to the veterinarian for immediate treatment to avoid animal suffering or death. Nominations should include specific information documenting that animal suffering or death will result if treatment is delayed until a compounded animal drug can be obtained pursuant to a prescription for an individually identified animal; and

• a discussion of any safety concerns associated with use of the nominated bulk drug substance or finished compounded product for the condition(s) in the species that the compounded drug is intended to address. If there are any safety concerns, an explanation, supported by veterinary literature, of why the concerns should not preclude inclusion of that bulk drug substance on Appendix A.

D. Nomination Process

For efficient consolidation and review of nominations, nominators are encouraged to submit their nominations in a format that explicitly addresses each item previously listed in the order that they appear. To consider a bulk drug substance for inclusion in Appendix A, FDA must receive adequate supporting data for the substance. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for inclusion on Appendix A prior to its initial publication. Nominations that are not evaluated during this first phase will receive consideration for later addition to Appendix A.

Individuals and organization may petition FDA to make additional amendments to Appendix A after it is published, in accordance with § 10.30.

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in the brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11983 Filed 5–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–D–1176 and FDA–2003–D–0202]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI) #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance describes FDA's policies with regard to compounding animal drugs from bulk drug substances. When final, the guidance will reflect FDA's current thinking on the issues addressed by the guidance.

FDA is also announcing the withdrawal of the compliance policy guide (CPG) entitled ''Section 608.400 Compounding of Drugs for Use in Animals,'' which was issued in July 2003. This 2003 CPG is being withdrawn because it is no longer consistent with FDA's current thinking on the issues it addresses.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 17, 2015. Submit written or electronic comments on the proposed collection of information by August 17, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance, including comments regarding the proposed collection of information, to *http://www.regulations.gov.* Submit written comments on the draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to this draft guidance:* Division of Compliance, Center for Veterinary Medicine, Food and Drug Administration (HFV–230), 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *CVMCompliance@fda.hhs.gov.*

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002; *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Draft Guidance

FDA is announcing the availability of a draft GFI #230 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance provides information to compounders of animal drugs and other interested stakeholders on FDA's application of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to the compounding of animal drugs from bulk drug substances.[1]

[1] FDA regulations define ''bulk drug substance'' as ''any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.'' 21 CFR 207.3(a)(4). ''Active ingredient'' is defined as ''any component that is intended to furnish

Sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the FD&C Act do not apply to the compounding of animal drugs. The FD&C Act does not distinguish between compounding animal drugs from bulk drug substances and any other manufacturing or processing of animal drugs. Except with respect to the limited exemption provided by the FD&C Act described in this document, statutory provisions applicable to manufactured animal drugs under the FD&C Act also apply to compounded animal drugs.

Section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)), provide a limited exemption from certain requirements for use for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extra-label use and the FD&C Act provides that a compounded drug is exempt from the approval requirements and requirements of section 502(f)(1) (21 U.S.C. 352(f)(1)) of the FD&C Act, if it meets the conditions set out in the statute and the extra-label use regulations at 21 CFR part 530.

This draft guidance does not address the compounding of animal drugs from approved animal or human drugs pursuant to the extra-label provisions of the law, nor does it address the repackaging of approved animal drugs. FDA is considering whether guidance is needed on those issues, and if so, will publish separate guidances. In section III, FDA is asking for comment on specific questions about several issues including the practice of compounding from approved animal and human drugs and the repackaging of drugs for animal use to help determine whether additional guidance is necessary on these topics.

This draft guidance describes conditions under which FDA does not generally intend to initiate enforcement action against State-licensed pharmacies, licensed veterinarians, and facilities registered as outsourcing facilities under section 503B of the FD&C Act (outsourcing facilities) that compound animal drugs from bulk drug substances. The draft guidance provides that FDA does not generally intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), and 502(f)(1) of the FD&C Act if a State-licensed pharmacy or a licensed veterinarian compounds drugs intended for use in animals from bulk drug substances in accordance with all of the applicable conditions set out in the guidance. In addition, the draft guidance provides that FDA does not generally intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if the drug product is compounded from a bulk drug substance by an outsourcing facility and that meets all of the applicable conditions set out in the guidance, and the drug product is compounded from a bulk drug substance that appears on Appendix A of the draft guidance.

Importantly, the draft guidance provides that FDA generally intends to enforce all other adulteration and misbranding provisions of the FD&C Act against entities compounding animal drugs from bulk drug substances.

To ensure FDA can timely identify and address safety issues related to animal drugs compounded from bulk drug substances, one of the conditions, if met, under which FDA does not generally intend to take action for violations of the provisions described previously is that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from a bulk drug substance to FDA, within 15 days of becoming aware of them, using Form FDA 1932a. FDA intends to use these adverse event reports to identify animal drugs compounded from bulk drug substances that present serious risks to animal health. Unlike for human drugs, there are no State Departments of Health or Federal Agencies, such as the Centers for Disease Control and Prevention (CDC), which are responsible for identifying and tracing the source of injury and/or disease in animals. Adverse event reporting regarding drugs compounded from bulk drug substances by compounding pharmacies and veterinarians will provide a mechanism for FDA to identify and possibly prevent adverse events associated with compounded animal drugs. This is another topic on which we are requesting specific comment in section III.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice soliciting nominations for bulk drug substances that should be included in Appendix A, ''List of Bulk Drug Substances That May Be Used By an Outsourcing Facility to Compound Drugs for Use in Animals.'' The notice also describes the information that should be provided to the Agency in support of such nominations.

II. Withdrawal of 2003 Compliance Policy Guide

In a notice published in the **Federal Register** of July 14, 2003 (68 FR 41591), FDA announced the availability of CPG Section 608.400 of the Compliance Program Guidance Manual entitled, ''Compounding of Drugs for Use in Animals.'' This document is being withdrawn because it is no longer consistent with FDA's current thinking on the issue it addresses. The current CPG does not focus on the three main concerns FDA has about animal drug compounding: compounding copies of approved animal or human drugs from bulk drug substances, compounding for food-producing animals from bulk drug substances, and compounding office stock from bulk drug substances. Because the CPG does not reflect FDA's current thinking, to leave it in effect until this draft guidance is finalized may confuse stakeholders about FDA's current enforcement priorities. Stakeholders should be aware that, until this draft guidance is finalized, FDA intends to look at the totality of the circumstances when determining whether to take enforcement action for unlawful animal drug compounding activities.

III. Specific Topics for Comment

In addition to comments on the draft guidance as written, we are specifically requesting comments on the following issues:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (*e.g.,* disruptions in the manufacture or supply chain; business decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)? If so:
  - How should these situations be addressed in the final guidance?
  - How should the final guidance define the terms ''shortage'' and ''unavailable''?
  - What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?
- Do United States Pharmacopeia and National Formulary (USP–NF) [2]

pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.'' 21 CFR 210.3(b)(7). Any component other than an active ingredient is an ''inactive ingredient.'' See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[2] Chapters <795> ''Pharmaceutical Compounding—Nonsterile Preparations'' and <797> ''Pharmaceutical Compounding—Sterile Preparations'' can be found in the combined *United*

Continued

chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?

- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- How should FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (*e.g.,* koi in a koi pond)?
- Should the final guidance include a condition on the amount or percentage of compounded animal drugs that a pharmacy or outsourcing facility can ship in interstate commerce? If so, what would a reasonable amount be?
- Should facilities registered as outsourcing facilities under section 503B of the FD&C Act be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies (*i.e.,* the conditions contained in section III.A. of the draft guidance)?
- Is additional guidance needed to address the repackaging of drugs for animal use?
  - How widespread is the practice of repackaging drugs for animal use?
  - What types of drugs are repackaged for animal use, and why are they repackaged?
  - Have problems been identified with repackaged drugs for animal use?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the FD&C Act and part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?
- As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (*e.g.,* the CDC) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:
  - How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?
  - Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (*e.g.,* State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?
  - For purposes of the guidance, how should FDA define the terms ''product defect'' and ''serious adverse event''?
  - Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?

IV. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on compounding animal drugs from bulk drug substances. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

V. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Compounding Animal Drugs from Bulk Drug Substances (OMB Control Number 0910–NEW)

Description of Respondents: The proposed collection of information would affect State-licensed pharmacies, licensed veterinarians, and outsourcing facilities that compound animal drugs from bulk drug substances.

Description: This draft guidance describes FDA's current thinking regarding compounding animal drugs from bulk drug substances and describes the conditions under which FDA does not generally intend to take action for violations of the following sections of the FD&C Act: 512, 501(a)(5), 502(f)(1), and, where specified, 501(a)(2)(B), when a State-licensed pharmacy, licensed veterinarian, or an outsourcing facility compounds animal drugs from bulk drug substances. The draft guidance provides three sets of conditions, one for each entity: State-licensed pharmacies, licensed veterinarians, and outsourcing facilities.

This draft guidance only addresses the compounding of animal drugs from bulk drug substances. It does not apply to the compounding of animal drugs from approved new animal or new human drugs. Such compounding can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act and part 530. In addition, this guidance does not address the compounding of drugs intended for use

States Pharmacopeia and National Formulary (USP–NF), available at *http://www.usp.org/.*

in humans, which is addressed in other guidances.

FDA estimates the burden of this collection of information as follows:

Reporting

This draft guidance contains no new reporting provisions. This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information regarding voluntary reporting of adverse drug experiences or product/manufacturing defects on Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' have been approved under OMB control number 0910–0284; the information collection provisions regarding establishment registration under section 510 of the FD&C Act (21 U.S.C. 360) have been approved under OMB control number 0910–0777. This draft guidance also refers to proposed collections of information regarding drugs made by an outsourcing facility during the previous 6-month period as described in FDA's notice of November 24, 2014 (79 FR 69857), announcing the availability of a draft guidance entitled ''Electronic Reporting for Human Drug Compounding Outsourcing Facilities.'' The proposed collections of information in the draft guidance are subject to review by OMB under the PRA. As required by the PRA, FDA published an analysis of the information collection provisions of the draft guidance (79 FR 69857 at 69858) and intends to submit them for OMB approval.

Recordkeeping

Entities compounding animal drugs from bulk drug substances should keep adequate records to demonstrate that they are compounding such drugs in accordance with all of the applicable conditions described in the draft guidance. FDA tentatively concludes that it is usual and customary for State-licensed pharmacies, veterinarians, and outsourcing facilities to keep such records, and that this draft guidance imposes no additional recordkeeping burden beyond those usual and customary for the respondents to this collection, with the exception of that described in section III.A.5. Nonetheless, table 1, row 1 provides a nominal estimate of potential recordkeeping burden that respondents may incur. FDA therefore specifically invites comment regarding whether these provisions impose any effort beyond that which would normally be incurred in absence of this draft guidance.

A condition set forth in section III.A.5. is that, if there is an FDA-approved animal or human drug with the same active ingredient(s), the pharmacy determines that the compounded drug cannot be made from the FDA-approved drug(s), and documents that determination.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
III; general recordkeeping beyond usual & customary.	138,551	1	138,551	0.01 (30 seconds)	1,386
III.A.5; documentation of determination that compound drug cannot be made from the FDA-approved drug(s).	75,000	84.67	6,350,000	0.01 (30 seconds)	63,500
Total	.....	.....	.....	.....	64,886

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For row 1, we base our burden estimates on the American Veterinary Medical Association's Market Research Statistics for 2013 for the total number of veterinarians in practice minus those veterinarians in food animal exclusive practice (63,500), the National Pharmacy Market Summary SK&A of March 2010 for the total number of pharmacy sites (75,000), and the number of registered outsourcing facilities as of March 20, 2015 (51), for a total of 138,551 respondents.[3]

For row 2, we estimate that approximately 75,000 pharmacies will receive approximately 6,350,000 prescriptions for compounded animal drugs annually, and we also estimate that it will take approximately 30 seconds (0.01 hours) to document that the compounded drug cannot be made from the FDA-approved drug(s) for a total of 63,500 hours recordkeeping burden.

A condition set forth in section III.A.2. of the draft guidance is that State-licensed pharmacies can compound a drug in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the State-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months. The records necessary for a State-licensed pharmacy to review to determine that its compounding practices are within the condition set forth in section III.A.2 of the draft guidance are records that State-licensed pharmacies would already be keeping as part of usual and customary business practice; therefore, no burden has been estimated for the recordkeeping associated with this condition.

This draft guidance also refers to proposed collections of information currently undergoing the process of OMB review under the PRA. Recordkeeping by outsourcing facilities, described in the draft guidance for industry, ''Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act'' announced July 2, 2014 (79 FR 37743), will be reviewed by OMB in response to an information collection request associated with that guidance.

Third-Party Disclosure

Prescriptions or Orders for Drugs Compounded From Bulk

This draft guidance contains new third-party disclosures as reported in table 2. Row 1 reflects a potential

[3] The AVMA's Market Research Statistics—U.S. Veterinarians—2013 can be found at this URL: (*https://www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-veterinarians.aspx*); the National Pharmacy Market Summary SK&A (March 2010) can be found at this URL: *http://www.skainfo.com/index.php;* and the list of registered outsourcing facilities can be found at this URL: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm.*

burden associated with section III.C.9. regarding the following condition: The veterinarian's prescription or order states, in addition to the species, the condition(s) for which the substance is listed in Appendix A. At this time, however, FDA has no data upon which to base an estimated number of prescriptions or orders to outsourcing facilities until the referenced list of bulk drugs (Draft Guidance; Appendix A) is finalized. For purposes of this analysis, however, we are providing an estimate of 1 as a placeholder.

In section III.A.4., the draft guidance sets forth the following condition: If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an identified individual patient that produces a clinical difference for that identified individual patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care. If the drug contains a bulk drug substance that is a component of a marketed FDA-approved animal or human drug, the prescription or documentation accompanying the prescription contains a statement that the change between the compounded drug and the FDA-approved drug produces a clinical difference for the individual identified patient. For example, the veterinarian could state that, ''This compounded drug is needed to treat [specifically identified patient] because the approved drug product(s) cannot be divided or diluted into the small dose required.''

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
III.C.9; documentation of condition to be treated.	1	1	1	0.017 (1 minute)	0.017
Statements on prescription (Section III.A.4 of the draft guidance).	63,500	100	6,350,000	0.017 (1 minute)	107,950
Total	.....	.....	.....	.....	107,950

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For row 2, we estimate that approximately 63,500 veterinarians will, on average, each produce approximately 100 prescriptions for compounded animal drugs annually for a total of 6,350,000 prescriptions. We also estimate that it will take approximately 1 minute (0.017 hours) to include the statement discussed in section III.A.4 of the draft guidance on each prescription for a total of 107,950 hours third-party disclosure burden, as reported in table 1.

It is usual and customary for licensed veterinarians to write prescriptions in the normal course of their activities. The conditions set forth in the guidance require veterinarians to include certain information on prescriptions for animals drugs compounded from bulk substances. It is usual and customary for veterinarians to include much of this information (except as noted previously); therefore, the time it would take to provide this information on prescriptions or documents accompanying prescriptions is not included in the burden estimate reported in table 2.

Sections III.A.3 and III.A.6.b of the draft guidance set forth the conditions that the following statements appear verbatim on or with prescriptions for animal drugs compounded from bulk drug substances:

- ''This patient is not a food-producing animal.'' (Section III.A.3).
- ''There are no FDA-approved animal or human drugs that can be used as labeled or in an extra-label manner under section 512(a)(4) and (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed.'' (Section III.A.6.b).

In addition, section III.C.3 of the draft guidance sets forth the condition that the following statement appears verbatim on or with prescriptions or orders for animal drugs compounded by outsourcing facilities from bulk drug substances listed on Appendix A:

- ''This drug will not be dispensed for or administered to food-producing animals.'' (Section III.C.3).

We tentatively conclude that these statements are ''public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

Labeling of Drugs Compounded From Bulk Drug Substances

The draft guidance sets forth conditions for the labeling of animal drugs compounded from bulk drug substances. The draft guidance indicates in sections III.A.11 and III.B.9 that, to meet the conditions of the guidance, State-licensed pharmacies and licensed veterinarians include on the label of any compounded drug: The species of the intended animal patient, the name of the animal patient, and the name of the owner or caretaker of the animal patient. It is usual and customary for State-licensed pharmacies and licensed veterinarians to include such information on the labels of compounded drugs in the normal course of their activities; thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

In addition, the draft guidance indicates in section III.C.10. that, to meet the conditions of the guidance, outsourcing facilities include on the label of any compounded animal drug pursuant to a specific prescription or order: The active ingredient; the dosage form, strength, and flavoring, if any; direction for use, as provided by the veterinarian prescribing or ordering the drug; the quantity or volume, whichever is appropriate; the lot or batch number of the drug; special storage and handling instructions; the date the drug was compounded; the beyond use date of the drug; the name of the veterinarian prescribing or ordering the drug; the inactive ingredients; and the address and phone number of the outsourcing facility that compounded the drug. It is usual and customary for outsourcing facilities to include such information on the labels of compounded drugs in the normal course of their activities; thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

The draft guidance indicates in section III.C.10 that, to meet the conditions of the guidance, outsourcing facilities compounding animal drug from bulk drug substances for office use in veterinary practices include on the label of any compounded drug these four statements:

- ''Not for resale.''
- ''For use only in [fill in species and any associated condition or limitation listed in Appendix A].''
- ''Compounded by [name of outsourcing facility].''
- ''Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a.''

We tentatively conclude that these four label statements are ''public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, the time it would take to provide this information is not included in the burden estimate reported in table 2.

This draft guidance also refers to previously approved collections of information. A condition set forth in sections III.A.7., III.B.6, and III.C.5 is that any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (including a foreign establishment that is registered under section 360(i) of the FD&C Act) and is accompanied by a valid certificate of analysis. The information collection related to the disclosure of the certificate of analysis is approved under OMB control number 0910–0139.

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the proposed information collection provisions. 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.

VI. Comments

Interested persons may submit either electronic comments regarding this draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with Docket No. FDA–2015–D–1176. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VII. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm* or *http://www.regulations.gov.*

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11982 Filed 5–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Review Committee, pursuant to Section 1104(i) of the Patient Protection and Affordable Care Act (ACA).

Time and Date: June 16, 2015, 9:00 a.m.–5:00 p.m. EST; June 17, 2015, 8:00 a.m.–5:15 p.m. EST.

Place: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Auditorium B and C, Hyattsville, Maryland 20782, (301) 458–4524.

Status: Open.

Purpose: The purpose of this hearing is to obtain information from the health care industry on the currently adopted standards, operating rules, code sets and identifiers used in administrative simplification transactions.

The objectives of this hearing are as follows: (1) Review currently adopted standards, operating rules, code sets and identifiers used in each of the HIPAA-named administrative simplification transactions and evaluate the degree to which they meet current industry business needs; and (2) Identify transactions, standards, operating rules, code sets and identifiers used in administrative simplification that require changes, deletions or new versions in order to meet industry needs.

We invite the public to prepare and submit written testimony on any and all areas covered by this hearing. We also invite testifiers to prepare and submit more extensive written testimony, in addition to the oral testimony they will be providing during the hearing. Written testimonies should be sent to Marietta Squire, Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Health Statistics, email *msquire@cdc.gov.*

Background on the Review Committee, including the Review Committee's Charter can be accessed at *http://www.ncvhs.hhs.gov/subcommittees-work-groups/subcommittee-on-standards/review-committee/.*

Contact Person for More Information: Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458–4614 or Terri Deutsch, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland 21244, telephone (410) 786–9462. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://ncvhs.us/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: May 13, 2015.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2015–12106 Filed 5–18–15; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Surgeon General of the United States Public Health Service, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that two meetings are scheduled for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the ''Advisory Group''). The meetings will be open to the public. Information about the Advisory Group and the agendas for these meetings can be obtained by accessing the following Web site: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html.*

DATES: The first meeting will be held on June 11, 2015, from 11:30 a.m. to 2:30 p.m. EST. The second meeting will be held on August 31 from 9:00 a.m. to

5:00 p.m. EST—September 1, 2015, from 9:00 a.m. to 1:00 p.m. EST.

ADDRESSES: The first meeting on June 11, 2015, will be held via teleconference. The second meeting on August 31—September 1, 2015, will be held in Washington, DC Teleconference and meeting location information will be published closer to the meeting dates at: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html.*

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave. SW.; Washington, DC 20201; 202–205–9517; *prevention.council@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary federal advisory committee that was initially established under Executive Order 13544, dated June 10, 2010, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council.

The Advisory Group was terminated on September 30, 2012, by Executive Order 13591, dated November 23, 2011. Authority for the Advisory Group to be re-established was given under Executive Order 13631, dated December 7, 2012. Authority for the Advisory Group to continue to operate until September 30, 2015, was given under Executive Order 13652, dated September 30, 2013.

It is authorized for the Advisory Group to consist of no more than 25 non-federal members. The Advisory Group currently has 21 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine.

Meeting descriptions and relevant materials will be published closer to the meeting dates at: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html.*

Members of the public have the opportunity to participate in each meeting and/or provide comments to the Advisory Group. Public comment will be limited to 3 minutes per speaker. Individuals who wish to participate in the meetings and/or provide comments must register by 12:00 p.m. EST on June 4, 2015, for the meeting on June 11, 2015, and by 12:00 p.m. EST on August 24, 2015, for the meeting on August 31–September 1, 2015. In order to register, individuals must send their full name and affiliation via email to *prevention.council@hhs.gov.* Individuals who need special assistance and/or accommodations, *i.e.,* sign language interpretation or other reasonable accommodations, should indicate so when they register. Members of the public who wish to have materials distributed to the Advisory Group members at these scheduled meetings should submit those materials by June 4, 2015, for the June meeting and by August 24, 2015, for the August/September meeting.

Dated: May 6, 2015.

Corinne M. Graffunder,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, Office of the Surgeon General.

[FR Doc. 2015–12104 Filed 5–18–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: June 4–5, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park, Washington DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: June 5, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications

Place: Warwick Seattle Hotel, 401 Lenora Street, Seattle, WA 98121.

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section.

Date: June 10, 2015.

Time: 8:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: George Washington University Inn, 824 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, *zhengli@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology A Study Section.

Date: June 11–12, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, Bethesda, MD 20892, (301) 435–2409, *grossmanrs@mail.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: June 11–12, 2015.

Time: 8:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW., Washington, DC 20037.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group, Tumor Microenvironment Study Section.

Date: June 15–16, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115.

Contact Person: Angela Y Ng, Ph.D., MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301–435–1715, *ngan@mail.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Neurodegeneration Study Section.

Date: June 16–17, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott-Courtyard Downtown, 500 East First Street, Long Beach, CA 90802.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapeutics.

Date: June 16, 2015.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.

Date: June 17–18, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Societal and Ethical Issues in Research Study Section.

Date: June 17, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group, Intercellular Interactions Study Section.

Date: June 18, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1191, *ipws@mail.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Gastrointestinal Mucosal Pathobiology Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Allerton Hotel, 701 N. Michigan Avenue, Chicago, IL 60611.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC 7850, Bethesda, MD 20892, (301) 594–1245, ivinsj@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 East Wacker Drive, Chicago, IL 60601.

Contact Person: Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Washington DC, Convention Center, 900 10th St. NW., Washington, DC 20001.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: June 18–19, 2015.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA.

Contact Person: Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301–435–4511, *ronald.adkins@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIB Clinical Pediatric and Fetal Applications.

Date: June 18, 2015.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell, Computational and Molecular Biology.

Date: June 19, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13–293: Gut Microbiota-Derived Factors in the Integrated Physiology and Pathophysiology of Diseases within NIDDK's mission.

Date: June 19, 2015.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 14–242: Role of the Microflora in the Etiology of Gastrointestinal Cancer.

Date: June 19, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Epidemiology and Environment.

Date: June 19, 2015.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Claire E. Gutkin, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, (301) 594–3139, *gutkincl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13–213: Outcome Measures for Use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities (R01).

Date: June 19, 2015.

Time: 2:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 East Wacker Drive, Chicago, IL 60601.

Contact Person: Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12010 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: June 15-16, 2015.

Time: June 15, 2015, 2:20 p.m. to 5:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room GE 610 and 640, 35A Convent Drive, Bethesda, MD 20892.

Time: June 15, 2015, 7:30 p.m. to 9:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Time: June 16, 2015, 9:00 a.m. to 5:05 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room GE 620/630 and 640, 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Jennifer E. Mehren, Ph.D., Executive Secretary, Division of Intramural Research Programs, National Institute of Mental Health, NIH, 35A Convent Drive, Room GE 412, Bethesda, MD 20892–3747, 301–496–3501, *mehrenj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 13, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12008 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications/contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA MOBC PAR—R21 applications.

Date: June 3, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Room CR2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA MOBC PAR—R01.

Date: June 8, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Room CR2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of Contract Proposals on Human Lab Paradigms.

Date: June 11, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIAAA, NIH, 5635 Fishers Lane, Room CR2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

and Research Supports Awards, National Institutes of Health, HHS)

Dated: May 13, 2015.

Melanie J. Gray-Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12012 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Inflammation and AD.

Date: June 18, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Epigenetic RFA.

Date: June 23, 2015.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: BITA NAKHAI, Ph.D., SCIENTIFIC REVIEW BRANCH, NATIONAL INSTITUTE ON AGING, GATEWAY BLDG., 2C212, 7201 WISCONSIN AVENUE, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Vascular Contributions to AD.

Date: June 29, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Novel Molecular Mechanism of Longevity.

Date: July 15, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 13, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12013 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Investigator Initiated Program Project Applications.

Time: June 11, 2015, 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4F100, 5601 Fishers Lane, Rockville, MD 20892.

Time: June 19, 2015, 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4F100, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Maja Maric, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3F21A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852, (240) 669–5025, *maja.maric@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12006 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Biomarkers for Acute Ischemic Stroke

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license, to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application No. 61/307,233, filed 23 February 2010
   HHS Ref. No.: E–023–2010/0–US–01
   Titled: Biomarkers for Acute Ischemic Stroke
2. PCT Patent Application No. PCT/US2011/025748, filed 22 February 2011
   HHS Ref. No.: E–023–2010/0–PCT–02
   Titled: Biomarkers for Acute Ischemic Stroke
3. U.S. Patent Application No. 13/580,571, filed 22 August 2012
   HHS Ref. No.: E–023–2010/0–US–03
   Titled: Biomarkers for Acute Ischemic Stroke

to VuEssence, Inc., a company incorporated under the laws of the State of Florida having its headquarters in

Odessa, Florida. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before June 18, 2015 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Jaime M. Greene, M.S., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5559; Email: *greenejaime@mail.nih.gov;* Facsimile: (301) 402–0220. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology is directed to gene biomarkers for the diagnosis and potential treatment of acute ischemic stroke. Stroke is the third leading cause of death in the United States, of which 87% are ischemic stroke and result in death within 30 days in 8–12% of the cases. Currently, recombinant tissue plasminogen activator (rtPA, trade name alteplase), is the only FDA approved ischemic stroke treatment, and it is only effective when administered to patients within three hours from the onset of symptoms. Unfortunately, the median time from stroke symptom onset to presentation to the emergency department is 3–6 hours. Although advances in neuroimaging and clinical management have helped with patient survival rates, these techniques are not infallible and at times result in misdiagnosis. The biomarkers identified in this technology may be used to develop a diagnostic testing device for determining stroke subtype in the field.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 12, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–12005 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in Gastroenterology.

Date: June 10, 2015.

Time: 2:00 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; NRCS Palliative Care and Survivorship.

Date: June 11, 2015.

Time: 11:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Martha L. Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: June 17–18, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Joseph D. Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 408–9465, *moscajos@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; BD2K: Biomedical Data Science Training Coordination Center.

Date: June 17, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0952, *espinozala@mail.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: June 18, 2015.

Time: 7:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington Embassy Row, 2015 Massachusetts Ave. NW., Washington, DC 20036.

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435–1195, *Chengy5@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Electrical Signaling, Ion Transport and Arrhythmias Special Panel.

Date: June 18, 2015.

Time: 7:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Lawrence E. Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435–8367, *boerboom@nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Gene and Drug Delivery Systems Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Amy L. Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, *rubinsteinal@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Chemo/Dietary Prevention Study Section.

Date: June 18, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Sally A. Mulhern, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 408–9724, *mulherns@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Developmental Therapeutics Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Sharon K. Gubanich, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 408–9512, *gubanics@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroimmunology and Brain Tumors Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

Contact Person: Jay Joshi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 408–9135, *joshij@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Paula Elyse Schauwecker, Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5211, Bethesda, MD 20892, *schauweckerpe@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Clinical Neurophysiology, Devices, Neuroprosthetics, and Biosensors.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, , 2401 M Street NW., Washington, DC 20037.

Contact Person: Cristina Backman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, *cbackman@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Behavioral Neuroscience.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree by Hilton Chicago Magnificent Mile, 300 E. Ohio Street, Chicago, IL 60611.

Contact Person: Kristin Kramer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5205, MSC 7846, Bethesda, MD 20892, (301) 437–0911, *kramerkm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Leonid V. Tsap, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7854, Bethesda, MD 20892, (301) 435–2507, *tsapl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA grant review meeting.

Date: June 18, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, *bloomm2@mail.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Vaccines Against Microbial Diseases Study Section.

Date: June 18–19, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street, Washington, DC 20001.

Contact Person: Jian Wang, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer, Cardiovascular and Sleep Epidemiology Panel B Study Section.

Date: June 18–19, 2015.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ellen K. Schwartz, EDD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, Bethesda, MD 20892, 301–828–6146, *schwarel@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

Date: June 18, 2015.

Time: 11:45 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 13, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12014 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Mechanisms of OCD Treatment.

Date: June 9, 2015.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIH Pathway to Independence Awards (K99).

Date: June 10, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Review of R25 Applications.

Date: June 10, 2015.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions.

Date: June 10, 2015.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW, Washington, DC 20036.

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NAPLS—miRNA and Immune System Project.

Date: June 12, 2015.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 13, 2015.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12007 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, June 4, 2015, 10:00 a.m. to June 4, 2015, 12:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, which was published in the **Federal Register** on April 29, 2015, 80 83 FR 2015–10003.

The date of the meeting was changed to June 11, 2015. The meeting is closed to the public.

Dated: May 13, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12011 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Musculoskeletal Tissue Engineering Study Section, June 01, 2015, 8:00 a.m. to June 02, 2015, 5:30 p.m., Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on May 13, 2015, 80 FR Pg 27333.

The meeting will be held on June 1, 2015 at 8:00 a.m. and end at 6:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12009 Filed 5–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2015–0020]

The U.S. Customs and Border Protection Airport and Seaport Inspections User Fee Advisory Committee (UFAC); Correction

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Public Committee Meeting; correction.

SUMMARY: U.S. Customs and Border Protection (CBP) published in the **Federal Register** on May 14, 2015 [80 FR 27694], a document announcing that the U.S. Customs and Border Protection Airport and Seaport Inspections User Fee Advisory Committee (UFAC) will meet on Tuesday, June 2, 2015, in Washington, DC. This document corrects that May 14, 2015, document to reflect the correct time zone for the meeting of Eastern Daylight Savings (EDS) time rather than Eastern Standard Time (EST) to prevent confusion, if any.

DATES: The UFAC will meet on Tuesday, June 2, 2015, from 1:00 p.m. to 2:30 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Ms. Michele Snavely, Paralegal, Regulations and Rulings, Office of International Trade, (202) 325–0354.

Correction

In notice document, FR Doc. 2015–11619, beginning on page 27694 in the issue of Thursday, May 14, 2015, make the following corrections in the first column on page 27695:

Remove ''EST'' and replace it with ''EDT'' the three (3) times that it appears in the **DATES:** section. Please note that all other information in the May 14, 2015, notice is unchanged.

Dated: May 14, 2015.

Joanne Roman Stump,

Acting Director, Regulations and Disclosure Law Division, U.S. Customs and Border Protection.

[FR Doc. 2015–12079 Filed 5–18–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–FHC–2015–N092; FF05F24400–FXFR13350500000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Horseshoe Crab Tagging Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on May 31, 2015. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before June 18, 2015.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail), or *hope_grey@fws.gov* (email). Please include ''1018–0127'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

Information Collection Request

OMB Control Number: 1018–0127.

Title: Horseshoe Crab Tagging Program.

Service Form Number(s): 3–2310 and 3–2311.

Type of Request: Extension of currently approved collection.

Description of Respondents: Tagging agencies include Federal and State agencies, universities, and biomedical companies. Members of the general public provide recapture information.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion when horseshoe crabs are tagged and when horseshoe crabs are found or captured.

Activity	Number of annual respondents	Number of annual responses	Completion time per response	Annual burden hours
FWS Form 3–2310	1,160	2,750	10 minutes	458
FWS Form 3–2311	18	18	95 hours*	1,710
Totals	1,178	2,768		2,168

* Average time required per response is dependent on the number of tags applied by an agency in 1 year. Agencies tag between 25 and 9,000 horseshoe crabs annually, taking between 2 to 5 minutes per crab to tag, record, and report data. Each agency determines the number of tags it will apply.

Estimated Annual Nonhour Burden Cost: None.

Abstract: Horseshoe crabs play a vital role commercially, biomedically, and ecologically along the Atlantic coast. Horseshoe crabs are commercially harvested and used as bait in eel and conch fisheries. Biomedical companies along the coast also collect and bleed horseshoe crabs at their facilities. Limulus Amoebocyte Lysate is derived from crab blood, which has no synthetic substitute, and is used by pharmaceutical companies to test sterility of products. Finally, migratory shorebirds also depend on the eggs of horseshoe crabs to refuel on their migrations from South America to the Arctic. One bird in particular, the red knot, feeds primarily on horseshoe crab eggs during its stopover. Effective January 12, 2015, the red knot was listed as threatened under the Endangered Species Act.

In 1998, the Atlantic States Marine Fisheries Commission (ASMFC), a management organization with representatives from each State on the Atlantic Coast, developed a horseshoe crab management plan. The ASMFC plan and its subsequent addenda established mandatory State-by-State harvest quotas, and created the 1,500-square-mile Carl N. Shuster, Jr., Horseshoe Crab Sanctuary off the mouth of Delaware Bay.

Restrictive measures have been taken in recent years, but populations are increasing slowly. Because horseshoe crabs do not breed until they are 9 years or older, it may take some time before the population measurably increases. Federal and State agencies, universities, and biomedical companies participate in a Horseshoe Crab Cooperative Tagging Program. The Maryland Fishery Resources Office, U.S. Fish and Wildlife Service, maintains the information that we collect under this program and uses it to evaluate migratory patterns, survival, and abundance of horseshoe crabs.

Agencies that tag and release the crabs complete FWS Form 3–2311 (Horseshoe Crab Tagging) and provide the Service with:

- Organization name.
- Contact person name.
- Tag number.
- Sex of crab.
- Prosomal width.
- Capture site, latitude, longitude, waterbody, State, and date.

Members of the public who recover tagged crabs provide the following information using the online submission

form (*http://www.fws.gov/crabtag/*) or via a toll-free telephone number:

- Tag number.
- Whether or not tag was removed.
- Condition of crab.
- Date captured/found.
- Crab fate.
- Finder type.
- Capture method.
- Capture location.
- Reporter information.
- Comments.

If the public participant who reports the tagged crab requests information, we send data pertaining to the tagging program and tag and release information on the horseshoe crab that was found or captured.

Comments Received and Our Responses

Comments: On February 10, 2015, we published in the **Federal Register** (80 FR 7490) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on April 13, 2015. We did not receive any comments.

Request for Public Comments

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: May 13, 2015.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2015–12048 Filed 5–18–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FW–R5–NCTC–2015–N093; FF09X35000–156–FXGO16610900600]

Proposed Information Collection; National Initiative To Understand and Connect Americans and Nature

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. We 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.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by July 20, 2015.

ADDRESSES: Send your comments on the IC to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or *hope_grey@fws.gov* (email). Please include ''1018–New'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract

Nature and the outdoors have always been an important part of the fabric of American life. But, there are major questions about the present and future role of nature and the outdoors in our increasingly diverse, technologically oriented, and rapidly changing society. For our programs to remain relevant to American life today and tomorrow, we must be aware of public sentiment toward the part nature plays in the quality of our lifestyles.

It is for these reasons that we plan to use a quantitative survey to collect: Information on the attitudes that the public maintains towards the natural environment; the effects of contact with nature on participants' health and quality of life; the extent of contact with nature and obstacles to greater contact with nature; general knowledge of nature and wildlife; concerns toward selected environmental issues; and socio-demographic variables. Results will help improve the design and delivery of new or existing programs aimed at engaging the public in nature-related activities (*e.g.,* outreach and educational programming at national wildlife refuges and national fish hatcheries).

II. Data

OMB Control Number: 1018–New.

Title: National Initiative to Understand and Connect Americans and Nature.

Service Form Number: None.

Type of Request: Request for a new OMB control number.

Description of Respondents: Individuals.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Estimated Number of Respondents: 8,950.

Estimated Number of Annual Responses: 8,950.

Completion Time per Response: 20 minutes.

Estimated Annual Burden Hours: 2,983.

Estimated Annual Nonhour Burden Cost: None.

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. 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.

Dated: May 13, 2015.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2015–12052 Filed 5–18–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–FHC–2015–N102; FXFR1334088TWG0W4–123–FF08EACT00]

Trinity River Adaptive Management Working Group; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a public meeting of the Trinity River Adaptive Management Working Group (TAMWG). The TAMWG is a Federal advisory committee that affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the Trinity Management Council (TMC). The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

DATES: *Public meeting:* TAMWG will meet from 9:30 a.m. to 4:45 p.m. Pacific Time on Tuesday, June 16, 2015, and from 9 a.m. to 2:30 p.m. Pacific Time on Wednesday, June 17, 2015. *Deadlines:* For deadlines on submitting written material, please see ''Public Input'' under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The in-person meeting will be held at the Weaverville Fire Hall, 125 Bremer Street, Weaverville, CA 96093.

FOR FURTHER INFORMATION CONTACT: Joseph C. Polos, U.S. Fish and Wildlife Service, 1655 Heindon Road, Arcata, CA 95521; telephone: 707–822–7201; *email: joe_polos@fws.gov.* Individuals with a disability may request an accommodation by sending an email to the point of contact.

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., we announce that the Trinity River Adaptive Management Working Group will hold a meeting.

Background

The TAMWG affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the TMC. The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

Meeting Agenda

- Designated Federal Officer (DFO) updates, election of officers, review of charter and bylaws, and administrative procedures,
- TMC Chair update,
- Executive Director's update,
- TRRP Workgroup/Science Coordinator update, and Decision Support System update,
- TRRP Implementation update, 2015 sites, 2016 sites, and status of permits,
- Flow management, Water Year 2015 Central Valley Project water management update, BOR long-term fall flow plan update, and fall flow plan for Water Year 2015,
- Solicitor's guidance on the TRRP watershed efforts,
- FY 2016 Budget/work planning,
- TMC current issues,
- TRRP background/refresher,
- Gravel augmentation short-term needs, and long-term gravel plan status,
- TRRP Communications plan, and status,
- Status of fish returns and goals of the TRRP,
- Joint meeting with TMC in August, and
- Public Comment.

The final agenda will be posted on the Internet at *http://www.fws.gov/arcata.*

PUBLIC INPUT

If you wish to	You must contact Joseph Polos (**FOR FURTHER INFORMATION CONTACT**) no later than
Submit written information or questions for the TAMWG to consider during the meeting.	June 8, 2015.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the TAMWG to consider during the meeting. Written statements must be received by the date listed in ''Public Input,'' so that the information may be available to the TAMWG for their consideration prior to this meeting. Written statements must be supplied to Elizabeth Hadley in one of the following formats: One hard copy with original signature, one electronic copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, PowerPoint, or rich text file).

Registered speakers who wish to expand on their oral statements, or those who wished to speak but could not be accommodated on the agenda, may submit written statements to Elizabeth Hadley up to 7 days after the meeting.

Meeting Minutes

Summary minutes of the meeting will be maintained by Elizabeth Hadley (see **FOR FURTHER INFORMATION CONTACT**). The minutes will be available for public inspection within 14 days after the meeting, and will be posted on the TAMWG Web site at *http://www.fws.gov/arcata.*

Dated: May 13, 2015.

Joseph C. Polos,

Supervisory Fish Biologist, Arcata Fish and Wildlife Office, Arcata, California.

[FR Doc. 2015–12070 Filed 5–18–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–18228; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before April 25, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by June 3, 2015. 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.

Dated: April 30, 2015.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

COLORADO

Las Animas County

Santa Fe Trail Mountain Route Trail Segment—Delhi Vicinity I, (Santa Fe Trail MPS), Address Restricted, Delhi, 15000313

Santa Fe Trail Mountain Route Trail Segment—Delhi Vicinity II, (Santa Fe Trail MPS), Address Restricted, Delhi, 15000314

Santa Fe Trail Mountain Route Trail Segment—Delhi Vicinity III, (Santa Fe Trail MPS), Address Restricted, Delhi, 15000315

ILLINOIS

Sangamon County

Central Springfield Historic District (Boundary Increase and Additional Documentation), Roughly Jefferson, Jackson, 2nd & 7th Sts., Springfield, 15000316

Strawbridge—Shepherd House, 5255 Shepherd Rd., Springfield, 15000317

KANSAS

McPherson County

Lindquist, P.J., Building, 116 S. Main St., Lindsborg, 15000318

MISSOURI

St. Louis Independent city

Shell Building, The, 1221 Locust St., St. Louis (Independent City), 15000319

NEVADA

Carson City Independent city

Nevada State Prison, 3301 E. 5th St., Carson City (Independent City), 15000320

NEW JERSEY

Burlington County

Florence Public School No. 1, 203 W. 2nd St., Florence Township, 15000321

OHIO

Franklin County

Drexel Theater, 2254 E. Main St., Bexley, 15000322

Graham, A.B., House, 159 Clinton Heights Ave., Columbus, 15000323

Theresa Building, 823 E. Long St., Columbus, 15000324

United States Carriage Company, 309–319 S. 4th St., Columbus, 15000325

Hamilton County

West Fourth Street Historic District (Boundary Increase), 309 Vine St., Cincinnati, 15000326

OKLAHOMA

Kay County

Hayes—Kennedy—Rivoli Theater Building, 122–124 S. Main, Blackwell, 15000327

Oklahoma County

Czech Hall of Oklahoma City—Lodge Laska, 515 SW. 6th St., Oklahoma City, 15000328

Tulsa County

Elizabeth Manor, 1820 S. Boulder Ave., W., Tulsa, 15000329

Washington County

Comer, C.A., House, (Bruce Goff Designed Resources in Oklahoma MPS) 1316 North Creek, Dewey, 15000330

OREGON

Jefferson County

Madras Army Air Field North Hanger, 2028 NW. Berg Dr., Madras, 15000331

TENNESSEE

Smith County

Moss Mounds, (Mississippian Cultural Resources of the Central Basin (AD 900–1450) MPS), Address Restricted, Elmwood, 15000332

Williamson County

Glass Mounds Discontiguous Archeological District, 4000 Golf Club Ln., Franklin, 15000333

TEXAS

Bastrop County

Hopewell School, (Rosenwald School Building Program in Texas MPS), 690 TX 21 W., Cedar Creek, 15000334

Harris County

Stowers Building, 820 Fannin, Houston, 15000335

Nueces County

Galvan Ballroom, 1632 Agnes, Corpus Christi, 15000336

Tarrant County

Parker—Browne Company Building, 1212 E. Lancaster Ave., Fort Worth, 15000337

Terry County

Abilene Courts, 633 S. 11th St., Abilene, 15000338

Wichita County

Perkins, Joe and Lois, House, 3301 Harrison St., Wichita Falls, 15000339

WISCONSIN

Sauk County

Downtown Baraboo Historic District, Roughly bounded by 5th & 2nd Aves., 5th, Ash, 1st, Oak & Birch Sts., Baraboo, 15000340

Walworth County

Wandawega Inn, W5453 Lake View Dr., Sugar Creek, 15000341

[FR Doc. 2015–12026 Filed 5–18–15; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–11]

Karen S. Dunning, N.P.; Decision and Order

On January 9, 2015, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Karen S. Dunning, N.P. (hereinafter, Respondent) of Kouts, Indiana. The Order to Show Cause and Immediate Suspension of Registration proposed the revocation of Respondent's DEA Certificate of Registration MD2249161, pursuant to which she was authorized to dispense controlled substances in schedules II through V as a practitioner, and the denial of any application to renew or modify her registration, on the ground that she has committed acts which render her ''continued registration inconsistent with the public interest.'' Show Cause Order, at 1.

More specifically, the Order alleged that Respondent, who is an Advanced Practice Nurse licensed by the Indiana State Board of Nursing, is not authorized under state law ''to prescribe controlled substances in Schedules III and IV for the purpose of weight reduction or to control obesity.'' Show Cause Order, at 1. The Order then alleged that ''between August 2007 and March 2014,'' Respondent issued prescriptions, ''on multiple occasions,'' for phendimetrazine, a schedule III controlled substance, and phentermine, a schedule IV controlled substance, for ''the purpose of weight loss or to control obesity, in violation of state and federal law.'' *Id.* at 2 (citing Ind. Code §§ 35–48–3–11; 25–22.5–8–2(a); 21 CFR 1306.03 & 1306.04(a)). The order then set forth specific allegations regarding Respondent's prescribing of the aforesaid controlled substances to nine patients. *Id.* at 2–4.

The Order also alleged that ''beginning in February 2014 and for several months thereafter,'' Respondent had violated federal law by issuing controlled substance prescriptions for weight loss medications that had been pre-signed by her collaborating physician, as well as that between February and August 2014, she issued controlled substance prescriptions ''without a collaborative agreement'' having been filed with the Indiana Board of Nursing. *Id.* at 4 (citing 21 CFR 1306.05 and 1306.03(a)(1); 848 Ind. Admin. Code § 5–1–1(a)(7)). The Order further alleged that Respondent had dispensed Bontril (phendimetrazine) to

a patient at an unregistered location. *Id.* Finally, the Order alleged that Respondent had failed to keep various records as required by DEA regulations. *Id.* at 5. Based on the totality of Respondent's misconduct, I concluded that her continued registration during the pendency of the proceeding ''would constitute an imminent danger to the public health and safety'' and therefore ordered that her registration be immediately suspended. *Id.* at 6–7.

Following service of the Order, Respondent timely requested a hearing on the allegations. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (ALJ) Christopher B. McNeil, who proceeded to conduct pre-hearing procedures.

However, the next day, the Government moved for summary disposition and to stay the proceeding, asserting that the Indiana State Board of Nursing had ordered the emergency suspension of Respondent's nursing license and advanced practice nurse prescriptive authority, and that she was without authority to dispense controlled substances and to possess a DEA registration in the State. Mot. For Summ. Disp., at 1–3. As support for its Motion, the Government attached a printout from a license verification Web page maintained by the State of Indiana. *See id.* at Attachment A. The printout showed that Respondent's Indiana Advanced Practice Nurse Prescriptive Authority license was the subject of an emergency suspension.[1] *Id.*

Upon review of the Government's Motions, the ALJ issued an Order for Stay and for Respondent's Response to Allegations Concerning Respondent's Lack of State Authority. R.D. at 2. Thereafter, Respondent timely filed her Response, in which she did not dispute that her license was suspended but asserted that section 824(a)(3) ''authorizes suspension or revocation of a DEA registration based on the loss of State privileges'' and thus ''gives a choice of remedies and clearly contemplates the exercise of administrative discretion.'' Respondent's Response, at 1.

Respondent contends that the Nursing Board has only suspended her license and advanced practice nurse prescriptive authority for ninety (90) days. *Id.* at 3. She further argues that the prior cases in which the Agency revoked a practitioner's registration based on a state's suspension of prescribing authority involved suspensions that ''were of indefinite rather than, as here, for a finite, definite, and limited time'' and that ''[t]his indefiniteness was the gravamen of the decisions holding revocation to be the appropriate remedy.'' *Id.* (citing *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)).

Respondent also argues that the temporary suspension of her license ''does not render her 'no longer authorized by State law' to dispense controlled substances. It only temporarily restrains her from dispensing controlled substances.'' *Id.* And she further argues that suspending her registration ''mean[s] that she is not holding a DEA Registration and would fully satisfy statutory requirements.'' *Id.* She thus contends that revoking her registration would be ''arbitrary, capricious, a clear abuse of discretion and not in accordance with the law.'' *Id.* at 4.

The ALJ correctly rejected these contentions, explaining that the CSA defines the term ''practitioner'' to ''mean[] a physician, dentist, veterinarian . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which [s]he practices to distribute [or] dispense a controlled substance in the course of professional practice,'' 21 U.S. C. 802(21), and that under section 823(f), only a person who is authorized to dispense controlled substances and is therefore a practitioner within the meaning of the Act can be registered. R.D., at 3; *see also* 21 U.S. C. 823(f) (''The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the States in which he practices.'').

Respondent contends, however, that the decision in *Anne Lazar Thorn, M.D.,* 62 FR 12847 (1997), stands for the proposition that the Agency's consistent practice of revoking registrations based on a loss of state authority ''rests on the indefinite nature of a State suspension.'' Respondent's Resp., at 2–3. Respondent quotes the following passage from *Thorn:*

> [T]he Acting Deputy Administrator recognizes that he has discretionary authority to either revoke or suspend a DEA registration. However, given the indefinite nature of the suspension of Respondent's state license to practice medicine, the Acting Deputy Administrator agrees with [the ALJ] that revocation is appropriate in this case.

Id. at 3 (quoting 62 FR at 12848).

Notwithstanding the implication of the above passage, no decision of this Agency has held that a suspension (rather than a revocation) is warranted where a State has imposed a suspension of a fixed or certain duration. To the contrary, in the case of practitioners, DEA has long and consistently interpreted the CSA as mandating the possession of authority under state law to handle controlled substances as a fundamental condition for obtaining and maintaining a registration. *See, e.g., Leonard F. Faymore,* 48 FR 32886, 32887 (1983) (collecting cases). As the *Thorn* decision further explained:

> DEA has consistently interpreted the Controlled Substances Act to preclude a practitioner from holding a DEA registration if the practitioner is without authority to handle controlled substances in the state in which he/she practices. This prerequisite has been consistently upheld.
>
> * * * * *
>
> The Acting Deputy Administrator finds that the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather it is whether the Respondent *is currently authorized to handle controlled substances in the state.* In the instant case, it is undisputed that Respondent is not currently authorized to handle controlled substances in the [state in which she practices medicine]. Therefore . . . Respondent is not currently entitled to a DEA registration.

62 FR at 128438 (citing and quoting 21 U.S. C. 823(f) and 802(21) and collecting cases). Accordingly, in *Thorn,* the Agency rejected the Respondent's contention that her registration should be suspended rather than revoked.

As for Respondent's contention that section 824(a) ''gives a choice of remedies and clearly contemplates the exercise of administrative discretion,'' it is acknowledged that the opening sentence of section 824(a) provides that a registration ''may be suspended or revoked by the Attorney General'' upon the Attorney General's finding that one of the five grounds set forth exists. 21 U.S. C. 824(a). However, this general grant of authority in imposing a sanction must be reconciled with the CSA's specific provisions which mandate that a practitioner hold authority under state law in order to obtain and maintain a DEA registration. *See Gozlon-Peretz* v. *United States,* 498 U.S. 395, 407 (1991) (''A specific provision controls over one of more general application.''); *see also Bloate* v.

[1] Subsequently, the Government also filed a copy of the Summary Suspension Order issued to Respondent by the Indiana State Board of Nursing. *See* Notice of Filing of Written Suspension Order (Exhibit A).

I take official notice of the registration records of this Agency, which establish that Respondent's registration will not expire until June 30, 2016. *See* 21 CFR 1316.59(e). Respondent may refute this fact by filing a properly supported motion for reconsideration no later than ten (10) business days from the date of issuance of this Decision and Order.

United States, 130 S.Ct. 1345, 1354 (2010) (quoting *D. Ginsberg & Sons, Inc.,* v. *Popkin,* 285 U.S. 204, 208 (1932) (''General language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment.'')).

Indeed, Respondent's argument has previously been tried and rejected. *See James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012) (unpublished). As the Fourth Circuit explained in Hooper:

> Section 824(a) does state that the DA may ''suspend or revoke'' a registration, but the statute provides for this sanction in five different circumstances, only one of which is loss of a State license. Because § 823(f) and § 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the DA's decision to construe § 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA.

Id. at 828.

Moreover, while Respondent points to the fact that the suspension imposed by the Board is ''temporary'' and only ''for ninety (90) days,'' Respondent's Resp. at 3, the Board's order was non-final. Thus, while Respondent may prevail before the Board, the Board may also impose an additional period of suspension or revoke her license and prescribing authority.

Accordingly, consistent with the Agency's longstanding precedent, revocation remains warranted.[2] *See Gary Alfred Shearer,* 78 FR 19009 (2013) (holding that revocation is warranted even where a state order has summarily suspended a practitioner's controlled substances authority and the state agency's order remains subject to challenge in either administrative or judicial proceedings); *Winfield Drugs, Inc.,* 52 FR 27070 (1987) (revoking registration based on state emergency suspension order notwithstanding state order was under appeal, noting that the ''[r]espondent is not currently authorized to handle controlled substances in the [s]tate'' and that ''[a]s a matter of law, the [DEA] does not have statutory authority . . . to issue or maintain a registration for a practitioner if the applicant or registrant lacks [s]tate authority to dispense controlled substances'').

Order

Pursuant to the authority vested in me by 21 U.S. C. 824 as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration MD2249161 issued to Karen S. Dunning, N.P., be, and it hereby is, revoked. This Order is effectively immediately.[3]

Dated: May 1, 2015.

Michele M. Leonhart,

Administrator.

Michelle F. Gillice, Esq., Paul A. Dean, Esq., for the Government.

Lakeisha C. Murdaugh, Esq., Scott L. King, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION AND FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDED DECISION OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Christopher B. McNeil. On January 9, 2015, the Administrator of the Drug Enforcement Administration issued an Order to Show Cause and Immediate Suspension of Respondent's DEA Certificate of Registration, No. MD2249161. The Order affords Respondent the opportunity to show cause why Respondent's DEA registration should not be revoked pursuant to 21 U.S. C. 824(a), on the grounds that Respondent's continued registration would be inconsistent with the public interest. The Order also seeks to deny any pending applications for registration, renewal or modification pursuant to 21 U.S. C. 823(f). In addition, the Administrator immediately suspended Respondent's registration pursuant to 21 U.S. C. 824(d), upon finding Respondent's continued registration constitutes an imminent danger to the public health and safety.

According to the Government's Notice of Service, Respondent was personally served with the Order to Show Cause on January 14, 2015. On February 18, 2015, the Office of Administrative Law Judges received Respondent's Request for Hearing, dated February 13, 2015. On February 19, 2015, this Office issued an Order for Prehearing Statements and Order Setting the Matter for Hearing.

On February 20, 2015, this office received Government's Motion for Summary Disposition and Motion to Stay Proceedings. The Government asserted that the Indiana State Board of Nursing ordered an emergency suspension of Respondent's nursing license and her advanced practice nurse prescriptive authority, effective immediately. Citing this lack of state authority, the Government requested that the matter be forwarded to the Administrator for a Final Order and that in the interest of efficiency, I grant a Motion to Stay the Proceedings and continue the deadlines pending the resolution of the Motion for Summary Disposition. In response to the Government's filing, I issued an Order for Stay and for Respondent's Response to Allegations Concerning Respondent's Lack of State Authority. In the Order, I required Respondent to file a response to the Government's Motion for Summary Disposition no later than February 27, 2015. Additionally, I stayed the matter and held all deadlines in abeyance.

On February 27, 2015, I received Respondent's Response to the Government's Motion for Summary Disposition. Respondent first cites 21 U.S. C. 824(a)(3) to demonstrate that the Administrator has the choice of authorizing suspension or revocation of Respondent's registration. Respondent then asks that I consider suspending her registration based on the premise that the 90 day suspension of her advanced practice nurse prescriptive authority is not equivalent to the indefinite suspensions in the case law cited by the Government.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's DEA Certificate of Registration must be revoked because Respondent does not have a nursing licensed issued by the state in which she practices. Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which she maintains her DEA registration.[1] Pursuant to 21 U.S. C. 823(f), only a ''practitioner'' may receive a DEA registration. Under 21 U.S. C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to maintain a practitioner's registration if that practitioner is not authorized to dispense controlled substances.[2]

[2] As for Respondent's contention that the temporary suspension of her license ''does not render her 'no longer authorized by State law' to dispense controlled substances,'' under Indiana law, ''[a] person who . . . practices nursing during the time the person's license issued under this chapter . . . is suspended or revoked commits a Class B misdemeanor.'' Ind. Code § 25–23–1–27(5). Thus, Respondent is not currently authorized to dispense controlled substances.

[3] Based on the same findings that led me to conclude that Respondent's continued registration during the pendency of the proceeding constitutes an imminent danger to public health and safety, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

[1] *See* 21 U.S. C. 801(21), 823(f), 824(a)(3); *see also House of Medicine,* 79 FR 4959, 4961 (DEA 2014); *Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA November 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA August 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA April 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA April 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA November 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[2] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA November 24, 1992), and cases cited therein. In *Chaplan,* DEA Administrator Robert C. Bonner adopts the ALJ's opinion that ''the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances.'' *Id.*

Respondent alternatively asks that I consider suspending her registration instead of revoking her registration. This exact issue was addressed in *James L. Hooper, M.D.; Decision and Order.*[3] Dr. Hooper was subject to a one-year suspension of his state license to practice medicine after which his license would be automatically reinstated.[4] In comparison to *Hooper,* Respondent in this case has a less persuasive case as there is no guarantee that her advanced practice nurse prescriptive authority will be restored after 90 days. Dr. Hooper sought a suspension of his DEA Registration for the same time period his medical license was suspended. DEA Administrator Michele M. Leonhart agreed with Chief Administrative Law Judge John J. Mulrooney, II who did not find Dr. Hooper's argument persuasive. Administrator Leonhart, like Respondent in the case at hand, cited to *Anne Lazar Thorn, M.D.*[5] Administrator Leonhart cites the Acting Deputy Administrator's statement in *Thorn* that ''the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances in the state.''[6] In *Hooper,* Administrator Leonhart concludes that ''even where a practitioner's state license has been suspended for a period of certain duration, the practitioner no longer meets the statutory definition of a practitioner.''[7] As detailed above, only a ''practitioner'' may receive a DEA registration. Therefore, I cannot and will not recommend the suspension of Respondent's DEA registration, but will instead recommend the registration be revoked.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S. C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which she seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: March 9, 2015

Christopher B. McNeil,

Administrative Law Judge

[FR Doc. 2015–12020 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

[3] *James L. Hooper, M.D.; Decision and Order,* 76 FR 71371–01, 71371 (DEA Nov. 17, 2011).

[4] *Id.*

[5] *Anne Lazar Thorn, Revocation of Registration* M.D, 62 FR 12847, 12848 (DEA Mar. 18, 1997).

[6] *Id.* at 12848.

[7] *Hooper,* 76 FR at 71372.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P. and David R. Stout, N.P.; Decision and Orders

On November 25, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued Orders to Show Cause to Bobby D. Reynolds, N.P. (hereinafter, Reynolds), of Limestone, Tennessee; Tina L. Killebrew, N.P. (hereinafter, Killebrew), of Kingsport, Tennessee; and David R. Stout, N.P. (hereinafter, Stout), of Morristown, Tennessee. GXs A, B, & C.

With respect to Applicant Reynolds, the Show Cause Order proposed the denial of his application for registration as a practitioner, on the ground that his registration ''would be inconsistent with the public interest'' as evidenced by his repeated violations of state and federal law in prescribing controlled substances to seven patients while employed as a nurse practitioner at the Appalachian Medical Center (AMC), a clinic located in Johnson City, Tennessee. GX A, at 1–2 (citing 21 U.S.C. 823(f)(2), (4) & (5)). The Show Cause Order alleged that he had made unintelligible entries in the medical records of three patients (N.S., T.H., and A.W.), that he had violated state law by referring N.S. to an unlicensed mental health counselor, that he had violated state law by making false entries in N.S.'s chart, that he had failed to maintain complete records for T.H., and that he failed to properly maintain the patient record of C.S. to accurately reflect nursing problems and interventions. GX A, at ¶¶ 5, 6, 7, 11, 12, and 15.

With respect to Applicant Killebrew, the Show Cause Order proposed the denial of her application for registration as a practitioner, on the ground that her registration ''would be inconsistent with the public interest'' as evidenced by her repeated violations of state and federal law in prescribing controlled substances to three patients while employed as a nurse practitioner at the AMC. GX B, at 1–2 (citing 21 U.S.C. 823(f)(2)(4) & (5)).

With respect to Registrant Stout, the Show Cause Order proposed the revocation of his practitioner's registration and the denial of his pending application to renew his registration on two grounds. GX C, at 1–2. First, the Order alleged that Respondent had materially falsified his renewal application when he failed to disclose that on March 10, 2010, the Tennessee Board of Nursing had summarily suspended his nurse practitioner's license and his Certificate of Fitness to prescribe legend drugs in Tennessee. GX C, at 13–14; *see also* 21 U.S.C. 824(a)(1). The Show Cause Order further alleged that Registrant Stout had failed to disclose that on September 3, 2010, he had entered into a Consent Order with the State Board, pursuant to which the suspension was terminated, but he was placed on probation for two years, his multistate privilege to practice in other party states was voided for the period of his probation, he was ordered to pay a civil penalty of $8,000, and other probationary terms were imposed. GX C, at 14. Second, the Show Cause Order alleged that Registrant Stout had ''committed such acts as would render his registration inconsistent with the public interest,'' in that he had violated state and federal law in prescribing controlled substances to five patients while employed as a nurse practitioner at the AMC.[1]

Following service of the Show Cause Orders, all three individuals timely requested a hearing on the allegations of the respective Order. The matters were then placed on the docket of the Agency's Office of Administrative Law Judges, and assigned to the Chief Administrative Law Judge, who consolidated the matters and proceeded to conduct prehearing procedures. However, after extensive prehearing litigation, each of the parties filed written notices waiving his/her respective right to a hearing, *see* GXs LL, MM, and PP, and the ALJ terminated the proceeding.[2]

[1] Each Show Cause Order made extensive and detailed allegations specific to each Applicant's conduct, as well as to Registrant Stout's conduct, in prescribing to the various patients. *See* GX A, at 2–26 (Reynolds OTSC); GX B, at 2–9 (Killebrew Order); GX C, at 2–14 (Stout Order). In its Request for Final Agency Action, the Government pursued only the allegations of unlawful prescribing by the three practitioners, as well as the allegations (which were raised in its prehearing statements) that Applicant Reynolds had made material false statements to a DEA Investigator.

[2] On March 27, 2014, NP Stout, through counsel, submitted a written request to the Government's counsel seeking to withdraw his application to renew his registration. GX RR. Government Counsel promptly forwarded the request to the Deputy Assistant Administrator. GX SS. According to Government Counsel, no action had been taken on the request as of September 16, 2014, the date on which the record was forwarded to this Office. *Id.* Nor has this Office been subsequently notified of any action having been taken on the request.

I conclude that granting Stout's request to withdraw would be contrary to the public interest and that he has otherwise failed to show good cause. Here, the Government has expended extensive resources in investigating the allegations, preparing for a hearing, and in engaging in pre-hearing litigation; it was also fully prepared to go to hearing on the allegations when Stout waived his right to a hearing. Moreover, Stout's counsel has made no offer as to how long he would wait before

Continued

Thereafter, the Government filed a Request for Final Agency Action and forwarded the entire record to my Office for review. Having reviewed the entire record, I find that the Government has established that Registrant Stout has committed such acts as would render his registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Accordingly, I will order that the registration issued to Registrant Stout be revoked and that his pending application to renew his registration be denied. I further find that the Government has established that granting a new registration to Applicants Reynolds and Killebrew would be ''inconsistent with the public interest.'' *Id.* § 823(f). Therefore, I will also order that their respective applications be denied. I make the following findings of fact.

Findings

Jurisdictional Facts

In 2002, Applicant Bobby D. Reynolds II, FNP, founded the Appalachian Medical Center, a clinic located in Johnson City, Tennessee; Reynolds owned the clinic until 2010, when it was closed. GX 42, at 2–3. Reynolds employed both Applicant Killebrew and Registrant Stout at AMC. *Id.*

Reynolds was previously registered under the Controlled Substances Act as a Mid-Level Practitioner, with authority to dispense controlled substances in schedules II–V at the registered address of the AMC, which was located at 3010 Bristol Highway, Johnson City, Tennessee. GX 1, at 1. However, this registration expired on April 30, 2011. On May 19, 2011, Reynolds filed a renewal application; it is this application which is the subject of the Show Cause Order issued to him. *Id.*

Tina L. Killebrew, F.N.P., was employed as a nurse practitioner at AMC from approximately June 2006 through March 11, 2010. GX L, at 13–14 (Brief in Response to Amended Order December 30, 2013). She was also previously registered as a Mid-Level Practitioner with authority to dispense controlled substances in schedules II–V at AMC's address. *Id.* at 11. However, this registration expired on December 31, 2010. On or about August 30, 2011, Killebrew submitted an application for a new registration; it is this application which is the subject of the Show Cause Order issued to her. *Id.*

David R. Stout, N.P., currently holds DEA Certificate of Registration MS0443046, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a Mid-Level Practitioner at the registered address of the AMC. GX 1, at 6. While his registration was due to expire on February 28, 2011, on February 16, 2011, Stout filed a renewal application. Accordingly, his registration remains in effect pending the final order in this matter. *Id.*

The Government's Evidence of Misconduct

In support of the allegations, the Government submitted patient files for seven patients, pharmacy records for four patients, along with various other documents. The Government also provided these materials to Amy Bull, Ph.D., a Board Certified Family Nurse Practitioner, who is licensed in Tennessee as both an Advanced Practice Nurse and Registered Nurse. GX 40, at 2–3. Dr. Bull is an Assistant Professor of Nursing at the Belmont University School of Nursing and previously taught at the Vanderbilt University School of Nursing, where she served as Director of the Family Nurse Practitioner Program, was the coordinator for courses in Advanced Pharmacotherapeutics and Health Assessment & Diagnostic Reasoning, and taught various courses. *Id.* at 1. Dr. Bull also continues to practice as a Nurse Practitioner at a clinic in Dickinson, Tennessee. *Id.* at 2.

Dr. Bull reviewed seven patient files. GX 68, at 6–7. Based on her review, Dr. Bull concluded that Reynolds, Killebrew, and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to the patients, *see* 21 CFR 1306.04(a), and also violated Tennessee Board of Nursing Rule 1000–04.08, which sets forth the standards of nursing practice for prescribing controlled substances to treat pain. *Id.* at 7–8. Dr. Bull specifically found that Reynolds, Killebrew and Stout ''repeatedly issued prescriptions . . . in the face of red flags that should have indicated to him [or her] that these individuals were abusing and/or diverting controlled substances and without taking appropriate action to prevent further abuse and/or diversion,'' and that in doing so, ''their conduct fell far below the standard of care in Tennessee and [was] contrary to generally recognized and accepted practices of a nurse practitioner in Tennessee.'' *Id.* at 8. What follows below is a discussion of the evidence with respect to patients N.S., T.H. and C.S.

N.S.

N.S.'s first visit to AMC was on June 8, 2004, when she presented complaining of neck and back pain. *See* GX 2, at 102. N.S. apparently was seen on this visit by a practitioner other than Mr. Reynolds,[3] Mr. Stout, or Ms. Killebrew. *See* GX 3, at 129–130. This practitioner specifically noted that N.S. had a ''tender neck and low back with decreased range of motion, low back tender to light touch'' and prescribed a thirty-day supply of thirty tablets of Avinza 60 mg (morphine, a schedule II drug), as well as Zanaflex, which is a non-controlled muscle relaxant. *See* GX 2, at 102; GX 3, at 129.

According to the Expert, the documentation contained in N.S.'s file did not support the prescribing of a thirty-day supply of Avinza 60 mg and the prescription was below the standard of care in Tennessee and outside the usual course of professional practice. GX 68, at 8. As the Expert noted, N.S.'s file contains radiologic reports (CT scans and plain radiographs of the neck and lower back) from June 28, 2001 which appear to have been generated in connection with N.S.'s prior visit to the emergency room (''ER'') due to a motor vehicle collision and which described previous surgery to the neck and degenerative changes in the lower back. *See id.* at 8–9; GX 2, at 116–120.

However, as the Expert then explained, these records were from examinations that were performed nearly *three years* before N.S.'s first AMC visit. GX 68, at 9. The Expert then observed that N.S.'s file lacked any documentation indicating what, if any, treatment she had received since the accident, nor contain any records of any prior treating physicians, nor any documentation relating to her substance abuse history. *Id.* Of further note, the Expert observed that N.S. did not list any medication she was then taking on the ''New Patient Information Sheet'' which she apparently completed at her first visit, *see* GX 2, at 9–10; and the record of her first visit does not document the she was taking any medications. *Id.* at 102; GX 68, at 9.

reapplying. *See* GX RR (''This proposal is in the public's interest because it saves time and money for valuable employees and staff. There will be no need to review documents, there will be no need to issue decisions and there will be no delay in Mr. Stout being able to show his good faith in hopes of someday being able to reapply.''). Finally, having reviewed the evidence, I conclude that the public interest would be ill-served by allowing him to withdraw his application and thereby avoid the findings of fact and conclusions of law which are clearly warranted by the evidence.

[3] According to the Expert, while Mr. Reynolds did not see N.S. at her June 8, 2004 visit, he had clearly reviewed the record of this visit as at the bottom of the visit note, there is a handwritten marking which, based on her review of the patient files, the Expert determined was the signature, or abbreviated signature of Reynolds. *See* GX 2 (ID) at 102; GX 68, at 10.

According to the Expert, the absence of this information in the file indicates that the AMC practitioner did not know what, if any, controlled substances N.S. was then being prescribed, her complete pain history, whether she was suffering from any coexisting diseases or conditions, who her prior treating physicians were, whether she had ever tried non-controlled substances, or whether she had ever received other treatment modalities to address her reported pain, such as physical rehabilitation. GX 68, at 9. The Expert then concluded that absent this information, N.S. should not have been issued a controlled substance prescription on her first visit, especially a schedule II controlled substance such as Avinza, which is a long-acting formulation of morphine. *Id.* The Expert further explained that if a controlled substance such as Avinza had been indicated, the starting adult dose would have been only 30mg daily (rather than 60mg which was prescribed).[4] *Id.*

On July 7, 2004, N.S. returned to AMC for a follow-up, but now was complaining of a migraine headache. *See* GX 2, at 101. Again, N.S. was seen by a practitioner other than Reynolds, Stout, or Killebrew. *See* GX 3, at 130.

Notably, the record states that N.S. displayed ''Slurred speech + Somnolence,'' which, according to the Expert was a potential red flag that N.S. was abusing prescription drugs.[5] GX 68, at 10. The Expert noted that the record indicated that N.S. had Tachycardia, as her pulse rate was above the normal rate for adults (60–100 beats per minute) and was nearly 20 beats higher than at her previous visit. *Id.* at 11. According to the Expert, while Tachycardia occurs for a variety of reasons, it can be caused by drug withdrawal. *Id.*

The Expert noted that the attending practitioner properly ordered a Urine Drug Screen (UDS) for N.S. *Id.* According to the Expert, a UDS is a particularly useful tool when the practitioner is presented with a red flag indicating that the patient may not be in compliance, such as when the patient presents at the office exhibiting the behaviors N.S. did on this visit. *Id.* As the Expert explained, a UDS can assist the practitioner in determining whether the patient has been taking the drug(s) that the practitioner has prescribed and if the patient was ingesting non-prescribed controlled substances, including illicit substances. *Id.* Thus, UDS results help practitioners to determine whether a patient is abusing and/or diverting controlled substances. *Id.*

While this other practitioner appropriately ordered a UDS, according to the Expert, he then inappropriately issued to N.S. another prescription for thirty tablets of Avinza 60 mg at this visit. *Id.* at 11–12. As the Expert found, at this visit, N.S.'s file still lacked any information of her prior treatment history and substance abuse history. *Id.* at 12. According to the Expert, in the absence of this information, and in light of the fact that N.S. presented at this visit demonstrating slurred speech and somnolence, the issuance of the Avinza prescription was below the standard of care in Tennessee and outside the usual course of professional practice and actually medically contraindicated given the mental status changes documented in her record. *Id.* at 12. The Expert further explained that under the circumstances presented by N.S., the standard of care and usual course of professional practice required that the practitioner refer the patient for a comprehensive evaluation (the emergency room) to determine the underlying cause of the symptoms of her increased heart rate, slurred speech, and somnolence. *Id.* Moreover, the patient should not have received prescriptions (of any type) at this visit until medical clearance was provided that she was not experiencing drug intoxication or an acute neurologic event. *Id.* Moreover, because N.S. was not referred or transferred for further evaluation, she should not have received any controlled medications until the urine drug screen results were available to the provider. *Id.*

Nearly three months later (on September 29, 2004), N.S. returned to AMC for her next visit and was seen by Mr. Reynolds. *See* GX 2, at 100; GX 3, at 71. Prior to this visit, AMC had received the report of the results of the UDS that had been administered to N.S. at her July 7, 2004 visit. *Id.* at 115. According to the Expert, on the date of the UDS, N.S. should have had Avinza left from the prescription issued at her first visit and should have still been taking the drug. *See* GX 2, at 102; GX 3, at 129; GX 68, at 12–13. However, the UDS was negative for opiates, positive for benzodiazepines, and positive for cocaine. *Id.;* GX 2, at 115.

According to the Expert, these results should have been a ''huge red flag of abuse and diversion'' for Mr. Reynolds because not only did N.S. test positive for cocaine, she also tested positive for three different benzodiazepines, none of which had been prescribed to her at her first visit. GX 68, at 13. The Expert further explained that the presence of the three benzodiazepines, in addition to the presence of cocaine, were consistent with the somnolence, slurred speech, and increased pulse rate that were documented during the July 7, 2004 visit. *Id.* The Expert also noted that N.S. tested negative for opiates, when she should have tested positive for the Avinza which she should have still been taking. *Id.*

The Expert also noted that as of this visit, Reynolds still had not acquired any information concerning N.S.'s prior treatment history or substance abuse history. *Id.* Also, the file contains no documentation that Reynolds had inquired of N.S. where she had been for the nearly three months since her July 7, 2004 AMC visit. *See generally* GX 2. According to the Expert, the standard of care required that Reynolds inquire about N.S.'s absence and determine what, if anything, she had been doing during this time to address her reported pain. GX 68, at 13. The Expert further noted that while the note for this visit was for the most part illegible, it appeared that Mr. Reynolds did not address N.S.'s absence. *See id;* GX 2, at 100.

Nonetheless, Reynolds issued N.S. another prescription for thirty tablets of Avinza 60 mg. *See* GX 2, at 100; GX 3, at 71. Based on the UDS results and notation in N.S.'s record that she displayed ''slurred speech & somnolence,'' the Expert concluded that Reynolds was on notice that she was likely diverting the Avinza she obtained at AMC for the purpose of obtaining the cocaine and the benzodiazepines. GX 68, at 14. The Expert also explained that at the time of these events, it was well known in the Tennessee health care community that prescription drug abuse and diversion was a problem that was plaguing East Tennessee. *Id.*

The Expert explained that the standard of care and usual course of practice under these circumstances

[4] The Expert acknowledged that as of the date of N.S.'s first visit, the Tennessee Board of Nursing had yet to adopt BON Rule 1000–04–.08, and that the Rule did not go into effect until January 1, 2005. GX 68, at 10. However, based on her knowledge and experience, the Expert explained that advanced nurse practitioners (''APNs'') in Tennessee were nevertheless employing the practices set forth in the Rule when they prescribed controlled substances for the treatment of pain. *Id.* Thus, the practices articulated in the guidelines reflected what, in her opinion, was the standard of care in Tennessee for family nurse practitioners as of June 2004. *Id.* The Expert explained that because of the lack of information of N.S.'s prior treatment history and substance abuse history, it was below the standard of care for a practitioner to issue N.S. a thirty-day supply of a schedule II controlled substance such as morphine at her first visit. *Id.*

[5] According to the Expert, these symptoms could represent several serious and even life-threatening medical conditions given N.S.'s complaint of a migraine headache. Also, N.S.'s slurred speech and somnolence could have been an indication that N.S. was having an acute neurologic event, such as a hemorrhagic stroke. GX 68, at 10–11.

would *not* have been to issue N.S. an additional thirty-day supply of morphine, because ''family nurse practitioners were not then, and are now not equipped, through their training and experience, to address the complex abuse and diversion issues N.S. was presenting.'' *Id.* According to the Expert, rather than continuing to issue N.S. prescriptions for more of the Avinza, the standard of care and usual course of practice required that Reynolds ''cease all controlled substances prescriptions to her, and instead referred [sic] her for a consultation with a pain management specialist who [was] equipped with the knowledge to treat a pain patient who has exhibited such aberrant behavior.'' *Id.* The Expert also explained that in the event that a local pain management practice did not have all of these specialists, Mr. Reynolds should have, in addition to sending her to a pain management specialist, referred her to a mental health specialist to address her possible psychological/drug abuse issues. *Id.* The Expert thus concluded that Reynolds' issuance of this prescription was below the standard of care in Tennessee, outside the usual course of professional practice, and for other than a legitimate medical purpose. *Id.*

N.S.'s file reflects that Reynolds, Stout, and Killebrew each continued to issue N.S. controlled substance prescriptions on multiple occasions subsequent to September 29, 2004. In fact, N.S. remained an AMC patient for over five more years and continued to receive numerous controlled substances prescriptions from AMC. *See generally* GX 2. Based on the evidence of N.S.'s abuse and/or diversion of controlled substances that was documented in her file, the absence of documentation of any prior treatment for pain, and the absence of any substance abuse history, the Expert opined that each and every controlled substance prescription that these three practitioners issued to N.S. from September 29, 2004 forward was below the standard of care, not for a legitimate medical purpose, and outside the usual course of professional practice. GX 68, at 15. However, ''because each of the three practitioners issued additional controlled substance prescriptions notwithstanding the existence of more red flags of N.S.'s abuse and/or diversion of controlled substances,'' the Expert addressed the invalidity of those prescriptions. *Id.*

On December 29, 2004, N.S. returned to AMC and saw Mr. Reynolds, who issued her a prescription for eight tablets of Avinza 60 mg. *See* GX 2, at 97; GX 3, at 76 According to the Expert, in addition to the previous evidence of N.S.'s abuse and diversion, Reynolds had received an admission report on December 3, 2004 from Johnson City Medical Center (''JCMC'') which notified him that N.S. was hospitalized for a drug overdose the same day. GX 68, at 15; GX 2, at 126–28. He also received notification from JCMC upon N.S.'s discharge on December 7, 2004. GX 2, at 158–61; GX 68, at 16. Reynolds evidently reviewed the report, as his signature marking appears at the bottom of the report's first page. GX 2, at 158. Notably, not only did the report state that N.S. had been admitted for a drug overdose, it also stated that N.S. had a history of multiple prior drug overdoses, the last one being in May 2004, one month before her first AMC visit, and a history of multiple suicide attempts. *Id.* at 126–27; 158–59.

Of further significance, the report listed two different primary care physicians for N.S., one of whom, Dr. Michael Dube, was not an AMC practitioner. *Id.* at 159. Also, the report stated that she was taking Lortab, a combination drug containing hydrocodone (which was then a schedule III controlled substance); Xanax, a schedule IV controlled substance; and Soma (carisoprodol), which was not federally scheduled at that time. *Id.* at 158. However, Reynolds had not previously prescribed any of these three drugs to N.S. *See generally* GX 2.

The report also stated that a urine toxicology test was performed on N.S. and that she tested positive for opiates and benzodiazepines. *Id.* at 159. However, as before, AMC had not prescribed any benzodiazepines to N.S. As the Expert explained, the report should have been another enormous red flag to Reynolds that N.S. was continuing to abuse and divert controlled substances and was engaging in doctor-shopping by obtaining controlled substances from multiple sources (AMC and Dr. Dube), another red flag of drug-seeking behavior. GX 68, at 16.

As of the December 29 visit, Reynolds also was aware that the physician who treated N.S. at JCMC had, three weeks earlier, discharged N.S. to Indian Path Pavilion (''IPP''), a local, in-patient mental health facility. *See* GX 2, at 160. In addition, on December 23, AMC received a fax showing that on December 21, N.S. had been admitted again to IPP for ''polysubstance abuse.'' *See* GX 2, at 153–56. Thus, as of N.S.'s December 29 visit, Reynolds was on notice that she may have suffered two overdoses in an approximately three-week period, that these would have been the latest of several overdoses she had suffered, and that she had been sent for mental health treatment on each of those two occasions. GX 68, at 17.

However, on reviewing N.S.'s patient file, the Expert found (as do I) that Reynolds did not contact: (1) The JCMC to obtain its records of N.S.'s multiple previous overdoses; (2) Dr. Dube to obtain records of the nature and extent of the treatment he had provided N.S., including the controlled substances he had prescribed her, (3) the IPP to obtain records regarding N.S.'s December 21, 2004 admission to that facility for polysubstance abuse; and/or (4) the pharmacy N.S. was using to fill her prescriptions to determine if she was obtaining controlled substances prescriptions from other practitioners. *Id.* According to the Expert, the standard of care and usual course of professional practice for a family nurse practitioner required that Reynolds obtain all of this information about N.S.'s history of overdoses, her suicide attempts, and her current hospitalizations, as well as information about other practitioners from whom she may have been obtaining controlled substance prescriptions, in order to determine the proper course to take in her care. *Id.*

As the Expert previously explained, a family practice nurse practitioner is not qualified to treat the complex issues presented by this type of patient. Thus, the Expert also explained that in light of the information contained in the December 3, 2004 JCMC and the December 21, 2004 IPP admission reports, the standard of care in Tennessee required that Reynolds cease all further controlled substance prescriptions (which he already should have), send N.S. to an out-patient or in-patient detoxification program and refer her to a pain management specialist. *Id.* at 18. Thus, the Expert concluded that the issuance of the December 29, 2004 Avinza prescription was outside the usual course of professional practice and lacked a legitimate medical purpose. *Id.*

Nevertheless, from January 2005 through June 2005, Reynolds continued to see N.S. at AMC on a monthly basis and continued to issue her monthly prescriptions for Avinza 60 mg. *See* GX 2, at 86–96; GX 3, at 76–79. According to the Expert, the issuance of each of these prescriptions was below the standard of care and outside the usual course of professional practice as well. GX 68, at 18. As the Expert explained, N.S. should not have been treated and prescribed controlled substances at a family practice in light of the drug abuse and diversion issues she presented, and

should have been referred to a specialist. *Id.*

According to the Expert, on January 1, 2005, the Board of Nursing's Rule 1000–04–.08 went into effect. *Id.* As a result, Reynolds was required to comply with the controlled substance prescribing guidelines contained in that Rule. However, as of January 6, 2005, Reynolds still had not obtained any information about her treatment history for the three years immediately preceding her first AMC visit on June 8, 2004. *See* TN BON Rule 1000–04–.08(4)(C)1; *see also generally* GX 2; GX 68, at 18. Moreover, Reynolds did not create a written treatment plan for N.S.; nor did he document that he had considered the need for further testing, consultations, referrals, or the use of other treatment modalities. GX 2; GX 68, at 18.

As the Expert explained, under the new Rule, Reynolds was required to create and maintain a ''written treatment plan tailored for the individual needs of the patient'' that ''include[d] objectives such as pain and/or improved physical and psychological function'' and was required to ''consider the need for further testing, consultations, referrals, or use of other treatment modalities dependent on patient response[.]'' GX 68, at 18 (quoting TN BON Rule 1000–04–.08(4)(c)2). As found above, in December 2004, the JCMC and IPP had forwarded to Reynolds information establishing that N.S. had a substantial history of substance abuse which had resulted in multiple drug overdoses and suicide attempts. Based on the results of the July 2004 UDS, he also had information that N.S. may not have been taking the Avinza and possibly was diverting the drug and that she was taking cocaine and benzodiazepines which had not been prescribed by his clinic. GX 68, at 19. The Expert thus concluded that Reynolds did not comply with the Rule and acted outside of the usual course of professional practice when he issued the Avinza prescription to N.S. *Id.*

The evidence further shows that beginning on February 8, 2005, Reynolds added Xanax 1 mg. to N.S.'s controlled substance regimen. *See* GX 2, at 94; GX 3, at 77–79. Reynolds issued this prescription after diagnosing N.S. with ''Major Depressive Disorder'' and ''GAD,'' the latter being an abbreviation for ''Generalized Anxiety Disorder.'' The Xanax prescription issued on February 8, 2005 was the first of numerous Xanax prescriptions N.S. received from Reynolds, Stout, and Killebrew over the course of the next five years. *See* GX 2.

According to the Expert, the decision of the nurse practitioners to address N.S.'s mental health issues by prescribing Xanax, was below the standard of care and outside the usual course of professional practice. GX 68, at 19. As support for her opinion, the Expert cited a treatise which she stated was generally recognized and accepted as authoritative by Tennessee family practitioners. *Id.* at 19–20 (citing Constance R. Uphold & Mary Virginia Graham, *Clinical Guidelines in Family Practice,* 4th Ed. (2003) (hereinafter, ''Uphold & Graham'')). This treatise was submitted as part of the record. *See* GX 41.

The Expert explained that ''according to Uphold & Graham, benzodiazepines, such as Xanax, are effective only for the *short-course treatment* of generalized anxiety disorder, or GAD, and family practitioners were cautioned against the use of this class of drugs for greater than a two week period because they carry 'the risk of dependence and withdrawal syndrome.' '' *Id.* at 20 (quoting GX 41, at 8). The Expert then noted that ''Uphold & Graham further instructs that if the patient's 'anxiety [is] associated with another psychiatric condition, most often depression,' the patient 'should be treated for the primary problem,' and 'most patients in this category should be referred to a specialist if possible.' '' GX 68, at 20 (quoting GX 41, at 9). Additionally, ''Uphold & Graham instructs that for 'patients with anxiety that is substance-induced' whether by licit or illicit drugs, family nurse practitioners are to 'provide the patient with counseling/referral to a drug detoxification program.' '' *Id.* According to the Expert, ''Uphold & Graham emphasizes that two of the 'categories of patients [who] should be referred to specialists for treatment' are '[t]hose with high suicide risk' and '[p]atients with comorbid conditions (primary anxiety disorder, substance abuse, dementia).' '' *Id.* (quoting GX 41, at 14).

Thus, based on Uphold & Graham, the Expert concluded that ''even assuming N.S. could have been treated for her purported major depressive order in a primary care setting, which she could not, she should *not* have been started on a benzodiazepine such as Xanax.'' *Id.* (citing GX 41, at 15). The Expert further noted that AMC asserted that its protocols were based on the Uphold & Graham Guidelines. *Id.* at 19–20 (citing GX 39).

According to the Expert, Reynolds, Stout, and Killebrew were required under Tennessee law to evaluate N.S. for a continuation or change of her medications at each periodic interval at which they evaluated her. GX 68, at 21; BON Rule 1000–04–.08(4)(c)4. However, while Xanax is a highly abused and diverted drug in Tennessee, Reynolds, Stout and Killebrew prescribed Xanax to N.S., ''at numerous periodic intervals over the course of the next several years and in the face of mounting evidence of her abuse of controlled substances, and without referring her for treatment by a specialist.'' GX 68, at 21. The Expert thus concluded that the prescriptions issued by the three nurse practitioners fell well below the standard of care and outside the usual course of their professional practice. *Id.*

On July 1, 2005, Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg. *See* GX 2, at 86; GX 3, at 79. Reynolds issued these prescriptions even though he had not obtained the results of the UDS he ordered for N.S. during her June 1, 2005 AMC visit (and apparently never did based on a review of N.S.'s patient file). *See* GX 2, at 87. In fact, N.S.'s patient file does not contain any record of her even having been administered the UDS. GX 68, at 21; *see also* GX 2.

In the Expert's opinion, Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 21. Based on the evidence of N.S.'s abuse and diversion of controlled substances set forth above, and the fact that Reynolds had not obtained the results for the UDS he ordered at N.S.'s previous visit, the standard of care and usual course of professional practice under these circumstances would *not* have been to issue N.S. further controlled substances prescriptions. *Id.* at 22. Instead, it would have been to locate the results, and if she had not taken the UDS, which would be a red flag based on her history, require her to provide one and cease all further controlled substances prescribing until the results could be reviewed. *Id.* (citing Board Rule 1008–04–08(2) & (4) (c)(2)).

Likewise, on August 2, 2005, Mr. Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg, each of which was for a thirty-day supply. *See* GX 2, at 85; GX 3, at 79. A note in the record of her August 2, 2005 visit states, ''Pt. called to request refill on Xanax. *Stated she had taken all she had before due date.* Script written for Xanax.'' GX 2, at 85 (emphasis added). Yet notwithstanding the extensive evidence that N.S. was abusing and diverting controlled substances, Reynolds issued her the prescription and did not refer her to an outside specialist to address her aberrant behavior. *See, e.g.,* GX 41, at 8–9, 14 (Uphold & Graham). The

Expert thus concluded that Reynolds' issuance of the prescription was below the standard of care and outside the usual course of professional practice. GX 68, at 22–23.

Twenty days later, on August 22, 2005, Mr. Reynolds issued N.S. a prescription for 20 tablets of Xanax 0.5 mg. *See* GX 2, at 84; GX 3, at 80. According to the Expert, this prescription was an extremely early refill, specifically, ten days early, in light of the fact that he had just issued N.S. a thirty-day supply of 60 tablets of Xanax 1 mg on August 2, 2005, and was further evidence that N.S. was either abusing the Xanax by taking extra pills in contravention of his directions, or was diverting the drugs he was prescribing to her. GX 68, at 23.

Moreover, on September 2, 2005, Mr. Reynolds issued N.S. prescriptions for 30 capsules of Avinza 60 mg and 60 tablets of Xanax 1 mg. *See* GX 2, at 82; GX 3, at 81. According to the Expert, Reynolds was then aware that N.S. had apparently not complied with his August 24, 2005 request for her to come into AMC for a pill count. *See* GX 68, at 24; GX 2, at 83. The Expert then explained that the failure of a patient to comply with a practitioner's request for a pill count, which is another tool utilized to monitor the patient's compliance with a controlled substances regimen, is another red flag of possible abuse and/or diversion. GX 28, at 24.

On October 3, 2005, Mr. Reynolds issued N.S. a prescription for 75 tablets of Xanax 1mg and 60 capsules of Kadian (a brand name for morphine) 30 mg. *See* GX 2, at 80; GX 3, at 81. N.S.'s file contains a handwritten note dated September 13, 2005, which was just *eleven days* after Reynolds had prescribed to her a thirty-day supply of 60 tablets of Xanax 1 mg, stating, ''Pt requested Xanax 1 mg TID for anxiety attacks.'' GX 68, at 25; GX 2, at 81. As of this date, Reynolds was aware that N.S. should have had 19 days of Xanax tablets remaining from the September 2nd prescription, and thus, she was requesting additional Xanax well before she should have consumed the prior prescriptions and was also requesting an increase from two (*i.e.,* ''BID'') to three tablets a day (*i.e.,* ''TID''). GX 68, at 25.

On November 1, 2005, Registrant Stout issued his first controlled substance prescriptions to N.S.; the prescriptions were for 75 tablets of Xanax 1 mg and 60 capsules of Kadian 30 mg. *See* GX 2, at 79; GX 3, at 82. According to the Expert, because this was N.S.'s. first visit with Stout, it was incumbent on him to review N.S.'s file before he issued her controlled substances prescriptions, so that he could determine the appropriate course of treatment. GX 68, at 26. Noting that under Board Rule 1000–04–.08, Stout was required to ''evaluate[ ] the patient for continuation or change of medications'' and to include in the patient record ''progress toward reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan,'' the Expert explained that an Advanced Practice Nurse cannot evaluate a patient for the continuation or change of medications, or determine the progress the patient is making towards reaching treatment objectives, or even know what the patient's treatment objectives are, without knowing the patient's treatment history. *Id.*

The Expert thus concluded that when Stout issued N.S. the Xanax and Kadian prescriptions, he should have been aware of N.S.'s prior abuse and diversion of controlled substances which was documented in her patient file. *Id.* Based on N.S.'s history, the Expert further concluded that the standard of care and usual course of professional practice under these circumstances would *not* have been for Mr. Stout to issue her further controlled substances prescriptions but to cease further prescribing and refer her to an outside specialist to address her aberrant behavior. *Id.* at 26–27 (citing GX 41, at 8–9, 14) (Uphold & Graham).

On July 20, 2006, Applicant Killebrew issued her first controlled substances prescriptions to N.S.; the prescriptions were for 75 tablets of Percocet 7.5/325 mg (oxycodone/acetaminophen, a schedule II controlled substance), and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 76; GX 3, at 84. For the same reasons she identified in her discussion of the validity of Stout's initial prescriptions to N.S., the Expert found that Killebrew's prescriptions were below the standard of care and outside the usual course of professional practice. GX 68, at 27.

The Expert further noted that this was N.S.'s first visit to AMC in nearly eight months, (her last visit having been a Dec. 1, 2005 visit with Reynolds), and that Killebrew had noted in the record of this visit that N.S. was ''[j]ust released from jail 7/6/06 . . . requesting to be put back on pain meds she was on for back and neck pain.'' *Id.* at 27–28 (citing GX 2, at 76). The Expert noted, however, that Killebrew did not document having asked N.S. about the reason for her incarceration, specifically, whether it was drug-related, whether she was on probation, and, if so, whether her probationary status may have prohibited her from possessing controlled substances. GX 68, at 28. Nor did Killebrew document having asked N.S. about how she had addressed her alleged pain during her incarceration when she had told Killebrew that she was not receiving any pain medications. *Id.* According to the Expert, given N.S.'s history, the standard of care and usual course of professional practice under these circumstances, would *not* have been to issue her additional controlled substances prescriptions but to refer her to a pain management practice to address her purported back and neck pain and possible continuing substance abuse. *Id.* (citing GX 41, at 8–9, 14) (Uphold & Graham).

On August 17, 2006, Stout prescribed N.S. 75 tablets of Percocet 7.5/325 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 75; GX 3, at 87. According to the medical record, on July 19, 2006, less than a month before he issued N.S. these prescriptions, Stout had treated N.S. while he was working in the North Side Hospital emergency room (''ER''). *See* GX 16, at 2–3. According to North Side's records, N.S. presented to the ER on that date complaining of neck pain from a fall. Stout noted in the record for the ER visit that N.S. ''[r]efused meds . . . Wants stronger narcotics. Admits to having long history of drug abuse. . . .'' In the ''Impressions'' section of this report, Stout had also noted that N.S. displayed ''[d]rug seeking behavior.'' *Id.*

Moreover, N.S.'s AMC record included the note for her July 20 visit (the day after Stout saw her in the ER). Thus, the Expert found that Stout should also have been aware that N.S.'s previous visit was her first visit to AMC in seven months and that she had just been released from jail and had requested to be put back on pain medications. GX 68, at 29; GX 2, at 76. The Expert further explained that ''[a]s was the case with N.S.'s visit with Killebrew, Stout did not question N.S. as why she had been incarcerated . . . whether it was drug-related, whether she was on probation, and, if so, whether her probationary status may have prohibited her from possessing controlled substances. He also did not question N.S. about how she had been addressing her alleged pain during her incarceration when she, based on her own report to Killebrew, had not received pain medications.'' GX 68, at 29. Based on these circumstances (including the amply documented history of N.S.'s abuse and/or diversion), the Expert found that Stout's issuance of these prescriptions was below the standard of care and outside

the usual course of professional practice. *Id.*

On October 11, 2006, Stout again saw N.S. and issued her additional prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 71, 73; GX 3, at 88. In addition to the previous documented incidents of N.S.'s abuse and/or diversion, N.S.'s file contained a note dated September 13, 2006, stating, ''[N.S.] selling perocet's (sic.).'' *See* GX 2, at 74. Moreover, in the record of the visit, Stout wrote, ''Confronted PT about ? selling meds. PT denies. States meds were stolen. Will do UDS today. Advised PT if UDS (-) drugs/abuse found would d/c. Has been taking meds for past week per pt.'' *See* GX 2, at 71, 73. Also, Stout had N.S. sign a Pain Management Agreement (''PMA''), which he and another AMC employee witnessed, and then issued her the controlled substance prescriptions. *See* GX 2, at 11–12.

According to the Expert, the fact that N.S. denied selling her drugs should not have overcome the evidence in her file, including the recent note of the report that she was selling her drugs and the extensive evidence of her history of abuse and/or diversion of controlled substances. GX 68, at 30. The Expert thus concluded that Stout's issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.*at 29–30 (citing GX 41, at 8–9, 14 (Uphold & Graham)).

The UDS results showed that N.S. tested negative for oxycodone/oxymorphone, despite the fact that she had been receiving oxycodone (Percocet) prescriptions from AMC on a monthly basis since July 20, 2006. *See* GX 2, at 71–75, 105–107; *see also* GX 3, at 4–5. The results also showed that N.S. tested positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed those drugs to her since she had returned to the practice. GX 2, at 107.

On November 10, 2006, Reynolds saw N.S. and issued her additional prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax 0.5 mg. *See* GX 2, at 70; GX 3, at 91. In addition to the various recent notes in her file, Reynolds should have been aware of the October 18, 2006 results of the UDS administered to N.S. at the October 11, 2006 visit. As the Expert explained, based on the UDS results, Reynolds was aware that N.S. had lied to Stout during her October 11, 2006 visit when she told him that she was taking her pain medications, and that she was likely selling her Percocet because she tested negative for this drug. GX 68, at 31. In addition, Reynolds was aware of Stout's warning to N.S. during her October 11, 2006, visit that she would be discharged (''d/c'') if the results were negative (which they were for oxycodone), or if she was found to be abusing drugs, which was established by her testing positive for hydrocodone, a drug that she had not been prescribed at AMC. *Id.* at 32.

The Expert thus found that the UDS results were further evidence of N.S.'s continued abuse and/or diversion of controlled substances. *Id.* at 31. The Expert further opined that the standard of care and usual course of professional practice under these circumstances would *not* have been to issue N.S. further controlled substance prescriptions, but to discharge her from the practice and to refer her to a pain management practice to address her purported pain issues or a substance abuse/addiction specialist to address her likely substance abuse issues. *Id.* at 32. Thus, the Expert concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 31 (citing GX 41, at 8–9, 14) (Uphold & Graham)).

On December 11, 2006, Stout issued N.S. prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Valium 5 mg. *See* GX 2, at 69; GX 3, at 91. At the time of the visit, Stout had received the results of the UDS and was aware that N.S. had lied to him during her October 11, 2006 visit, when she told him she was taking her pain medications. N.S.'s patient record shows that Stout attempted to refer N.S. to two different pain management practices at this visit—''Appalachian Pain Rehab'' (Dr. Tchou) and ''Pain med associates.'' *See* GX 2, at 67. However, N.S. had apparently already been seen at those two practices and neither practice was willing to again accept her as a patient.[6] *Id.*

According to the Expert, this additional information should have been another red flag that N.S. was abusing and or diverting controlled substances. GX 68, at 33. The Expert thus concluded that under the circumstances, the standard of care and usual course of professional practice would *not* have been to issue N.S. more prescriptions, but to enforce the terms of the Pain Management Agreement and to follow through on the warning Stout had given N.S. during her October 11 visit that she would be discharged from AMC if she failed the UDS. *Id.* Additionally, the standard of care and usual course of professional practice would have been to attempt to refer N.S. to a mental health or an addiction specialist to address her purported pain issues and her likely substance abuse issues. *Id.* at 33–34 (citing GX 41, at 8–9, 14 (Uphold & Graham excerpts)). Yet Stout failed to either discharge her or refer her to a specialist.

On February 27, 2007, Reynolds issued N.S. prescriptions for 75 tablets of Percocet 7.5 mg and 60 tablets of Xanax .5 mg. *See* GX 2, at 66; GX 3, at 93. At the time of the visit, Reynolds was aware of the December 11, 2006 notes stating that neither Appalachian Pain Rehab nor Pain Med Associates would see N.S. *See* GX 2, at 67. For the same reasons discussed above, the Expert concluded that Reynolds' issuance of the prescriptions was well below the standard of care and outside of the usual course of professional practice. GX 68, at 32.

On June 1, 2007, Reynolds issued N.S. additional controlled substances prescriptions for 90 tablets of MS Contin 30 mg and 90 tablets of Xanax 0.5 mg. *See* GX 3, at 96. Notwithstanding that the quantity of both prescriptions had been increased by fifty percent from N.S.'s previous visit, her patient file does not contain a record of Reynolds having seen her on this date, nor any information as to why N.S. was not seen on this occasion. *See* GX 2, at 63–64. Based on the other documented evidence of N.S.'s abuse and/or diversion, the Expert concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 34–35 (citing Rule 1000–04–.08(4)(c) (requiring periodic re-evaluation for continuing or changing control substance prescriptions)).

On July 2, 2007, after N.S. called in and said she had run out of prescriptions the day before, Killebrew directed that prescriptions be called in for 40 tablets of Lortab 10 mg (hydrocodone/acetaminophen) and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 63; GX 3, at 96. While Killebrew should have been aware of N.S.'s extensive history of abuse and diversion, according to N.S.'s patient file, she issued these prescriptions without requiring that N.S. come in for an office visit and after being notified that N.S. had called AMC and requested new prescriptions because she was out of her medications. *See* GX 2, at 63. The Expert further noted that N.S. evidently had not been seen at AMC since her May 3, 2007 office visit and that this

[6] Notes in the file state that N.S. ''has been double dotted'' at Appalachian Pain Rehab, which ''means won't see,'' and that N.S. ''already has been to Pain med associates + can't be seen there either!!'' GX 2, at 67.

was a further red flag given N.S.'s history. GX 68, at 35. Moreover, once again, there is no information in the file documenting why N.S. could not have been seen. *Id.* The Expert thus concluded that the issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. *Id.*

On November 16, 2007, Reynolds issued N.S. prescriptions for 30 tablets of Lortab 10 mg and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 52; GX 3, at 102. The Expert found that N.S. was seeking an early refill of her controlled substances, because fifteen days earlier, Reynolds had prescribed her thirty-day supplies of 90 tablets each of Xanax 0.5 mg, MS Contin 30 mg, and Percocet 7.5/500 mg, each of which had a dosing of ''one po tid,'' or one tablet three times per day. *See* GX 68, at 36; GX 2, at 53–54; GX 3, at 102. N.S.'s early refill request presented another red flag of her potential abuse and/or diversion of controlled substances, which Reynolds ignored. GX 68, at 36. Moreover, N.S.'s Pain Management Agreement stated that ''medications taken early due to reasons not discussed with your provider [will not] be replaced early.'' GX 2, at 5. Yet Reynolds did not enforce the Pain Management Agreement. GX 68, at 36.

The Expert also concluded that given N.S.'s numerous prior red flags of drug abuse and diversion, Reynolds should have taken steps to determine if she was in fact taking the drugs he had been prescribing, or if she was diverting them. *Id.* at 37. The Expert explained that Reynolds should have required her to submit to a UDS, and that he also should have checked the Tennessee Controlled Substances Monitoring Database (''CSMD''), which became available on January 1, 2007, in order to determine if she possibly was doctor-shopping. *Id.* The Expert also noted that Reynolds did not ask why she was seeking an early refill. *Id.* The Expert thus concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 36–37 (citing Board Rule 1000–04–.08(4)(c) (2) & (4) and GX 41, at 8–9, 14 (Uphold & Graham)).

On January 3, 2008, Reynolds issued N.S. a prescription for 90 tablets of MS Contin 30 mg, 90 tablets of Xanax 0.5 mg, and 30 tablets of Percocet 7.5 mg. *See* GX 2, at 47–48; GX 3, at 103. According to her file, on November 30, 2007, N.S. had called and sought an early refill. Moreover, documentation in her file establishes that Reynolds should have known (having received reports on both December 22 and 26), that on December 22, N.S. had been admitted to JCMC and diagnosed with, among other conditions, ''polysubstance abuse.'' *See* GX 2, at 139–140. Here again, the Expert found that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice and that she should not have been issued any further controlled substance prescriptions. GX 68, at 37 (citing GX 41, at 8–9, 14 (Uphold & Graham)).

On December 22, 2008, Killebrew issued N.S. prescriptions for 60 tablets of Lortab 7.5 mg and 30 tablets of Xanax 0.5 mg. *See* GX 2, at 40–41; GX 3, at 106. Notably, the chart indicates that this was N.S.'s first visit to AMC since February 2008 because she was pregnant, *see* GX 2, at 42–44, and that during the intervening ten months N.S had reportedly been receiving Suboxone/Subutex treatment from another practitioner and apparently had been able to function during the previous ten months without the need for Lortab and Xanax. *Id.* at 40.

According to the Expert, based on N.S.'s representations, Killebrew should have taken steps to determine whether N.S. had a legitimate medical need for these drugs prior to prescribing them. GX 68, at 38–39. The Expert explained that the usual course of professional practice would have been for Killebrew to determine the name of the practitioner who had provided Suboxone treatment to N.S. and contact that practitioner to determine the nature and extent of the treatment and to obtain a copy of the records. *Id.* at 39. The Expert also opined that given N.S.'s history of red flags, Killebrew should have run a check of the Tennessee CSMD to determine if her representations were accurate and to ensure that N.S. was not doctor-shopping. *Id.* However, according to N.S.'s file, Killebrew did not do so. GX 2. The Expert also found that Killebrew did not document any new illness or injury to N.S. as of this visit. GX 68, at 39. Also, on review of N.S.'s record, the Expert concluded that Killebrew had performed a cursory physical exam and that the lack of additional diagnostics or further evaluation by Killebrew further demonstrates that she failed to establish N.S.'s need for controlled substances at this visit. *Id.* Thus, the Expert concluded that Killebrew's issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. *Id.* at 38–39 (citing TN BON Rule 1000–04–.08(4)(c)1, 2, and 4).

On June 4, 2009, Reynolds prescribed N.S. 60 tablets of MS Contin 30 mg, 30 tablets of Percocet 7.5 mg, and 90 tablets of Xanax 0.5 mg. *See* GX 2, at 38–39; GX 3, at 107. Significantly, Reynolds issued the prescriptions notwithstanding that N.S. had not been seen at AMC since her December 22, 2008 visit with Killebrew. *See* GX 2, at 40–41. Moreover, the record of the June 4, 2009 visit does not contain any documentation of what N.S. had been doing to treat her purported pain over the course of the previous five plus months. *Id.* at 38–39. The Expert also found that Reynolds should have been aware that N.S.'s December 22, 2008 visit had been her first visit to AMC since February 2008, after she had called AMC and informed staff that she was two months pregnant and had destroyed her medications. GX 68, at 39–40.

As with the previous visit, the Expert explained that the usual course of practice would have been for Reynolds take steps to determine whether N.S. had a legitimate medical need for the drugs prior to prescribing them. *Id.* at 40. These steps included asking N.S. what she had been doing over the past six months to address her purported pain and, given her history of abuse and diversion, running a check of the Tennessee CSMD to determine if she had been obtaining controlled substances from any other practitioners over the past six months. *Id.* However, according to N.S.'s file, Reynolds did not conduct such a check. GX 2. The Expert thus concluded that Reynolds' issuance of these prescriptions was below the standard of care and outside the usual course of professional practice. GX 68, at 39–40 (citing TN BON Rule 1000–04–.08(4)(c)(1, 2, 4)).[7]

[7] The Expert also explained that Reynolds' decision to issue N.S. controlled substances prescriptions on June 4, 2009 was contrary to the additional guidelines AMC was employing at that time as part of its practice protocols. GX 68, at 40. According to the Expert, she reviewed a February 23, 2010 letter Reynolds had sent to a Tennessee Department of Health Investigator, as well as several documents that were enclosed with the letter, including copies of AMC's practice protocols. *Id.; see also* GX 39. The Expert noted that Reynolds stated in his letter that one of the attached documents was ''a copy of the current treatment recommendations for chronic pain in the primary care setting as outlined by the *American Family Physician* in their [sic] November 2008 article 'Chronic Nonmalignant Pain in Primary Care' '' which was authored by R. Jackman, J.M. Purvis, and B.S. Mallett (hereinafter, ''Jackman article''). GX 68, at 40–41. According to Reynolds, AMC ''currently [is] referencing this article in our charting notes and intend to add these guidelines as an Addendum to our protocols when they are renewed in July 2010.'' GX 39, at 1. In his record of N.S.'s June 4, 2009 visit, Reynolds wrote: ''[t]his patient's pain has been approached with specific attention to the *American Family Physician's* November 2008 analysis that indicates nonmalignant pain should be addressed in the primary care setting.'' GX 2, at 38.

The Expert noted that her review of N.S.'s file found that Reynolds overlooked several recommendations contained within that article. GX

On November 11, 2009, Reynolds issued another prescription to N.S. for 14 tablets of Xanax 0.25 mg. *See* GX 2, at 25; GX 3, at 108. According to N.S.'s file, N.S. sought a refill claiming that the Xanax Reynolds had prescribed to her on October 29, 2009 had been stolen. GX 2, at 25. According to the Expert, a patient reporting that her controlled substances were stolen is another classic red flag of a patient's potential abuse and/or diversion of controlled substances. GX 68, at 43 (citing GX 39, at 11 (Jackman article's examples of aberrant behavior)).

According to the Expert, the standard of care and the usual course of professional practice would have been for Reynolds to enforce the terms of N.S.'s Pain Management Agreement, and refuse to provide her additional controlled substances. GX 68, at 43–44 (quoting GX 2, at 5; ''Lost or stolen medicines will not be replaced''). Also, according to the Expert, Reynolds should have required N.S. to submit to a UDS, and to run a check of the CSMD to determine if N.S. was engaged in diversion. GX 68, at 44. According to N.S.'s file, Reynolds did not take either action and simply issued her an additional Xanax prescription for 36 tablets of .25 mg. GX 2, at 25; GX 3, at 70. The Expert thus concluded that Reynolds' issuance of the prescription was below the standard of care and outside the usual course of professional practice. GX 68, at 43–44.

According to N.S.'s file, her visits to AMC ended in February 2010 after a nearly six-year relationship with the practice. GX 2. Summarizing her findings, the Expert noted that while during that time, N.S. presented numerous red flags of abuse and diversion, the monitoring of her controlled substances use by Reynolds, Stout, and Killebrew was woefully inadequate, and far below the standard of care in Tennessee. GX 68, at 44. The Expert also observed that over the course of nearly six years, N.S. was only asked to provide two UDSs, both of which she failed by testing positive for a drug she had not been prescribed at AMC (including cocaine on one of the tests), and testing negative for the drug which she had been prescribed. *Id.*

The Expert also noted that N.S. was required to come into AMC for but a single pill count, and there was no documentation showing that she even complied with the request. *Id.* The Expert then noted that even though the CSMD had been available since January 1, 2007, the only time N.S.'s prescription history had been checked was on the date of her last visit in February 2010. *Id.; see also* GX 2, at 129–131. The Expert also observed that there was no documentation that prior to the implementation of the CSMD, the practitioners had ever checked with N.S.'s pharmacy to ascertain whether she was engaged in drug-seeking or diversionary behavior. GX 68, at 44.

The Expert concluded by observing that none of these steps were taken, notwithstanding that: (1) N.S. showed up at her second visit exhibiting somnolence and slurred speech; (2) failed the UDS that was administered at that visit, and (3) several months later, suffered a drug overdose that the practitioners learned was the latest of several prior drug overdoses, in addition to multiple prior suicide attempts. *Id.* at 44–45. As the Expert found, Reynolds, Stout, and Killebrew ignored numerous warning signs that N.S. was abusing and/or diverting controlled substances that continued throughout her nearly six-year association with AMC, and they continued to provide her with controlled substances when they knew or should have known that she was acquiring the controlled substances for other than legitimate medical purposes. *Id.* at 45.

In a letter to a DEA Diversion Investigator, Reynolds addressed AMC's treatment of N.S. He asserted that N.S. was kept on the same medication that she had been prescribed by a neurosurgeon who had referred her to AMC. GX 42, at 7. Yet as the Expert noted, no such documentation exists in N.S.'s file.

Reynolds did acknowledge that on December 3, 2004, N.S. was admitted to a local hospital by a Dr. James for a drug overdose; he also stated that she was subsequently ''transferred to Indian Path Pavilion and continued on her then prescribed medications'' and that ''Dr. James added Soma and Lortab to the AMC regimen.'' GX 42, at 7. However, Reynolds also asserted that after this incident, N.S. ''never had another overdose incident while being treated at AMC'' and ''[s]he never again displayed signs of addiction to include requesting increases in medication without cause, going to numerous providers, aberrant behavior, contacting provider for medication after hours or on weekends, early refills, or refusal to follow plans of care.'' *Id.* Finally, Reynolds further asserted that ''[i]n October of 2006, she passed drug screens and observation by AMC providers.'' *Id.*

T.H.

T.H.'s initial visit was on October 3, 2005. *See* GX 17, at 4, 47. According to the record of this visit, T.H. was seen by an AMC practitioner other than Reynolds, Stout, or Killebrew. He reported that he was suffering from back pain, but said that it was not due to trauma or injury. *Id.* at 47; *see also id* at 4 (report of ''Back Pain''). T.H.'s record does not, however, quantify the extent of the pain he reported, nor document how long he had been suffering from back pain. *Id.* at 47. T.H. also reported a history of anxiety with panic attacks. *Id.* According to the intake paperwork that T.H. completed, he reported that he was not currently seeing any other provider, *id.* at 3, and also reported that he was not taking any drugs other than asthma medications. *Id.* at 4.

According to the Expert, the record of T.H.'s first visit is noteworthy for the absence of any information about his history and potential for substance abuse. GX 68, at 45; GX 17, at 47. Also, the record does not contain a written treatment plan that documents objectives for evaluating progress from the use of controlled substances. GX 68, at 45; GX 17, at 47. As the Expert explained, all of these issues were required to be, but were not addressed before T.H. was prescribed controlled substances. GX 68, at 46 (citing TN BON Rule 1000–04–.08(4)(c)1 and 2).

The Expert further found that the record of T.H.'s first visit revealed the first of several red flags of his potential abuse and/or diversion of controlled substances. *Id.* These included that on the initial intake form he completed,

68, at 41. These included the article's statement that ''[o]pioids pose challenges with abuse, addiction, diversion, lack of knowledge, concerns about adverse effects, and fears of regulatory scrutiny. These challenges may be overcome by adherence to the Federation of State Medical Board's guidelines, use of random urine drug screening, monitoring for aberrant behaviors, and anticipating adverse effects.'' *See id.* (quoting GX 39, at 5). The Expert further noted that the article also states that ''[w]hen psychiatric comorbidities are present, risk of substance abuse is high and pain management may require specialized treatment or consultation. Referral to a pain management specialist can be helpful,'' and that the evaluation of the patient must include ''[a] thorough social and psychiatric history [that] may alert the physician to issues, such as current and past substance abuse, development history, depression, anxiety, or other factors that may interfere with achieving treatment goals.'' *Id.*

The Expert also noted the article's statement that ''[f]or patients at high risk of diversion and abuse, consider *the routine use* of random urine drug screens to assess for presence of prescribed medications and the absence of illicit substances.'' GX 68, at 42 (quoting GX 39, at 9 of 22) (emphasis added). Finally, the Expert noted the article's statement that ''[a]berrant behavior that may suggest medication misuse includes use of pain medications other than for pain treatment, *impaired control* (of self or of medication use), compulsive use of medication . . . selling or altering medications, *calls for early refills, losing prescriptions, drug-seeking behavior (e.g. doctor-shopping),* or reluctance to try nonpharmacologic intervention.'' *Id.* (quoting GX 39, at 11) (emphasis added).

T.H. reported that he had ''frequent or recurring problems'' with alcohol. GX 17, at 4. He also reported that either he or a close family member had suffered from ''Alcoholism'' and ''Mental Illness.'' *Id.*

According to the Expert, T.H.'s disclosure of issues with alcohol abuse and mental illness were red flags of his potential drug abuse; she also noted that the Pain Management Agreements which T.H. was required to sign provided that ''[t]he use of alcohol and opioid medications is contraindicated.'' GX 68, at 46 (citing GX 17, at 5). According to the Expert, T.H.'s disclosures should have been explored further by the nurse practitioner who saw him, but according to the record were not assessed. *Id.* The Expert further opined that without a further evaluation of these issues, the practitioner should not have issued T.H. a prescription for controlled substances. *Id.*

The Expert also explained that if T.H. was in recovery from alcoholism, he should have been referred to a comprehensive pain specialist program, and should not have been treated by a primary care nurse practitioner. *Id.* As the Expert explained: '' '[p]atients who are alcohol dependent and who also have a psychiatric disorder should be referred for treatment for the underlying disorder as these patients are usually complex.' '' *Id.* (quoting GX 41, at 23 (Uphold & Graham)). Thus, according to the Expert, the decision to issue him any controlled substance prescriptions at this initial visit was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c)1 & 2, and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.* at 46–47. Nonetheless, T.H. was issued prescriptions for 30 Lortab 7.5 mg and 30 Xanax .25 mg. GX 17, at 47.

During his second visit on October 25, 2005, T.H. reported that he had recently lost his job and was looking for a new one. He also reported increased stress, that he was not sleeping, and that he was having ''roller coaster feelings.'' *Id.* at 46. According to the Expert, ''the reported loss of income by a patient who is receiving opioids, such as hydrocodone (Lortab), is also a red flag of potential diversion. The practitioner must consider the risk that the patient may try to sell those drugs to generate the income he no longer is obtaining from his job.'' GX 68, at 47. The Expert noted, however, that there is no documentation in the visit note that the issue of how he was going to pay for his treatments and medications was discussed, nor is there any evidence that T.H. was asked to submit to a UDS to see if he was taking the drugs he had been prescribed. *Id.*

The practitioner also diagnosed T.H. as suffering from anxiety and depression. GX 17, at 46. According to the Expert, diagnosing the potential source of a patient's stress is critical in determining the appropriate course of treatment. GX 68, at 47. Thus, the decision to issue T.H. any controlled substance prescriptions at this visit based on the information he reported was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c)1,2,4, and accordingly, below the standard of care and outside the usual course of professional practice. *Id.* (citing GX 41 (Uphold & Graham)). However, here again T.H. was issued prescriptions for 45 Lortab 7.5 mg and 30 Xanax .5 mg. GX 17, at 46.

At T.H.'s third visit on November 28, 2005, the practitioner noted that he discussed marriage counseling, thus indicating that he was having marital problems. *Id.* at 45; GX 68, at 47. According to the Expert, this was another potential red flag with respect to the prescribing of opioids given T.H.'s reports of anxiety and depression, as well as his prior report that he had lost his job. GX 68, at 47–48. T.H. was referred to another provider (Dr. Williams), and directed to return for a follow-up visit in ''2 months.'' GX 17, at 45. He was also issued prescriptions 60 Lortab 7.5 mg and 30 Xanax .5 mg. *Id.*

Nearly three months later on February 21, 2006, T.H. returned to AMC and saw Reynolds. See GX 17, at 43. In the interim, on December 5, 2005, T.H. was seen at Dr. T. Williams' pain clinic, Pain Medicine Associates. *See* GX 17, at 57–58; 45–46. John Powell, a Physician Assistant in Dr. Williams' clinic, identified a possible source of the ''mechanical low back pain'' that T.H. was reporting. GX 17, at 57. Notably, the pain clinic recommended that ''facet blocks should be undertaken as a diagnostic procedure followed by radiofrequency denervation if positive.'' GX 17, at 58. Also, the pain clinic recommended that T.H. be prescribed 90 tablets of Lortab 10 mg, one tablet three times a day, ''*until we can get the above accomplished.*'' *Id.* (emphasis added).

Based on her review of the pain clinic's letter, the Expert concluded that the clinic had issued T.H. a prescription for a thirty-day supply of Lortab 10 mg to hold him over until he received the facet blocks. GX 68, at 48. In addition, and significantly, Mr. Powell documented that T.H. had again disclosed that he ''had an alcohol problem in the past'' and ''still drinks occasionally.'' GX 17, at 57. Furthermore, Mr. Powell noted that T.H.'s ''chronic low back pain'' had been going on for ''two years.'' *Id.*

According to the record of his Feb. 21, 2006 visit, T.H. specifically ''Requested Bob.'' GX 17, at 43. The Expert found that the record of this visit is largely unintelligible due to Reynolds' incomprehensible handwriting. GX 68, at 48. However, there is no evidence in T.H.'s file that the facet blocks had been performed in the two and one-half months since he had seen Mr. Powell. *Id.; see also* GX 17. In fact, there is no evidence in the file that the facet blocks were ever done. GX 17. Also, there is no documentation of what, if anything, T.H. had been doing to address his pain for the past month when he would have been out of the drugs prescribed by Mr. Powell.[8] *See* GX 68, at 48–49; GX 17, at 43.

Nonetheless, at the visit, Reynolds issued T.H. prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 Xanax 1 mg. *See* GX 17, at 43; GX 5, at 13. According to the Expert, Reynolds' issuance of these prescriptions was contrary to the guidelines set forth in TN BON Rule 1000–04–.08 and, accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. GX 68, at 49.

According to the Expert, Reynolds lacked ''an appropriate medical justification for adding a prescription for a schedule II controlled substance such as OxyContin 40 mg to treat [T.H.'s] purported pain,'' given that the pain specialist (Mr. Powell) was of the opinion that ''T.H. did not require anything more than a short-term prescription for Lortab [then a schedule III controlled substance], and for only as long as it took to get the facet blocks completed.'' *Id.* Also, even though Reynolds was now aware (based on Mr. Powell's report) that T.H. had been having back problems for two years, there was still no documentation or records of any prior treatments he had received before he started at AMC in October 2005. *See* GX 68, at 49–50 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''pertinent evaluations by another provider'')).

[8] In his letter to the DI, Reynolds asserted that TH ''returned to AMC on February 21, 2006 from pain management on long-term medication, Oxy[C]ontin, 40 milligrams, twice daily, and Lortab, 10 milligrams, #30. This medication was continued until the patient's death.'' GX 42, at 4. There is, however, no evidence in T.H.'s file (such as a discharge summary form Pain Medicine Associates) which supports this assertion.

The Expert also found that up to this point, neither Reynolds nor the AMC practitioner who had treated T.H. at his previous visits had adequately documented and evaluated his prior alcohol problems and the extent of his current consumption of alcohol. *Id.* at 49 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''history of and potential for substance abuse'')). The Expert also found it significant that neither Reynolds nor his colleague had sufficiently explored T.H.'s psychological problems, specifically, the anxiety and increased stress that T.H. previously had reported despite circling ''anxious'' and ''depressed'' in the examination section of the record of this visit. *Id.* at 49–50 (citing TN BON Rule 1000–04–.08(4)(c)1 (requiring documentation of historical data that includes ''pertinent coexisting diseases and conditions'' and ''psychological functions'')). And the Expert noted that Reynolds did not inquire about T.H.'s current employment status, which, in her view, could be significant if he was still unemployed. *Id.* at 49.

The Expert observed that Reynolds' failure to evaluate these issues prior to issuing the Xanax prescription was contrary to AMC's own practice guidelines. *Id.* at 50. Specifically, the Expert explained that according to Uphold & Graham, '' '[s]ubstance abuse can also produce anxiety. . . . Anxiety can also occur as part of the withdrawal from the following: alcohol, cocaine, sedatives, hypnotics, anxiolytics.' '' *Id.* (quoting GX 41, at 5). Continuing, the Expert explained that according to Uphold & Graham, '' '[a]nxiety associated with other psychiatric disorders (depression and alcohol dependence) is common. Discriminating between an anxiety disorder and a depressive illness is quite difficult because of the overlap in symptoms.' '' *Id.* at 50 (quoting GX 41, at 6.) The Expert thus concluded that ''without a detailed evaluation of T.H.'s anxiety and psychosocial history and substance abuse history (including a drug toxicology screen, or UDS), it was inappropriate for Mr. Reynolds to prescribe Xanax for the treatment for anxiety. He lacked any understanding of the etiology of that reported condition at that juncture.'' *Id.*

The Expert also explained that the combination and quantity of prescriptions Reynolds issued at the visit was further evidence that these prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose. *Id.* According to the Expert, ''the combination of OxyContin and Lortab together would not be the next step for a patient with uncontrolled pain. In this situation, the patient's medication [was] escalated to a long-acting opioid, such as OxyContin 10 mg twice daily, which is done when pain management is expected to be for a prolonged period of time.'' *Id.* at 50–51. The Expert then noted that Reynolds had prescribed a starting dose of 40mg twice daily, which is four times the normal starting dose, and that ''when starting a patient on a long-acting opioid, a short-acting opioid may be used for break-through pain, but not typically at the initial prescribing of the long-acting medication.'' *Id.* at 51.

The Expert also explained that Lortab and OxyContin given in combination ''may increase the risk of CNS and respiratory depression, profound sedation and hypotension,'' and that Lortab and Xanax in combination ''may increase risk of CNS depression and cause psychomotor impairment'' due to additive effects. *Id.* Also, according to the Expert, OxyContin given in combination with Xanax may result in ''vasodilation, severe hypotension, CNS and respiratory depression, [and] psychomotor impairment due'' to additive effects. *Id.* Finally, the Expert noted that the dose and the amount of Xanax prescribed was excessive as it was six times the total daily dosage of T.H.'s previous prescriptions and could be lethal, especially if taken in combination with two opioids. *Id.*

Citing Reynolds' failure to perform a proper evaluation of T.H., the illogical and potentially dangerous escalation of opioid and benzodiazepine dosages in the prescriptions he issued, and the red flags of potential drug abuse and diversion that T.H. presented, the Expert concluded that the prescriptions he issued to T.H. at this visit were below the standard of care for a primary care provider and outside the usual course of professional practice. *Id.*

On March 22, 2006, T.H. returned for a follow-up visit and saw Stout. *See* GX 17, at 42. The Expert found that the record of this visit was sparse, as ''Stout simply noted that T.H. was ''[h]ere for a follow-up. Denies recent trauma or illness. No fever, chills, nvd,'' and then circled entries on the record indicating that T.H. was anxious, depressed, and had lower back pain and cervical pain. GX 68, at 51.

Stout issued T.H. additional prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 42; GX 5, at 13. However, the Expert found that Stout did not document any evidence of the appropriateness of therapy by failing to quantify or evaluate T.H.'s pain and that there was also no information provided about the efficacy of the medications or the functionality of the patient. GX 68, at 52 (citing TN BON Rule 1000–04.08(4)(c)). The Expert also noted that while Stout acknowledged that T.H. was anxious and depressed, the visit notes had no additional information about the psychosocial situation of the patient. *Id.*

The Expert also observed that Stout did not generate a written treatment plan for T.H. and, as such, there was still no written treatment plan for T.H. *Id.* (citing TN BON Rule 1000–04.08(4)(c)2). Nor did Stout evaluate or assess T.H.'s history of, or potential for, substance abuse. *Id.* (citing TN BON Rule 1000–04.08(4)(c)1). The Expert thus concluded that these prescriptions were issued contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c) and, accordingly, below the standard of care and outside the usual course of professional practice. *Id.*

On April 21, 2006, T.H. returned to AMC and saw Reynolds, who issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 41; GX 5, at 13. Once again, the Expert found that the record for the visit was largely unintelligible. GX 68, at 52. She also observed that while Reynolds documented that T.H. was complaining of right upper quadrant pain and referred him for possible ventral hernia, there did not appear to be any documentation in the file that the prior deficiencies in complying with the guidelines of TN BON Rule 1000–04–.08 had been corrected. *Id.* at 51–52. Also, no AMC practitioner, including Mr. Reynolds and Mr. Stout, had created a written treatment plan for T.H, *id.* at 53 (citing TN BON Rule 1000–04.08(4)(c)2); and Reynolds still had not evaluated or assessed T.H.'s history of, or potential for, substance abuse. *Id.* (citing TN BON Rule 1000–04.08(4)(c)1).

According to the Expert, ''opioids typically would not be indicated in a case of new onset of abdominal pain, or even contraindicated pending an evaluation of the cause of the pain.'' *Id.* Given that T.H. had reported losing his job, the Expert also found it significant that the visit noted stated that he had a ''$310 balance; ins no pay.'' *Id.* (quoting GX 17, at 41). According to the Expert, this was a red flag for potential diversion which should have been explored because ''it indicates that T.H. [wa]s likely uninsured with increasing medical bills [and] [a] practitioner would have to be concerned about how T.H. was going to pay for not only the balance he owed to AMC, but also the drugs he was being prescribed in the

absence of insurance and possibly (still) a job.'' *Id.*

The Expert also found that T.H. presented another red flag in that, according to the visit note, he did not complain ''of constipation.'' *Id.* According to the Expert, ''[i]f T.H. actually was taking the amount of narcotics he had been prescribed, Mr. Reynolds should have expected T.H. to complain of constipation and need a prescription to treat this condition. Absence of a constipation complaint may be a signal [that] T.H. was NOT taking the drugs and instead was diverting them.'' *Id.*

The Expert then explained that under these circumstances, the standard of care and usual course of professional practice required that T.H. undergo a UDS to determine if he was taking the drugs that were prescribed and not diverting them. *Id.* However, the Expert found that there was no documentation in the visit note, or anywhere else in T.H.'s file, that he was asked to submit to a UDS at this visit. *Id.; see also* GX 17. The Expert thus concluded that Reynolds' issuance of the April 21, 2006 prescriptions was contrary to the guidelines set forth in TN BON Rule 1000–04–.08(4)(c) and, accordingly, below the standard of care and outside the usual course of professional practice. GX 68, at 53–54.

On May 22, 2006, T.H. returned to AMC and was seen by both Reynolds and Stout. *See* GX 17, at 40.[9] According to the Expert, the handwriting of both Stout and Reynolds appears on the record of this visit, even though the visit noted was signed by Mr. Stout. GX 68, at 54.

During the visit, Stout noted that T.H. reported that he had been seeing another practitioner at the same time that he was obtaining controlled substances from AMC. GX 17, at 40. Specifically, Stout wrote: ''[Patient] has spoken with Bob Reynolds about seeing Dr. Doobie [(sic)]. [Patient] states has not seen since 4/2006.'' *Id.*

As the Expert explained, this was another red flag for diversion and abuse, ''which is commonly referred to as 'doctor-shopping.' '' GX 68, at 54. Moreover, ''T.H.'s disclosure established that he had violated the Pain Management Agreement,'' which included the provision that he would '' 'use only one physician to prescribe and monitor all opioid medications and adjunctive analgesics,' '' and that '' '[a]ny evidence of . . . acquisition of any opioid medication or adjunctive analgesia from other physicians . . . may result in termination of the doctor-patient relationship.' '' GX 68, at 54–55 (quoting GX 17, at 5). Indeed, in his letter to a DEA Diversion Investigator, Reynolds acknowledged that T.H. had signed the Pain Management Agreement at his first visit to AMC. GX 42, at 4.

Notwithstanding T.H.'s clear violation of the Agreement, Reynolds issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 40; GX 18, at 30. As the Expert explained, when Reynolds issued these prescriptions, T.H. presented with multiple red flags in addition to that of doctor shopping. These included his financial, mental health, and alcohol issues. GX 68, at 55. However, ''T.H.'s file contains no indication that either Reynolds or Stout took the measures that a reasonable and prudent practitioner would have taken, such as to contact the other doctor [Dr. Dube] to confirm that he was no longer seeing T.H. and to ascertain the nature and extent of his treatment of T.H.'' *Id.* Also, neither Reynolds nor Stout took ''any other steps to ascertain the scope of T.H.'s abuse and/or diversion of controlled substances,'' such as by requiring him to provide a UDS. *Id.; see also* GX 17, at 5 & 40. Moreover, while in the Pain Management Agreement, T.H. had agreed to use only one pharmacy (the Hillcrest pharmacy), GX 17, at 5; neither Reynolds nor Stout checked with the pharmacy to determine if he was, in fact, presenting all of his AMC prescriptions there and if he was also presenting controlled substances prescriptions from other practitioners. *See generally* GX 17.

According to the Expert, ''each of these steps was an action that a reasonable and prudent family nurse practitioner would have taken when presented with this information, and was required by the standard of care in Tennessee.'' GX 68, at 55–56. The Expert thus explained that under the circumstances, the standard of care and the usual course of professional practice required the enforcement of the terms of the Pain Management Agreement, *see* GX 17, at 5 (pars. 1, 3, and 9); the cessation of the issuance of more controlled substances prescriptions; the taking of measures to ascertain whether T.H. was diverting the drugs he had been prescribed by requiring a UDS and contacting his pharmacy; and the referral of T.H to either a pain management specialist and/or a psychological/addiction specialist. GX 68, at 56.

On June 20, 2006, T.H. returned to AMC and was again seen by Reynolds. GX 17, at 39. Once again, Reynolds issued T.H. more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See id.;* GX 18, at 30. Moreover, at this visit, T.H. presented a further red flag—specifically, Reynolds learned that T.H. was being treated with Suboxone, a schedule III controlled substance used to treat narcotic dependency, at the same time he had been receiving narcotics from AMC. GX 17, at 39. As the Expert found, the record of this visit contains an entry apparently made by A.N., a Registered Nurse, stating: '' 'observed note regarding Medicine Shoppe in Jonesboro TN & Suboxone 8 mg (Knoxville region) & Oxycodone 40 mg from Appalachian Med Center & will consult proprietor of Appalachian Med Center Bob Reynolds FNP regarding urine screen possibly needed & how to proceed in care of this pt. Contact person at Medicine Shoppe is Jeff Street.' '' GX 68, at 56–57 (quoting GX 17, at 39).

In reviewing T.H.'s file, the Expert observed that the note referenced by A.N. was not in the file. *Id.* at 57. The Expert also observed that T.H.'s file did not contain any documentation indicating that Reynolds had investigated the information documented by the RN, such as documentation that Reynolds had contacted the pharmacy about T.H.'s Suboxone treatment or obtained a record of the prescriptions T.H. had presented and filled at the pharmacy. *Id.* And the Expert further explained that the fact that the Medicine Shoppe had prescription information for T.H. was also a red flag because T.H. had agreed to use only the Hillcrest pharmacy to fill his prescriptions. *See id.* The Expert thus concluded that Reynolds' issuance of the prescriptions was outside of the usual course of professional practice.[10] *Id.* at 56–57.

On July 19, 2006, T.H. returned to AMC. Reynolds again issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg. *See* GX 17, at 38; GX 18, at 29. And once again, Reynolds had received additional information indicating that T.H. was likely engaged in abuse. GX 68, at 58.

[9] The Expert based her conclusion on the fact that in course of reviewing the records, she had become familiar with the respective handwriting of Reynolds, Stout, and Killebrew. GX 68, at 54.

[10] The Expert further explained that the usual course of professional practice required that the Pain Agreement be enforced, the cessation of controlled substance prescriptions, that the Medicine Shoppe be contacted to follow-up on the items noted, that T.H. be required to submit a UDS, and that T.H. be referred to either a pain management specialist, and/or a psychological/addiction specialist. GX 68, at 57.

More specifically, T.H.'s file contains four documents that apparently were faxed to AMC from ''Northside Admin,'' and appear to have been faxed on the same date.[11] *See* GX 17, at 59–62. However, the date on the fax banner at the top of each page is cut-off. *See id.*

Notably, one of the documents was an April 21, 2006, letter from Dr. Michael Dube informing T.H. that he ''will no longer be treated as a patient at Medical Care Clinic and/or Watauga Walk-in Clinic.'' *See* GX 17, at 61. A second document showed that as of March 31, 2006, T.H. owed $230 to Medical Care Clinic. *Id.* at 59. A third document showed that as of June 6, 2006, T.H. owed $2,976 to Pain Medicine Associates (Dr. Williams' clinic), where T.H. was seen on December 5, 2005, having been referred by AMC. *Id.* at 60. The fourth document showed that on June 12, 2006, T.H. had received a prescription for Zoloft, a non-controlled drug used to treat depression, from a medical doctor in Knoxville, Tennessee. *Id.* at 62.

As the Expert explained, the letter from Dr. Dube confirmed the information that Reynolds and Stout received at T.H.'s April 20, 2006 visit, namely, that he was seeing another provider at the same time he was receiving controlled substances from AMC, and thus likely doctor-shopping. GX 68, at 58. The billing statements from Medical Care Clinic (Dr. Dube's practice) and Pain Medicine Associates (Dr. Williams' practice), ''provide[d] further evidence that T.H. was having significant financial difficulties.'' *Id.* at 58–59. According to the Expert, the fact that T.H. was approximately $3000 in debt to two medical practices should have been viewed as another red flag of his possible diversion of controlled substances. *Id.* at 59.

As for the Zoloft prescription, the Expert observed that this was evidence that T.H. was having his mental health issues addressed by another provider. *Id.* As such, it was also a red flag that T.H. was possibly obtaining controlled substances from another practitioner after he was discharged by Dr. Dube. *Id.* The Expert further explained that Reynolds should have been interested in knowing if the Zoloft prescriber was the same Knoxville-based practitioner who reportedly was providing T.H. with Suboxone as mentioned in the RN's note for T.H.'s previous visit. *Id.*

Noting that there was no evidence that Reynolds had contacted Dr. Dube, the Zoloft prescriber, the Hillcrest Pharmacy, or the Medicine Shoppe Pharmacy; nor evidence that he had required that T.H. provide a UDS; the Expert concluded that Reynolds' issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. *Id.* at 58–59. The Expert further opined that under the circumstances, the standard of care and usual course of professional practice would *not* be to issue T.H. additional controlled substances prescriptions but to enforce the terms of the Pain Management Agreement and cease further prescribing of controlled substances to T.H. *Id.* at 59.

On August 10, 2006, T.H. returned to AMC, even though this was just twenty-two days since his last visit. GX 17, at 37. Reynolds again saw T.H. and issued him prescriptions for 10 tablets of Lortab 10 mg and 15 tablets of Xanax 1 mg, which he authorized T.H. to fill on that date, as well as prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 60 tablets of Xanax 1 mg, which could not be filled until August 15, 2006. *See* GX 17, at 37; GX 5, at 13. Reynolds issued these prescriptions notwithstanding the evidence that T.H. was abusing and/or diverting controlled substances discussed above, and even though T.H. was seeking an early refill of his Lortab and Xanax prescriptions on this visit. GX 68, at 60. As the Expert explained, T.H. should have had eight days of Xanax tablets remaining on the prescription Reynolds issued him on July 19, 2006. *Id.* (citing GX 18, at 29).

Here again, T.H.'s early refill request was another red flag that T.H. was abusing and/or diverting the controlled substances that Reynolds was prescribing to him. *Id.* For the same reason as stated above, the Expert concluded that ''the standard of care and usual course of professional practice under these circumstances would *not* be to issue T.H. additional controlled substances prescriptions.'' *Id.* Rather, the standard of care and usual course of professional practice required that Reynolds ''enforce the terms of the'' Pain Contract, see GX 17, at 5 (par. 9), ''cease issuing further controlled substances to T.H., contact Hillcrest Pharmacy and Medicine Shoppe pharmacy to determine the prescriptions T.H. had filled, and order T.H. to take a UDS to determine if he was taking or diverting the controlled substances he had been issued or was taking controlled substances he had not been prescribed at AMC.'' GX 68, at 60.

On September 7, 2006, T.H. returned to AMC and was seen by Stout, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 45 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 36; GX 18, at 8. According to the Expert, Stout noted in the record of this visit that ''[T.H.] got meds filled early on 08/10/06—Rx dated 08/15/06.'' GX 68, at 61. As the Expert explained, Stout was clearly aware of this red flag and should have questioned if T.H. was taking more than the prescribed amount or if he was selling the drugs. *Id.* Notwithstanding this, as well as the extensive other evidence in T.H.'s record that he was either abusing and/or diverting controlled substances, Stout issued the prescription. GX 18, at 8. For the same reasons set forth with respect to T.H.'s previous visit, the Expert concluded that Stout's issuance of the prescriptions was below the standard of care and outside of the usual course of professional practice. GX 68, at 61.

On September 29, 2006, T.H. returned to AMC and was seen by Reynolds, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 75 tablets of Xanax 1 mg, and 45 Lortab 10 mg. GX 17, at 35; GX 18, at 8. Once again, T.H. presented a red flag in that he was seeking an early refill of both his OxyContin and Xanax prescriptions. GX 68, at 62. According to the Expert, T.H. should have had eight days left on the previous OxyContin prescription (which was for a thirty-day supply) and at least three days left on the previous Xanax prescription (which provided 75 tablets with a dosing of one tablet every 8–12 hours). *See* GX 68, at 62; GX 17, at 36; GX 18, at 8.

The Expert also noted that while T.H. had been receiving narcotics from AMC for nearly one year and had yet to be subjected to a UDS, and T.H.'s file documents that Reynolds sent him for blood work after this visit to check his blood counts, thyroid, and metabolic panel, *see* GX 16, at 50; Reynolds did not require that T.H. provide a UDS. GX 68, at 62. ''Based on this new red flag and the prior information indicating T.H.'s abuse and/or diversion of controlled substances,'' the Expert concluded that ''it was below the standard of care and outside the usual course of professional practice for Reynolds to issue these prescriptions without taking any steps to monitor his controlled substances use, including conducting a UDS and checking with

[11] The Expert acknowledged that the fax banner on the copies in T.H.'s file was cut off. However, the Expert explained that she had reviewed copies of the same four documents that were sent to another provider (*see* GX 22), which were provided by DEA, and that the date appearing on the fax banner was July 5, 2006. It is clear, however that these documents were faxed and received by AMC because the next day, one William Clever, another Advance Nurse Practitioner at AMC, wrote a letter to T.H. on AMC's letterhead that he was ''withdrawing from further professional attendance with you,'' suggested that T.H. find ''another provider without delay,'' and that ''after receipt of this letter, we will no longer be able to prescribe narcotics to you.'' GX 21, at 1.

his pharmacy for controlled substances prescriptions he was filling.''[12] *Id.*

On January 3, 2007, T.H. went to AMC and saw Killebrew, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10/325 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 32; GX 18, at 28. Killebrew noted in the record of this visit that T.H. was ''[g]etting [d]ivorced,'' complaining of increased anxiety due to his divorce, and was crying. *See* GX 17, at 32. The visit note also documents that T.H. had lost six pounds since his last visit. *Id.*

According to the Expert, this may indicate that T.H. had depression given the information T.H. shared about his divorce and Killebrew wrote him a prescription for an antidepressant (Celexa) at this visit. GX 68, at 63 (citing GX 17, at 32). T.H. also reported that his pain was a seven out of ten, which indicates that the drug regimen he had been prescribed previously at AMC was not controlling his pain. *Id.* Killebrew also had T.H. sign a new Pain Management Agreement, which she witnessed. GX 17, at 2.

The Expert explained that based on the information T.H. reported at this visit, as well as the information in his file from prior visits, T.H. should have been considered a ''high-risk patient for managing chronic pain'' and whose ''care extend[ed] beyond the scope of'' a nurse practitioner engaged in family practice ''at this point.'' GX 68, at 63. The Expert further noted that a prudent practitioner would have considered T.H. to be ''a risk for suicide and diversion'' and would have referred him ''to a mental health specialist and a comprehensive pain management program.'' *Id.* Yet, the Expert found no evidence in the file that Killebrew did so. *Id.*

The Expert also noted that there was no documentation in T.H.'s file indicating that Killebrew had checked with the pharmacy T.H. had identified on his pain contracts as the sole pharmacy he would use to fill his prescriptions to determine if he still was engaging in doctor-shopping. *Id.* The Expert also found no evidence that Killebrew required him to submit to a UDS. *Id.* at 63–64. Based on the red flags T.H. presented and Killebrew's failure to take these steps to monitor T.H.'s use of controlled substances, the Expert opined that the issuance of the prescriptions was contrary to the Board's Rule 1000–04–.08(4)(c), and, accordingly, below the standard of care and outside the usual course of professional practice. *Id.* at 64.

On March 2, 2007, T.H. visited AMC and saw Stout, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 29; GX 18, at 27. The Expert opined that Stout's notes for this visit were ''sparse, at best'' as they state only that T.H. was ''[h]ere for follow-up. Denies recent trauma or illness. Patient states pain medication is controlling his pain. Describes pain as 4/10 while on pain medication. Denies fever, chills, nvd.'' GX 68, at 64 (quoting GX 17, at 29). The Expert also observed that the visit notes contained no discussion of T.H.'s anxiety issues which Killebrew had documented during the January 3, 2007 visit. *Id.* The Expert also found that there was ''no documentation of any evaluation or assessment of the alcohol and financial red flags that were presented at several prior visits,'' that Stout ''neglected to inquire about whether T.H. was now employed or whether he was currently drinking alcohol'' even though the form contained a section for alcohol use (''ETOH''), nor elaborated on his purported finding that T.H. was ''anxious.'' *Id.*

The Expert also found that there was still no evidence that a written treatment plan was created for T.H. identifying objectives of treatment, or an update on the treatment plan as required by TN BON Rule 1000–04–.08(4)(c)2 & 4. *Id.* Moreover, the Expert found that while on January 1, 2007, the Tennessee prescription monitoring program (CSMD) had become available to practitioners to assist them in determining whether their patients were seeing other providers, there was no evidence in the file that Stout conducted a check on T.H. at this visit, even though T.H.'s record documented multiple instances in which AMC obtained information that T.H. was engaged in doctor-shopping. *Id.* at 64–65. Nor did the Expert find any evidence in the file that Stout had checked with the pharmacy T.H. identified on his pain contracts as the sole pharmacy he would use to fill his prescriptions to determine if he was doctor shopping. *Id.* at 65. The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and, accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On May 1, 2007, T.H. visited AMC and saw Stout, who again issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 27; GX 18, at 25–26. Once again, the Expert found that Stout's record of the visit was ''very sparse,'' as it stated only: ''Here for follow-up. PT denies trauma. Patient states back pain is controlled by pain medication. Denies radiation of pain or urinary incontinence. Denies chest pain or sob. Denies fever, chills, nvd.'' GX 68, at 65. Once again, the Expert observed that the visit note did not document that Stout had discussed with T.H. his use of alcohol (the ETOH portion of the form being blank), his anxiety,[13] and his employment and financial situation. *Id.*

The Expert also found that there was still no evidence of a written treatment plan for T.H. identifying treatment objectives, or an update on the treatment plan as required by TN BON Rule 1000–04–.08(4)(c)2, 4; she also found that Stout failed to quantify T.H.'s pain on this visit. *Id.* at 66. And once again, the Expert found that Stout did not take any steps to monitor whether T.H. was currently doctor-shopping and seeing other practitioners. *Id.* The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On June 26, 2007, T.H. visited AMC and saw Stout, who again issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 75 tablets of Xanax 1 mg. *See* GX 17, at 23–24; GX 5, at 14–17. While the Expert noted that AMC had started using electronic medical records and that Stout had noted that T.H. ''is satisfied with the current treatment plan,'' she still found that there was no documentation in the record of a written treatment plan. GX 68, at 66 (citing TN BON Rule 1000–04–.08(4)(c)2). The Expert further noted that while Stout documented that T.H. reported he was having ''some increases [sic] problems situationally lately with their [sic] anxiety and depression,'' Stout again neglected to inquire about T.H.'s use of alcohol, which could have been the source of his anxiety and depression problems. *Id.* (quoting GX 17, at 23); also citing GX 41, at 6 (Uphold & Graham).

According to the Expert, Stout's failure to address this issue was contrary to the requirements of TN BON

[12] Reynolds also saw T.H. on November 6 and December 4, 2006; at each visit, Reynolds issued him prescriptions for 60 OxyContin 40 mg, 30 Percocet 10/325 mg, and 75 Xanax 1 mg. GX 17, at 33–34; GX 18, at 9–10.

[13] While the note stated that T.H. was ''anxious,'' the Expert explained that Stout ''failed to elaborate on his finding.'' GX 68, at 65.

Rule 1000–04–.08(4)(c)2 because ''[w]ithout knowing about the status of his alcohol issues, Mr. Stout was unable, and in fact did not 'consider [the] need for further testing, consultations, referrals, or use of other treatment modalities.' '' *Id.* at 67. Also, while Stout noted that T.H. was having ''work issues'' and ''financial problems,'' he failed to document whether T.H. was in fact now employed and capable of paying for his continued treatment (including medications). *Id.* Moreover, the Expert found no evidence that Stout took any steps to monitor whether T.H. was currently doctor-shopping and seeing other practitioners. *Id.* The Expert thus opined that Stout's issuance of these prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care in Tennessee and outside the usual course of professional practice. *Id.*

On July 24, 2007, T.H. returned to AMC and saw Killebrew, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 21–22; GX 18, at 24. T.H. reported that his pain was a 4 out of 10, that he was having problems with anxiety (which, according to the Expert indicated that the Xanax was not controlling his anxiety), and that he was trying to quit alcohol. GX 17, at 21. T.H. also reported that he had made an appointment with a local mental health facility. Killebrew noted that T.H. presented with ''Hand tremors, anxious today'' and that he had an elevated blood pressure. *Id.* According to the Expert, these findings may have been signs of anxiety or alcohol/drug withdrawal. GX 68, at 68.

According to the Expert, alcohol abuse was a red flag and Killebrew should have considered that if T.H. was abusing alcohol, he may also have been abusing opioids and/or illicit substances. *Id.* (citing GX 41, at 20–21 (Uphold & Graham)). Relying on Uphold & Graham, the Expert further noted that '' '[p]atients who are alcohol dependent and who also have a psychiatric disorder should be referred for treatment for the underlying disorders as these patients are usually complex.' '' *Id.* (quoting GX 41, at 23); *see also* GX 41, at 15 (stating that ''[p]atients with comorbid conditions (primary anxiety disorder, substance abuse, dementia)'' should be referred to a specialist). According to the Expert, ''Killebrew's findings on this visit are further evidence that T.H. required care that was beyond the scope of family practice nurse practitioners.'' GX 68, at 68.

While the Expert noted that Killebrew had documented in T.H.'s record that she had provided him with information on Alcoholics Anonymous and other recovery groups, *id.* (citing GX 17, at 21); the Expert then explained that ''a patient who is trying to quit alcohol is not an appropriate patient for [a] primary care nurse practitioner to attempt to manage his chronic pain'' *Id.* The Expert thus found that ''Killebrew should have ceased issuing T.H. further controlled substance prescriptions and sent him for evaluation by a mental health specialist,'' and further concluded that Killebrew's issuance of the prescriptions was ''contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, not consistent with the standard of care and outside the usual course of professional practice.'' *Id.*

On August 23, 2007, Killebrew again saw T.H. and issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Lortab 10 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 19–20; GX. 18, at 23. Killebrew noted in the visit record that T.H. had recently gone to the JCMC emergency room after injuring his left leg. *See* GX 17, at 19.

According to the Expert, this information was also a red flag suggestive of either abuse or an injury caused by over sedation, as the latter could have resulted from T.H.'s combined ingestion of Valium (which she had previously prescribed to him) and alcohol, or Valium alone, given the high dosage (10 mg three times per day) she had prescribed. GX 68, at 69 (citing GX 17, at 21–22; GX 18, at 24).

The Expert further noted that Killebrew neither asked T.H. if he had obtained any pain medications at his JCMC ER visit, nor obtained any records from the JCMC to determine whether T.H. had been given any prescriptions. *Id.* at 69. The Expert also found that Killebrew neither contacted T.H.'s pharmacy to obtain a recent dispensing history, nor conducted a check of the CSMD to see if he had been receiving controlled substances from other practitioners. *Id.*

While Killebrew again noted in the record that T.H. was ''trying to quit [alcohol]'' and ''[h]as made an appt. with Frontier Health,'' she did not document that she discussed with T.H. his efforts to quit alcohol since his previous visit or that she had discussed with T.H. whether he had been seen by the mental health clinic. GX 17, at 19. As the Expert found, Killebrew simply issued T.H. ''additional controlled substance prescriptions in the face of all of the red flags of T.H.'s abuse and diversion of controlled substances set forth in the paragraphs above.'' GX 68, at 69–70. The Expert thus concluded that Killebrew's issuance of the additional controlled substance prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice. *Id.* at 70 (citing Uphold & Graham, GX 41, at 14, 23).

On September 19, 2007, T.H. returned to AMC and saw Reynolds, who issued him prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10/650 mg, and 90 tablets of Valium 10 mg. *See* GX 17, at 17–18; GX 18, at 23. According to the Expert, Reynolds issued these prescriptions without discussing with T.H. his visit at the mental health facility and did not obtain any records from the facility, even though the two previous visit notes mentioned that T.H. had made such an appointment. GX 68, at 70. Reynolds also did not acquire any information from T.H. about his efforts to quit alcohol, even though this was also mentioned in the two previous visit notes, and Reynolds did not document that he even addressed with T.H. his alcohol issues. *Id.;* GX 17, at 17–18. Nor is there any documentation that Reynolds discussed with T.H. his recent visit to the Emergency Room and T.H.'s file contains no record of his visit to the ER. GX 17, at 17–18.

The Expert further noted that Reynolds ''failed to take any other steps to monitor T.H.'s controlled substances use, despite the numerous red flags of potential drug abuse and diversion that T.H. had presented on prior visits.'' GX 68, at 70. The Expert thus concluded that ''Reynolds' issuance of the additional controlled substance prescriptions was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice.'' *Id.*

On October 17, 2007, T.H. returned to AMC and again saw Reynolds, who issued him more prescriptions for 60 tablets of OxyContin 40 mg, 30 tablets of Percocet 10 mg, 90 tablets of Xanax 1 mg, and Celexa 20 mg (a non-controlled anti-depressant). *See* GX 17, at 13–15; GX 19, at 2–6. In the visit note, Reynolds documented that T.H. ''has had increased problems with depression and had ran out of his Prozac, he is going to seek counseling at wmh and we will restart antidepressant today.'' GX 17, at 13.

Notably, T.H. had not previously been prescribed Prozac by anyone at AMC. *See generally* GX 17, at 17–47.

According to the Expert, this information should have placed Reynolds ''on notice that T.H. was seeing another practitioner, in particular a mental health specialist.'' GX 68, at 71. The Expert further explained that:

> [i]f a mental health specialist had taken over care for T.H. and his depression was worsening, as . . . Reynolds' notes of this visit reflect, then the usual course of practice would have been for the primary care nurse practitioner to contact the specialist and have the specialist manage T.H.'s care. Under these circumstances, Mr. Reynolds, as the primary care nurse practitioner, should not have changed T.H.'s antidepressant from Prozac to Celexa, and he should not have prescribed him Xanax and opioids, especially in the quantities he did, which have lethal potential in someone with increasing depression and history of alcohol use/abuse.

Id. at 71–72.

According to the Expert, Reynolds should also have asked T.H. about his use of Prozac, run a CSMD check, and required T.H. to submit to a UDS before issuing him more prescriptions. *Id.* at 71. However, according to T.H.'s record, Reynolds did none of these. *See* GX 17, at 13–15; GX 68, at 71. Moreover, according to the Expert, while T.H. would still have had several days left on his Valium 10 mg prescription, ''Reynolds should have, but according to the record did not'' instruct T.H. to stop taking the drug even though Reynolds had prescribed Xanax 1 mg along with the opioids (OxyContin and Percocet). GX 68, at 72 (citing GX 17, at 17–18; GX 18, at 23). According to the Expert, ''[a]dding 10 mg Valium to a drug regimen of OxyContin 40 mg, Percocet 10 mg, and Xanax 1 mg had the potential to be a lethal combination because of the respiratory depressing effects of these drugs.'' *Id.* The Expert thus concluded that Reynolds' issuance of the controlled substances prescriptions at this visit ''was contrary to the guidelines set forth in Tennessee BON Rule 1000–04–.08(4)(c), and accordingly, below the standard of care and outside the usual course of professional practice.'' *Id.*

T.H. died the following day. GX 24, at 2. According to the Medical Examiner's report, ''[p]ostmortem blood toxicology showed oxycodone (and its metabolite) in a supratherapeutic to potentially lethal concentration, alprazolam in a therapeutic to toxic concentration and diazepam (and its metabolite) in a therapeutic concentration.'' *Id.* at 1. The Medical Examiner thus concluded that ''[a]lthough the drugs may be present in therapeutic to potentially lethal concentrations, the combined/synergistic effects of the drugs caused death by central nervous system depression.'' *Id.*

Summarizing her findings, the Expert explained that during the two-year period in which T.H. went to AMC, he presented ''numerous red flags of abuse and diversion'' and yet he ''was never asked to take a UDS, nor was he ever asked to come into AMC for a pill count.'' GX 68, at 72. The Expert also explained that while ''the CSMD was available for the last ten months of his AMC visits, none of the practitioners ever conducted a CSMD check for him.'' *Id.* The Expert thus opined that ''the monitoring of [T.H.'s] controlled substances use by Mr. Reynolds, Mr. Stout, and Ms. Killebrew was woefully inadequate, and far below the standard of care in Tennessee.'' *Id.*

C.S.

On December 12, 2008, C.S. made her first visit to AMC and was seen by Reynolds. GX 26, at 45–46. C.S. completed a patient intake form stating that she had shoulder, knee, and back pain; she wrote that she had suffered injuries from a car accident which resulted in a metal rod in her femur and a plate and screw in her ankle. *Id.* at 10–11. Notably, on this form, C.S. stated that she did not have a current healthcare provider and did not list any medications that she was currently taking. *Id.* at 10, 11. C.S. also signed a Pain Management Agreement at this visit, which Reynolds also signed. *Id.* at 9. Reynolds prescribed a thirty-day supply of 90 tablets of Percocet 7.5/500 mg (oxycodone/acetaminophen, a schedule II drug) and 60 tablets of Valium 5 mg. *See* GX 26, at 45–46; GX 29, at 3.

The Expert observed that while Reynolds noted in the record that C.S. had ''a longstanding [history] of back pain,'' ''he did not have any information regarding treatment C.S. had been receiving for the fourteen months immediately preceding her first visit to AMC.'' GX 68, at 76 (citing GX 26, at 45). The Expert further observed that the only documentation of prior treatments in C.S.'s file were records Reynolds obtained from a physician who treated her between June 2007 and October 25, 2007.[14] *Id.* Significantly, that physician had noted that C.S. ''takes extra Rx pain pills in contrast to my recommendations'' and that he did ''not think she can self-medicate. . . .'' GX 26, at 58–61.

According to the Expert, this information ''should have been a red flag to Reynolds that C.S. misused and abused previous medications she had been prescribed.'' GX 68, at 76. Yet the Expert found that ''C.S's file indicates that Reynolds did not take any steps to follow-up on this information, such as contacting the previous physician about these entries and the nature, extent and duration of his treatment of C.S.'' *Id.* Nor, according to the Expert, did Reynolds ''obtain any other information related to C.S.'s history of[,] and potential for[,] substance abuse, despite being placed on clear notice of such issues.'' *Id.* The Expert also found that Reynolds ''failed to conduct a CSMD check, which would have provided him information about previous treatments with controlled substances and her substance use and abuse history.'' *Id* at 76–77.

The Expert further found that Reynolds ''failed to create a patient record that appropriately documented C.S.'s medical history and pertinent historical data, such as pain history, pertinent evaluations by other providers, history of and potential for substance abuse, and pertinent coexisting diseases and conditions. He also did not create a written treatment plan tailored for C.S.'s individual needs, nor did he consider the need for further testing, consultations, or referrals, or the use of other treatment modalities.'' *Id.* at 77 (citing Tenn. BON Rule 1000–.04–.08(4)(c)1 & 2. The Expert thus concluded that Reynolds' decision to immediately start C.S. on a controlled substances regimen contravened the guidelines of TN BON Rule 1000–04–.08. *Id.*

The Expert also noted that Reynolds had written in C.S.'s record that her pain was being treated in accordance with the guidelines in the Jackman article, which AMC had purportedly adopted for its treatment protocols.[15] *Id.* at 73. Consistent with her analysis and conclusions regarding N.S. and T.H., the Expert concluded that Reynolds ignored several recommendations contained within that article in his treatment of C.S. *Id.*

These included that ''[w]hen psychiatric comorbidities are present, risk of substance abuse is high and pain management may require specialized treatment or consultation. Referral to a pain management specialist can be helpful.'' *Id.* (quoting GX 39, at 5) As the Expert explained, the article then instructed that the evaluation of the

[14] The file does include records indicating that from June–October 2007 C.S. was taking Percocet and Ativan, as well as Effexor, a non-controlled drug prescribed to treat major depressive disorder, anxiety and panic disorder. GX 26, at 58–61.

[15] *See* Robert P. Jackman, M.D., *et al.,* ''Chronic Nonmalignant Pain in Primary Care,'' *American Family Physician* (Nov. 2008) (GX 39, at 5–12).

patient must include ''[a] thorough social and psychiatric history [that] may alert the physician to issues, such as current and past substance abuse, development history, depression, anxiety, or other factors that may interfere with achieving treatment goals.'' *Id.* at 74.

According to the article, ''[b]y identifying patients at risk of possible opioid misuse (*e.g.* persons with past or current substance abuse, persons with psychiatric issues), physicians can choose to modify the monitoring plan or to refer the patient to a pain specialist.'' GX 39, at 5. The article further stated that ''[f]or patients at high risk of diversion and abuse, consider *the routine use* of random urine drug screens to assess for presence of prescribed medications and the absence of illicit substances.'' *Id.* at 9 (emphasis added). The article also advised that ''[a]berrant behavior that may suggest medication misuse includes use of pain medications other than for pain treatment, *impaired control* (of self or of medication use), compulsive use of medication . . . selling or altering medications, *calls for early refills, losing prescriptions, drug-seeking behavior (e.g. doctor-shopping),* or reluctance to try nonpharmacologic intervention.'' *Id.* at 11 (emphasis added).[16]

Based on the guidance contained in the Jackman article, the Editorial, and the requirements set forth in TN BON Rule 1000–04–.08(4)(c), the Expert concluded that ''Reynolds['] issuance of the controlled substances prescriptions to C.S. at her first visit was below the standard of care and outside the usual course of professional practice.'' GX 68, at 75. Moreover, based on her review ''of C.S.'s patient file through her last visit on November 30, 2009,'' the Expert concluded that both Reynolds and Stout ''failed to comply with the Rule's guidelines on subsequent visits by C.S.'' *Id.* at 77. More specifically, the Expert found that Reynolds and Stout ''never acquired the information that was lacking at C.S.'s initial visit and, therefore, the controlled substances prescriptions they issued at subsequent visits were contrary to the Rule's guidelines for the same reasons as the prescriptions issued on the initial visit.'' *Id.*

The Expert also found that ''at each periodic interval, Reynolds and Stout failed to appropriately evaluate C.S. for continuation or change of medication, and include in the patient record her progress towards reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan.'' *Id.* at 77–78 (citing TN BON Rule 1000–04–.08(4)(c)4). The Expert thus concluded that on C.S.'s subsequent visits, such as those of March 12, 2009 and April 10, 2009, when Stout prescribed 90 tablets of Percocet 7.5/500 mg, 60 tablets of Valium 5 mg, and 30 tablets of Fastin 30 mg (phentermine, a schedule IV drug) to her, he acted in contravention of the Rule's guidelines, as well as the standard of care. *Id.* at 78 (citing GX 26, 28–37, 40; GX 27, at 2, 4, 5; GX 29, at 4).

The Expert also found that both Reynolds and Stout ignored red flags of abuse and diversion that were presented to them at C.S.'s subsequent visits, and did so even though C.S. had violated the terms of her Pain Management Agreement. *Id.* For example, on July 9, 2009, Reynolds issued C.S. prescriptions for 45 tablets of Roxicodone 15 mg (oxycodone), 60 tablets of Valium 5 mg and 30 tablets of Fastin 37.5 mg. *See* GX 26, at 29–30; GX 28, at 2. Reynolds issued these prescriptions even though on June 12, 2009, Reynolds documented that he had received a phone call from a person at ''Genesis Healthcare,'' which was a ''new practice in Boones Creek''; according to the note, Reynolds was informed that C.S. had told Genesis Healthcare that ''she did not have a family practice [and] was seeking to establish new [patient] care.'' GX 26, at 31. Reynolds was further informed that C.S. also used another name (''goes by [C.M.]).'' *Id.* Reynolds received this call three days after he had seen C.S. at AMC (on June 9, 2009), and had prescribed to her 45 tablets of Roxicodone 15 mg and 60 tablets of Valium 5 mg. *See* GX 26, at 33–34; GX 28, at 2. Of further note, the call from Genesis occurred two days after C.S. had called AMC seeking a refill of Fastin, which Reynolds refused to issue. GX 26, at 32.

According to the Expert, the telephone call from Genesis Healthcare was ''a huge red flag.'' GX 68, at 79. The Expert explained that it ''should have been alarming'' to Reynolds ''that C.S. told another practice that she did not have a family practice when she had been going to AMC monthly for the past seven months'' and that she was also using a second name. *Id.* As the Expert explained, after the phone call, Reynolds was aware that C.S. had misled both AMC and the other practitioner, and likely was doctor-shopping. *Id.* This was a violation of the terms of her Pain Management Agreement, which included the provision that: ''I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or anti-anxiety medicines from any other doctors.'' *Id.* (quoting GX 26, at 9).

Yet, at her July 9, 2009 visit, Reynolds did not discuss or otherwise confront C.S. about the information he had received from Genesis. *Id.* (citing GX 26, at 29–30). Moreover, C.S.'s patient record contains no documentation that Reynolds addressed C.S.'s violation of her PMA, even though its terms provided that if she broke the agreement, ''my provider will stop prescribing controlled substances immediately and only provide care for life threatening and chronic medical conditions'' and that she would ''either be discharged from th[e] practice or [o]ffered only alternative treatments such as non-narcotic medications and treatment center options.'' *Id.* at 79–80 (quoting GX 26, at 9); *see also* GX 26, at 29–30.

Moreover, the medical record contains no evidence that Reynolds took steps to monitor C.S.'s controlled substances use, such as by conducting a check of the CSMD before issuing the prescriptions. *Id.* at 79–80; *see also* GX 26. He also did not require her to submit to a UDS to determine if she was taking the drugs she had been prescribed at AMC and if there were any non-AMC prescribed drugs in her system. *Id.* at 80; GX 26.

''For all of these reasons,'' the Expert concluded that ''Reynolds' decision to continue issuing [C.S.] controlled substance prescriptions on July 9, 2009 was contrary to [the] guidelines set forth in Tenn. BON Rule 1000–.04–.08, and accordingly, below the standard of care and outside the usual course of professional practice.'' GX 68, at 80. Relying on the Jackman article and

[16] The Jackman article was supplemented in the same edition of *American Family Physician* by an Editorial, which provided additional guidance on the ''risk of drug misuse, abuse, and addiction'' that exists when treating patient with long-term opioids, a topic that was not fully explored in the Jackman article. *See* GX 49. The Editorial discussed the steps physicians should take to ''monitor'' these risks, including focusing on the patient's medical history, obtaining information from family members, focusing on physical signs of possible aberrant drug-taking behavior, such as slurred speech, small pupils, and unusual affect, and the use of urine drug screening that ''should be positive for prescribed medications, negative for medications that have not been prescribed, and negative for illicit drugs.'' *Id.* at 1–2. The Editorial, moreover, emphasized that ''[t]he current standard of care used by pain management specialists to treat patients with chronic pain and aberrant drug-taking behavior is an abstinence-oriented approach.'' *Id.* at 2. According to the Editorial, ''[i]n this approach, patients initially discontinue their opioid use for a 'drug holiday.' Formal inpatient or outpatient detoxification is sometimes required to stabilize opioid withdrawal syndrome. Following this, patients are given multidisciplinary treatment for opioid dependency and chronic pain, including cognitive behavior therapy (*i.e.* for chronic pain and a substance abuse disorder) that is concurrent with nonopioid pain management.'' *Id.*

accompanying Editorial, the Expert further concluded that ''the standard of care and usual course of professional practice . . . would have been to enforce the terms of C.S.'s [Pain Mgmt. Contract], cease prescribing her controlled substances, and refer her to a pain management specialist and/or addiction specialist to address her drug-seeking behavior.'' *Id.*

On August 4, 2009, C.S. returned to AMC and saw Stout, who issued her prescriptions for 45 tablets of Roxicodone 15 mg, 60 tablets of Valium 5 mg, and 30 tablets of Fastin 37.5 mg. *See* GX 26, at 27–28; GX 27, at 2; GX 28, at 2 & 14. Stout issued these prescriptions even though he had since received further evidence unequivocally showing that C.S. had engaged in doctor-shopping at both Genesis Healthcare and a third practitioner, as well as pharmacy-shopping. GX 68, at 80. Notably, on the date of this visit, AMC ran two CSMD queries to determine what controlled substances had been dispensed to C.S. during the period August 1, 2008, through August 4, 2009; the report was placed in C.S.'s AMC patient file. *Id.* (citing GX 26, at 54–57). The query was run using both of the names C.S. was known to have used when she sought controlled substances. *Id.* As the Expert explained, this demonstrates that AMC and Stout were aware of the fact that C.S. used multiple names. *Id.* at 80–81.

According to the Expert, the two CSMD reports revealed the following information:

> (a) On June 3, 2009, C.M. received prescriptions for 56 oxycodone 7.5 mg and 15 Alprazolam 1 mg from the above-referenced practitioner in Boones Creek, Tennessee, which was six days before she visited AMC on June 9, 2009 and obtained prescriptions for 45 tablets of Roxicodone 15 mg and 60 tablets of Valium 5 mg from Reynolds.
>
> (b) On June 15, 2009, C.S. received a prescription for phentermine 37.5 mg, another schedule IV controlled substance for weight loss, from a third different practitioner just six days after her June 9, 2009 visit to AMC, and five days after Reynolds refused her request to refill her prescription for Fastin.
>
> (c) C.S. had been treated for narcotic dependence during the several months preceding her first visit to AMC. Specifically, the CSMP report shows that C.S. was treated with Suboxone throughout 2008. Significantly, the CSMP report showed that on October 10, 2008, just two months before C.S. began as a patient at AMC, she was issued a Suboxone prescription by Dr. Vance Shaw, AMC's Medical Director.
>
> (d) C.S. was pharmacy shopping, in addition to doctor-shopping. On May 11, 2009, C.S. presented to Church Hill Drugs prescriptions for a thirty-day supply of oxycodone and alprazolam that she had obtained from AMC (Reynolds). Twenty-four days later, on June 3, 2009, C.S. presented to a different pharmacy, Wilson Pharmacy, the oxycodone and alprazolam prescriptions she obtained from the Boones Creek practitioner. Then, six days later, on June 9, 2009, which would have been the thirty-day expiration date of the May 11, 2009 prescriptions, C.S. returned to Church Hill Drugs to present the oxycodone and diazepam prescriptions she obtained from AMC (Reynolds). Thus, the CSMP report alerted Stout to the fact that C.S. was consciously selecting different pharmacies at which to present prescriptions for the same types of controlled substances so as to avoid being detected for doctor-shopping and to obtain early refills.

Id. at 81–82 (citing GX 26, at 49–57).

Thus, the CSMD reports clearly showed that C.S. had violated the terms of her Pain Management Agreement by both doctor shopping and pharmacy shopping (*i.e.,* filling her controlled substance prescriptions at multiple pharmacies).[17] *Id.* at 82. Notwithstanding the ''information showing that C.S. was seeing three different practices at the same time, was pharmacy-shopping, was in violation of her PMA, and was being treated for narcotics dependence for the several months leading up to her first AMC visit, which she had not disclosed to AMC, Stout issued her the above-referenced controlled substances prescriptions.'' *Id.*

Indeed, according to C.S.'s file, during the visit, Stout did not even discuss the CSMD reports with C.S. GX 26, at 27–28. Nor did he require her to provide a UDS or subject her to a pill count, which, according to the Expert, would have been reasonable responses to the red flag information he possessed. *Id.* The Expert thus found that Stout's decision to issue her more controlled substance prescriptions on August 4, 2009 was ''contrary to guidelines set forth in Tenn. BON Rule 1000–.04–.08, and accordingly, below the standard of care and outside the usual course of professional practice.'' GX 68, at 83.

Reynolds and Stout issued additional controlled substances prescriptions for oxycodone and benzodiazepines (Valium and Xanax) to C.S. on September 3, 2009, September 30, 2009, October 29, 2009, and November 30, 2009. *See* GX 26, at 19–26. For the reasons previously stated, the Expert found that Reynolds' and Stout's decisions to issuance C.S. more controlled substance prescription on these dates was contrary to AMC's professed protocols and the Board's Rule 1000–04.–.08(4)(c), and was therefore ''below the standard of care and outside the usual course of professional practice.'' GX 68, at 84.

Moreover, the Expert found that on September 30, 2009, another CSMD report was obtained on C.S., presumably by Stout who saw her on this date. GX 68, at 84; GX 26, at 49–52. Significantly, the report showed that on August 4–5, 2009, C.S. presented the prescriptions she received from Mr. Stout on August 4, 2005, *see id.* at 23–24; to two more pharmacies, Cave's Drugs and P&S Pharmacy. *See id.* at 49, 51. Stout, however, also ignored this additional violation of the Pain Management Agreement and issued C.S. prescriptions for 45 Roxicodone 15 mg and 60 Valium 5 mg. GX 68, at 84.

On October 29, 2009, Reynolds saw C.S. and actually increased her Roxicodone prescription from 45 to 60 tablets; he also issued her a prescription for 60 tablets of Valium 5 mg. GX 26, at 22. Not only did he ignore the information regarding C.S.'s doctor and pharmacy shopping, he also did so while noting in the visit record: ''No recent accidents or injuries and no significant changes in current medical condition. . . . Pt has no interest in further intervention and is satisfied with current treatment plan. . . .'' *Id.* at 21.

On November 30, 2009, C.S. made her last visit to AMC and saw Reynolds, who again prescribed to her 60 tablets of Roxicodone 15 mg. *Id.* at 20. Moreover, while the note contains the same statement that there were ''no significant changes in current medical condition'' and that the C.S. was ''satisfied with current treatment plan,'' Reynolds changed her prescription from Valium to 90 dosage units of Xanax .5 mg. *Id.* at 19–20.

To be sure, the visit note states her psychiatric condition as follows: ''Patient states that they [sic] have had some increases [sic] problems situationally lately with anxiety and depression. This seems to be related to social stressors such as family problems, work issues, financial stressors and sometimes for no reason to mention.'' *Id.* at 19. Yet this was the exact same statement that Reynolds provided in his documentation of C.S.'s psychiatric condition at her previous visit. *See id.* at 21. The record thus contains no explanation as to why Reynolds changed her prescription.

C.S. died the next day. Her death certificate lists the cause of death as ''multiple drug toxicity—oxycocodone, benzodiazepines, carbamates.''[18] *Id.* at 5.

[17] In her Pain Management Agreement, C.S. had agreed to use only Church Hill Drugs to fill her controlled substance prescriptions. *See* GX 26, at 9.

[18] While not discussed above because it was not a controlled substance during the period in which

Summing up her conclusion with respect to the latter prescriptions, the Expert found that Reynolds and Stout acted below the standard of care and outside the usual course of professional practice. GX 68, at 84. Consistent with her conclusions regarding the previous prescriptions, the Expert concluded that Reynolds and Stout should have ''enforced the terms of the [Pain Management Agreement], ceased issuing her further controlled substances prescriptions, and immediately referred her to a pain management specialist and/or addiction specialist for treatment.'' [19] *Id.* at 85.

Discussion

As found above, each of the NPs has an application currently pending before the Agency, and by virtue of his having filed a timely renewal application, Mr. Stout also holds a registration. Pursuant to Section 304(a) of the Controlled Substances Act (CSA), a registration to ''dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Thus, in determining whether the revocation of an existing registration is necessary to protect the public interest, the CSA directs that I consider the same five factors as I do in determining whether the granting of an application would be consistent with the public interest. These factors are:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.; see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am ''not required to make findings as to all of the factors.'' *Volkman,* 567 F.3d at 222; *see also Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). However, even where an Applicant or Registrant ultimately waives his right to a hearing on the allegations, the Government has the burden of proving, by substantial evidence, that the requirements are met for both the denial of an application and the revocation or suspension of an existing registration. 21 CFR 1301.44(d)–(e).

In this matter, I have considered all of the factors. Based on the Government's evidence with respect to factors two and four, I conclude that each practitioner has engaged in misconduct which establishes that granting his or her application, and in the case of Stout, continuing his registration, would be ''inconsistent with the public interest.'' [20] 21 U.S.C. 823(f) & 824(a)(4).

Factors II and IV—The Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. *Carlos Gonzalez, M.D.,* 76 FR 63118, 63141 (2011).

Fundamental to the CSA's scheme is the Agency's longstanding regulation, which states that ''[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430

C.S. was obtaining the prescriptions from AMC's practitioners, the evidence shows that she had also received Soma (carisoprodol) prescriptions at AMC on multiple occasions in the months prior to her death. *See* GX 26, at 20, 22–23, 26–27, 30. Carisoprodol is a derivative of carbamate. It has since been placed in schedule IV of the Controlled Substance Act because of substantial evidence of its abuse, particularly when taken in conjunction with narcotics and benzodiazepines. *See Placement of Carisoprodol Into Schedule IV,* 76 FR 77330 (2011).

[19] In reviewing C.S.'s medical record, the Expert also found that on the nine occasions on which Reynolds saw C.S. between December 12, 2008 and November 30, 2009, he created identical, verbatim records for each visit which included the following entries:

''Pt reports having increased pain with movement and decreased pain with rest'';

''Pt states their pain is a 4 out of 10 and that they have a better quality of life and are able to 'do more'";

''Patient states that they have had a headache for the last 1–2 days, radiating from their neck and around their temples. They relate it to increases in stressors such as home, work, financial, or problems with their family. They note some nause (sic), photophobia, and increased intensity with noise'';

''Anxiety and depression noted in patients (sic) mannerisms and actions during interview.''

GX 68, at 85 (quoting GX 26, at 19–46). Moreover, Reynolds and Stout documented the exact same physical exam findings at each of her visits. *See id.*

[20] As for factor one, the recommendation of the state licensing authority, while each of the practitioners apparently retains his/her Advanced Practice Nurse license, the Tennessee Board of Nursing has not made a recommendation to the Agency as to whether he/she should be granted a new DEA registration. Moreover, although each practitioner is currently licensed by the State and thus satisfies an essential condition for obtaining (and maintaining) a registration, *see* 21 U.S.C. 802(21) & 823(f), DEA has held repeatedly that the possession of state licensure '' 'is not dispositive of the public interest inquiry.' '' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, 472 Fed Appx. 453 (9th Cir. 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Thus, this factor is not dispositive either for, or against, the granting of Respondent's application. *Paul Weir Battershell,* 76 FR 44359, 44366 (2009) (citing *Edmund Chein,* 74 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

Regarding factor three, there is no evidence that Reynolds, Stout, or Killebrew has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. 21 U.S.C. 823(f)(3). However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and thus, it is not dispositive. *David A. Ruben,* 78 FR 38363, 38379 n.35 (2013) (citing *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011)).

F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (stating that the prescription requirement likewise stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares.'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law and standards of practice to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR at 30642.

Moreover, while a finding that a practitioner has violated 21 CFR 1306.04(a) establishes that the practitioner knowing and intentionally distributed a controlled substance in violation of 21 U.S.C. 841(a)(1), ''the Agency's authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.'' *Bienvenido Tan,* 76 FR 17673, 17689 (2011) (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998)); *see also Dewey C. MacKay,* 75 FR at 49974. As *Caragine* explained: ''[j]ust because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify'' the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601.

''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'' *MacKay,* 75 FR at 49974; *see also Patrick K. Chau,* 77 FR 36003, 36007 (2012). Likewise, ''[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if [he] is merely gullible or naïve.'' *Jayam Krishna-Iyer,* 74 FR 459, 460 n.3 (2009); *see also Chau,* 77 FR at 36007 (holding that even if physician ''did not intentionally divert controlled substances,'' State Board Order ''identified numerous instances in which [physician] recklessly prescribed controlled substances to persons who were likely engaged in either self-abuse or diversion'' and that physician's ''repeated failure to obtain medical records for his patients, as well as to otherwise verify their treatment histories and other claims, created a substantial risk of diversion and abuse'') (citing *MacKay,* 75 FR at 49974).

As explained by the Government's Expert, in 2004, the Tennessee Board of Nursing promulgated Rule 1000–04–.08, setting forth guidelines for determining whether the prescribing practices of Advance Practice Nurses are within ''the usual course of professional practice for a legitimate purpose in compliance with applicable state and federal law''; this rule became effective on January 1, 2005.[21] Board Rule 1000–04–.08(4); GX 68, at 10. This rule provided that the patient's medical record ''shall include a documented medical history and physical examination by the Advance Practice Nurse . . . providing the medication.'' Board Rule 1000–04–.08 (4)(c)(1). It further stated that the ''[h]istorical data shall include pain history, any pertinent evaluations by another provider, history of and potential for substance abuse, pertinent coexisting diseases and conditions, psychological functions and the presence of a recognized medical indication for the use of a controlled substance.'' *Id.*

The Rule also provided that ''[a] written treatment plan tailored for individual needs of the patient shall include objectives such as pain relief and/or improved physical and psychosocial function, and shall consider need for further testing, consultations, referrals or use of other treatment modalities dependent on patient response.'' *Id.* at 4(c)(2). Also, the rule provided that ''[a]t each periodic interval'' at which the patient is evaluated ''for continuation or change of medications, the patient record shall include progress toward reaching treatment objectives, any new information about the etiology of the pain, and an update on the treatment plan.'' *Id.* at (4)(c)(4). And the Expert also testified that Advanced Nurse Practitioners were employing the practices set forth in the guidelines in prescribing controlled substance before the Rule became effective on January 1, 2005.

As found above, the Government's Expert reviewed the medical records maintained by AMC on patients N.S., T.H., and C.S. and concluded that in issuing the prescriptions, Messrs. Reynolds and Stout, as well as Ms. Killebrew, failed to comply with the Board's Rule and the standard of care as set forth in various practice guidelines which the clinic asserted it followed. Most importantly, the Government's Expert concluded that Reynolds, Stout, and Killebrew had issued multiple controlled substance prescriptions without a legitimate medical purpose and outside of the usual course of professional practice and thus also violated 21 CFR 1306.04(a).

N.S.

N.S. was initially seen at AMC by providers other than Reynolds, Stout, and Killebrew. However, at the time of her first visit with Reynolds, the latter knew that N.S. has previously been subjected to a UDS and tested positive for several benzodiazepines, even though these drugs had not been prescribed to her by the other NPs at AMC, as well as cocaine. She also tested negative for opiates even though she had been prescribed Avinza (morphine) at AMC, and on the date of the test, she should still have been taking the drug. Reynolds also knew that at N.S's previous visit, she had shown signs of somnolence, slurred speech, and rapid heart rate. Finally, N.S.'s file still lacked information concerning her prior treatment history and substance abuse history, and given that three months had passed since N.S.'s previous visit, Reynolds should have asked N.S. where she had been, but failed to do so. Reynolds failed to refer her to a specialist who could have addressed her aberrant behavior, and instead, issued her another Avinza prescription.

As found above, throughout the lengthy course of her visits to AMC, N.S. continued to engage in aberrant behavior, which was largely ignored by Reynolds, Stout, and Killebrew, who continued to prescribe controlled substances to her. These episodes included overdoses resulting in multiple hospitalizations including for mental health treatment. Moreover, the discharge summary for the first of these, which occurred while N.S. was obtaining drugs at AMC, referenced her

[21] *See also* Board Rule 1000–04–.08(1)(d) (defining ''[p]rescribing pharmaceuticals or practicing consistent with the public health and welfare'' as ''[p]rescribing pharmaceuticals and practicing Advanced Practice Nursing for a legitimate purpose in the usual course of professional practice'').

history of multiple overdoses and suicide attempts; listed two physicians as her primacy care providers (one of whom was not affiliated with AMC); stated that N.S. was taking hydrocodone, Xanax, and carisoprodol, none of which had been prescribed to her at AMC; and reported the results of a UDS, which again showed she was positive for benzodiazepines.

Yet, notwithstanding these multiple red flags, Reynolds continued to prescribe Avinza to N.S. and did so without having obtained information about her treatment before coming to AMC, did not create a written treatment plan, and did not document that he had considered the need to refer her for further testing or consultations.

Thereafter, Reynolds added Xanax for N.S.'s anxiety, notwithstanding that because of her obvious psychiatric issues, she should have been referred to a specialist. As the Expert explained, this was contrary to the Uphold & Graham Guidelines, which Reynolds claimed were the protocols that AMC followed.

Following this, N.S. sought multiple early refills for Xanax; Reynolds also had directed her to come in for a pill count, but N.S. failed to comply. Yet Reynolds continued to issue her more Xanax, and even did so on an occasion when she should have had 19 days left on a prescription.

As for Stout, while he did not prescribe to N.S. until seventeen months into her visits to AMC, the Expert explained that because it was her first visit with him, he was obligated to review her patient file before prescribing controlled substances to determine whether it was appropriate to continue or change her medications. The Expert thus concluded that Stout should have been aware of N.S.'s history of substance abuse and diversion, which was documented in her file, and that Stout breached the standard of care and acted outside of the usual course of professional practice when he issued her Xanax and Kadian prescriptions, rather than cease further prescribing and refer her to a specialist who could address her aberrant behavior.

While Killebrew did not see N.S. until July 2006, when she had been going to AMC for more than twenty-five months, the Expert found that she too acted outside of the usual course of professional practice because she was obligated to review N.S.'s patient file and should not have prescribed controlled substances to her given her history of drug abuse and diversion. Moreover, this was N.S.'s first visit to AMC in seven months, and Killebrew noted that N.S. had recently been released from jail. However, Killebrew failed to ask why she had been incarcerated and how she had addressed her pain issues during that period. Killebrew nonetheless issued N.S. prescriptions for Percocet and Xanax.

Thereafter, N.S. continued to see Reynolds and Stout (and occasionally Killebrew) and repeatedly obtained more controlled substance prescriptions while the practitioners ignored additional red flags. For example, in August 2006, Stout prescribed Percocet and Xanax to N.S., even though the day before N.S.'s July 20 visit with Killebrew, he had treated her while working in a local emergency room and documented that N.S. had admitted ''to having a long history of drug abuse'' and displayed ''drug seeking behavior.'' Stout also failed to address with N.S. why she had been jailed and how she addressed her pain issues while she was incarcerated.

Two months later, Stout issued N.S. more Percocet and Xanax prescriptions, even though her file contained a note (dated one month) earlier stating that she had been selling Percocet. N.S. denied this, claiming her medications had been stolen, but then said she had been taking her medications for the past week. While Stout required that N.S. take a UDS, she tested negative for oxycodone (which she claimed she was taking) but positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed those drugs to her. And notwithstanding these results, which showed that she was abusing and/or diverting, and demonstrated that N.S. had lied to him, Stout issued her more Percocet and Xanax prescriptions.

Several months later, Stout attempted to refer her to two different pain management practices. However, N.S. had already been seen at these practices and neither would accept her as a patient. Once again, Stout issued her more prescriptions for Percocet and Xanax, and several months later, Reynolds issued more of the same prescriptions, ignoring the evidence that N.S. was abusing and diverting, and acted outside of the usual course of professional practice in doing so.

Several months later, Reynolds increased the quantity of N.S.'s prescriptions (she had been switched from Percocet to morphine), by fifty percent from those issued at the previous visit, and yet there is no evidence that Reynolds saw her on this occasion and no explanation in her record as to why she was not seen. And the following month, N.S. called AMC and stated that she had run out of her prescriptions and Killebrew directed that prescriptions for Lortab and Xanax be called in for her; however, N.S. had not been seen at AMC in two months, which according to the Expert, also raised a red flag.

Thereafter, N.S's behavior continued to present red flags, such as in November 2007, when she twice sought refills of controlled substances, including refills which were fifteen days early; yet Reynolds issued her more prescriptions. And the following month, N.S. was admitted to a local hospital which sent AMC both admission and discharge summaries; notably, the summaries listed ''polysubstance abuse'' as one of her diagnoses. Yet, even after receiving this information, Reynolds prescribed more MS Contin, Xanax, and Percocet to her.

Thereafter, N.S. became pregnant and did not visit AMC between February and late December 2008, and apparently had received Suboxone or Subutex treatment from a physician (who was not affiliated with AMC) during her pregnancy. Yet, on N.S.'s return, Killebrew prescribed to her both 60 Lortab 7.5 mg and 30 Xanax .5 mg. However, Killebrew did not even obtain the name of the physician who had provided the Suboxone/Subutex treatment, let alone contact him/her. She also did not conduct a check of the State's prescription monitoring database, even though in the Expert's view, N.S's history of doctor shopping warranted this. Moreover, Killebrew did not document that N.S. had incurred a new illness or injury, and according to the Expert, performed a cursory physical exam. I thus adopt the Expert's conclusion that Killebrew acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions. 21 CFR 1306.04(a).

Following this visit, N.S. did not return to AMC for more than five months. Yet on her return, Reynolds issued her prescriptions for even more potent controlled substances and in even greater quantities (60 MS Contin 30 mg, 30 Percocet 7.5 mg, 90 Xanax .5 mg). However, Reynolds did not document how N.S. had managed her purported pain since her last visit, failed to run a check on her with the CSMD, and failed to conduct a UDS on her. Once again, the Expert concluded that these prescription were issued in violation of 21 CFR 1306.04(a).

As the Expert explained, over the course of the nearly six-year period in which N.S. obtained controlled substances at AMC, she presented numerous red flags (including overdoses) and yet was subjected to only two UDSs, both of which she failed, and but a single pill count.

Moreover, the only time her prescription history was obtained from the CSMD was on the date of her last visit. Also, there were several episodes in which N.S. had not appeared at AMC for months on end, and yet was given more prescriptions without the treating practitioner even attempting to verify her explanation for her absence, asking her how she addressed her pain during her absence, contacting her purported treating physicians, or performing an adequate physical examination. I therefore conclude that all three practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued controlled substance prescriptions to N.S. 21 CFR 1306.04(a).

I also conclude that all three practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing multiple controlled substance prescriptions to T.H. As explained by the Expert, from T.H.'s initial visit, the practitioners knew that T.H. had problems with alcohol as well as mental health issues, and yet they failed to adequately evaluate his alcohol-related issues and refer him to a specialist who could properly address his mental health issues.

Moreover, while T.H. was referred to a pain management clinic, which recommended that he undergo facet blocks and that he take only three Lortab 10 mg per day and do so only for as long as it took to have the procedures performed, T.H. returned to AMC where he saw Reynolds, who failed to determine whether T.H. had ever undergone the procedures. Also, while T.H. should have been out of the controlled substance prescribed by the pain management clinic for a month, Reynolds made no inquiry as to how T.H. had managed his pain. Yet Reynolds then proceeded to escalate T.H.'s prescriptions to 60 OxyContin 40 mg, 30 Lortab 10 mg, and 90 Xanax 1 mg. As the Expert explained, there was no medical justification for adding OxyContin 40 mg to T.H.'s medications, which she explained was four times the normal starting dose. The Expert also explained that the amount of Xanax Reynolds prescribed was excessive as it was six times the daily dosage T.H. had previously received and could be lethal when taken with the narcotics that Reynolds prescribed. The Expert further noted that Reynolds did not properly evaluate T.H.'s alcohol-related problems or his anxiety. I agree with the Expert that Reynolds lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions. 21 CFR 1306.04(a).

At the next visit, T.H. saw Stout, who issued him more prescriptions for the same three drugs. Yet as the Expert explained, Stout did not properly evaluate T.H.'s pain and psychosocial situation, the efficacy of the drugs on his ability to function, did not develop a written treatment plan, and did not evaluate T.H.'s history or potential for abuse. I agree with the Expert's conclusion that Stout lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the prescriptions. *Id.*

During the course of the two years in which T.H. visited AMC, he presented multiple red flags. These included that: (1) He was receiving high doses of narcotics and yet never complained of opioid-induced constipation; (2) he admitted that he was simultaneously seeing another physician, yet neither Reynolds nor Stout contacted the physician to determine the nature of the treatment T.H. was receiving; (3) a pharmacy reported that T.H. was receiving Suboxone treatment from still another physician (again, neither Reynolds nor Stout contacted the physician); (4) T.H. was clearly using multiple pharmacies notwithstanding that he had agreed to use only a single pharmacy; (5) AMC had received a fax which included various documents establishing that T.H. had been treated at three other clinics; (6) T.H. was being treated for depression by a physician; (7) T.H. owed approximately $3,000 to two medical practices; (8) T.H. sought multiple early refills; (9) and T.H. was trying to stop abusing alcohol.

However, T.H. was never required to provide a UDS, was never subjected to a pill count, and a CSMD report was never obtained on him. Moreover, according to the Expert, at no point did any of the three practitioners (including Killebrew, who saw T.H. and prescribed to him on several occasions) create a written treatment plan and properly evaluate his use of alcohol. Yet all three practitioners continued to prescribe both OxyContin and either Percocet or Lortab, as well as Xanax, to T.H., up until the day before he overdosed and died. Based on the Expert's extensive findings, I conclude that each of the practitioners acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued T.H. the prescriptions for multiple narcotics and benzodiazepines.[22] 21 CFR 1306.04(a).

I also agree with the Expert's conclusions that both Reynolds and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued various controlled substance prescriptions to C.S. As the Expert noted, C.S. claimed that she had suffered injuries in a car accident and suffered from back pain (at a level of 4 out of 10) as well as neck pain, although the records also state: ''Pt has no interest in further intervention and is satisfied with current treatment plan.'' The note for her first visit further stated that C.S. reported that she had ''increase[d] problems situationally lately with their anxiety and depression.''

According to the Expert, at C.S.'s first visit, Reynolds failed to create a patient record that appropriately documented her medical history, including her pain history, pertinent evaluations by other practitioners, her history of, and potential for, substance abuse, and pertinent coexisting diseases and treatments. The Expert also found that he did not create a treatment plan which was tailored for her individual needs.

[22] It is noted that Ms. Killebrew's involvement with T.H. was limited to only three visits and that the prescriptions she issued were generally the same as those issued by Reynolds and Stout. With respect to T.H.'s first visit with Killebrew, the Expert opined that the information he reported regarding his impending divorce and increased anxiety rendered him a ''high-risk patient for managing chronic pain and whose care extended beyond the scope of a nurse practitioner engaged in family practice,'' and that a ''prudent practitioner would have considered T.H. to be a risk for suicide and diversion and would have referred him to a mental health specialist and a comprehensive pain management program,'' which Killebrew failed to do. GX 68, at 63.

While the Expert's discussion sounds in malpractice, the Expert further noted that as of the date of his first visit with Killebrew, T.H.'s file contained extensive evidence that he was abusing and/or diverting controlled substances yet Killebrew failed to take steps to monitor his use of controlled substances. I thus agree with the Expert's conclusion that Killebrew acted outside of the usual course of professional practice when she prescribed to T.H. 60 OxyContin 40 mg, 30 Percocet 10 mg, and 75 Xanax 1 mg. *Id.* at 63–64.

Similarly, at T.H.'s second visit with her, he reported that he was having problems with anxiety, that he trying quit alcohol, that he had made an appointment at a mental health facility and had hand tremors; according to the Expert, the latter was a sign of anxiety or alcohol/drug withdrawal. Killebrew did not, however, refer T.H. for treatment by specialists as was called for in the Uphold & Graham practice guidelines which AMC had previously adopted as its practice protocols. GX 39, at 15. Instead, she issued him more prescriptions, these being for 60 OxyContin 40 mg, 30 Lortab 10 mg, while changing his prescription for Xanax to 90 Valium 10 mg. She also ignored other red flags which were documented in T.H.'s patient file. At T.H.'s next visit, Killebrew issued T. H. these same prescriptions, again ignoring the red flags he presented and AMC's practice protocols. Consistent with the Expert's testimony, I conclude that Killebrew acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to T.H. 21 CFR 1306.04(a).

While Reynolds made an entry in the medical record that he had performed a physical exam, notably, with the exception of her vital signs, the physical exam notes for each of her visits are repeated verbatim.

Notwithstanding that C.S. had reported increased problems with anxiety and depression, and according to the clinic's protocols, presented a higher risk of substance abuse, Reynolds did not refer her to a specialist and did not document that he had even considered doing so. Moreover, while C.S. had reported injuries, she also wrote on her intake form that she did not have a current health care provider. As the Expert explained, there is no evidence that Reynolds inquired as to how she had addressed her pain if she had no current provider. Moreover, while Reynolds could have run a CSMD check to verify if C.S. had, in fact, recently seen another provider, as well as obtain information as to her substance abuse history, he did not do so. Of note, that report would have shown that in the period preceding her visit, she had obtained Suboxone from three different physicians. Reynolds started her on Percocet and Valium. I agree with the Expert's conclusion that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a).

At some point, Reynolds did obtain C.S's medical records from a physician who treated her over a five-month period, which had ended more than thirteen months before her first visit to AMC. Most significantly, the physician had documented that C.S. was taking more pain medications than he recommended and explained that he did not think that she could ''self-medicate.'' Yet both Reynolds and Stout continued to prescribe multiple controlled substances including Percocet, Valium, and phentermine to C.S. Moreover, there is no evidence that either Reynolds or Stout ever contacted that physician.

The Expert further found that neither Reynolds nor Stout properly evaluated C.S. at her follow-up visits to determine whether her medications should be continued or changed. Moreover, both Reynolds and Stout repeatedly ignored red flags that C.S. was engaged in both doctor and pharmacy shopping and thus violating her pain contract. These incidents included one in which Reynolds received a phone call from another clinic reporting that C.S. had sought to become a patient, claiming that she did not have a family practice, and that she also used two names at various practices. Neither Reynolds nor Stout documented having addressed this incident with her. Instead, they continued to issue her more prescriptions and never ran a UDS on her.

Moreover, while AMC eventually obtained CSMD reports on her (two months after the above report), they again ignored multiple items of information in those reports which showed that C.S. had been treated for narcotic dependency prior to her first visit at AMC (and had obtained Suboxone from three physicians), that she had recently obtained controlled substances from two other physicians, and that she had also filled prescriptions at multiple pharmacies in violation of her pain agreement. Yet Reynolds and Stout continued to issue her prescriptions for both oxycodone and benzodiazepines up until her death. I therefore agree with the Expert's conclusion that both Reynolds and Stout acted outside of the usual course of professional practice and lacked a legitimate medical purpose when they issued the prescriptions to C.S. 21 CFR 1306.04(a).

In summary, I find that the Government's evidence with respect to factors two and four establishes that each of the three practitioners issued prescriptions in violation of the CSA's prescription requirement and engaged in the knowing diversion of controlled substances. I further hold that the Government has established by substantial evidence that the misconduct of each practitioner is sufficiently egregious to conclude that he/she has committed acts which render his/her ''registration inconsistent with the public interest.'' 21 U.S.C. 823(f) & 824(a)(4). With respect to each of the three practitioners, these findings are sufficient to support the denial of their applications, and in the case of Stout, to revoke his registration.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The Government also contends that practitioner Reynolds engaged in actionable misconduct under this factor when he wrote a letter to a DEA Diversion Investigator which contained various material false statements regarding AMC's treatment of N.S. I agree with the Government.

As recognized by the Sixth Circuit, ''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a [practitioner's] registration is consistent with the public interest.'' *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005). To be actionable, the Government is required to show that the statement was false and material to the investigation. *See Roy S. Schwartz,* 79 FR 34360, 34363 n.6 (2014); *Belinda R. Mori,* 78 FR 36582, 36589 (2013). As the Supreme Court has explained, a false statement is material if it '' 'has a natural tendency to influence, or was capable of influencing the decision of the decisionmaking body to which it was addressed.' '' *Kungys* v. *United States,* 485 U.S. 755, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)). The Court has further explained that:

> it has never been the test of materiality that the misrepresentation . . . would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation. Rather, the test is whether the misrepresentation . . . was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.

485 U.S. at 770–71. ''It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.'' *United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985).

The Government first argues that Reynolds made a materially false statement when he wrote that N.S. ''was admitted to JCMC on December 3, 2004 by Dr. . . . James with drug overdose. She was transferred to [IPP] . . . and continued on her then prescribed medications.'' Req. for Final Agency Action, at 42 (quoting GX 42, at 7). Based on an affidavit it obtained from Dr. James, the Government argues that Reynolds' statement was false because Dr. James ''did not continue N.S. on her then prescribed medications'' but ''ceased prescribing'' all controlled substances to her because she had ''been admitted [to JCMC] for a drug overdose, had a history of multiple overdoses and suicide attempts, and was [being transferred] to IPP for inpatient psychiatric treatment.'' *Id.* at 43.

Notwithstanding Dr. James' statement (which may well have reflected her instructions), the discharge summary for N.S.'s hospitalization (which was part of her patient file), lists Soma, Xanax, MSCN (morphine), and Lortab as ''medications to continue'' and is blank in the space for listing ''medications to discontinue.'' GX 2, at 160. While the form was apparently completed by a nurse and not Dr. James, absent proof that Reynolds had otherwise obtained knowledge that Dr. James had instructed that N.S.'s medications were to be discontinued, it was not unreasonable for him to conclude that the nurse had

accurately reflected Dr. James' instructions on the discharge summary. I thus reject the contention that Reynolds knowingly made a material false statement when he wrote that N.S. had been continued on her then-prescribed medications.[23]

Reynolds, however, also claimed that N.S. ''never had another overdose incident while being treated at AMC'' after a December 3, 2004 hospitalization at Johnson City Medical Center. GX 42, at 7. The Government, however, produced a copy of a report created upon N.S.'s admission to the Johnson City Medical Center on August 19, 2005, which clearly stated that ''[t]he patient was transferred from Northside Hospital because of unresponsiveness secondary to drug overdose.'' GX 14, at 29.

The report further stated that N.S. had told her mother that she had taken five Soma tablets, that her mother found her unresponsive on the floor, that she was taken to Northside Hospital where ''she was found unresponsive to painful stimuli . . . with pinpoint pupils,'' and that Narcan, a drug used to counter the effects of opioids, ''was not helpful.'' *Id.* The report also listed ''[d]rug overdose'' under the attending physician's impressions, and noted that she was to be admitted to the ICU. *Id.* at 30. Finally, the attending physician listed Reynolds as N.S.'s primary care provider and listed him as a recipient of a copy of the report. *Id.*

Based on the above, I conclude that Reynolds knew that N.S. had been hospitalized for a second overdose incident after the December 3, 2004 hospitalization and that his statement was false. I further conclude that the statement was material because it was clearly made by Reynolds to the DI in an attempt to excuse the misconduct he and his fellow practitioners engaged in when they continued to prescribe controlled substances to N.S. even when faced with knowledge that she was drug abuser. *See* GX 42, at 2 (Reynolds' letter to DI; ''I am including in this letter the documents that I have developed to explain my actions and the rationale behind the decisions that have been called into question by the Office of General Counsel of Tennessee and I assume the DEA.'') As explained above, that misconduct is clearly within the Agency's jurisdiction and his statement was clearly capable of influencing the decision of the Agency to pursue this matter.

In his letter, Reynolds also stated that Dr. James (the physician who admitted N.S. to the JCMC for her December 2004) ''took the medical and social history from [N.S.'s] family [and] not the patient.'' GX 42, at 7. The Government notes that in the Admission Report, Dr. James documented that N.S. ''has had multiple episode of over dose in the past, the last one was in May 2004, when she was admitted to the Intensive Care Unit with drug overdose'' and that N.S.'s ''[h]istory [wa]s obtained mainly from the emergency room records and the patient's parents.'' Req. for Final Agency Action, at 45.

The Government argues that taken within the context of the letter, Reynolds' statement was materially false and was made ''for the purpose of demonstrating that the history noted by Dr. James . . . of 'multiple over dose in the past' was somehow inaccurate because'' it had not been obtained ''directly from N.S.'' *Id.* Notably, in his letter, Reynolds further asserted that when, after the overdose incident, N.S returned to AMC, ''[s]he argued with [him] that her overdose was a one-time mistake she had made'' which was caused by ''domestic issues at home'' and that he ''gave her the benefit of the doubt'' and prescribed more controlled substances to her. GX 42, at 7.

Here again, I agree with the Government that the statement was made to justify Reynolds' decision to ignore the clear evidence that N.S. was a substance abuser and to excuse his misconduct (as well as that of his fellow practitioners) in continuing to prescribing controlled substances to her. I further conclude that the statement was false and was capable of influencing the Agency's investigation and was therefore material.

Next, the Government argues that Reynolds made a material false statement when he wrote that after the December 3, 2004 hospitalization, N.S. '' 'never again displayed signs of addiction to include . . . aberrant behavior . . . [and] early refills.' '' Req. for Final Agency Action, at 44 (quoting GX 42, at 7). As found above, the record contains substantial evidence that N.S. displayed numerous signs of addiction and aberrant behavior. These included: (1) Her nearly eight-month absence from the practice (between Dec. 1, 2005 and July 20, 2006) and her reappearance at AMC during which she told Killebrew that she had been in jail; (2) Stout's having treated her the day before her reappearance at AMC at a local hospital's ER and noting that she wanted ''stronger narcotics'' and had ''displayed drug seeking behavior''; (3) a Sept. 13, 2006 report that N.S. was selling Percocet; (4) an Oct. 11, 2006 UDS which was positive for narcotics she had not been prescribed but negative for narcotics which she had been prescribed; (5) her false statement at that visit that she was taking the prescribed medications; (6) the December 2006 refusal of two different pain management practices, both of which had previously seen her, to accept her as a patient; (7) her having sought (in November 2007) a refill fifteen days early; (8) her admission to a local hospital in late December 2007, which diagnosed her with various conditions including poly-substance abuse; (9) the more than five-month gap between her December 22, 2008 and June 4, 2009 visit; and (10) her November 2009 claim that her drugs had been stolen and she needed a refill.

Here again, Reynolds clearly knew of these various incidents and his statement was clearly made to excuse the misconduct he and his fellow practitioners engaged in by continuing to prescribe controlled substances to N.S. in the face of her aberrant behavior. I therefore find that the statement was materially false.

Reynolds further stated that ''[i]n October of 2006, [N.S.] passed drug screens and observations by MC providers.'' GX 42, at 7. As found above, this statement was clearly false as N.S. tested positive for hydrocodone/hydromorphone, even though no one at AMC had prescribed these drugs to her, and tested negative for oxycodone/oxymorphone, even though she had received a Percocet prescription at her previous visit to AMC. Here again, Reynolds' statement was false and clearly made to excuse the misconduct that he and his fellow practitioners engaged in by continuing to prescribe controlled substances to N.S.

Based on the multiple materially false statements Reynolds made in his letter to a DEA Investigator, I further find that Reynolds has engaged in additional conduct which may threaten public health or safety. This finding provides a further reason to deny Reynolds' application.

Sanction

Under agency precedent, ''where a registrant [or applicant] has committed acts inconsistent with the public interest, [he or] she must accept responsibility for his [or her] . . . actions and demonstrate that he [or she] . . . will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009); *see also Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Here, each practitioner has waived his/her right to a hearing and

[23] Even were I to hold that a negligently made false statement is actionable under factor five, no argument has been made as to why Reynolds was negligent when he relied on the discharge summary.

therefore the opportunity to present evidence to refute the Government's showing that he/she has committed acts which render his/her registration ''inconsistent with the public interest,'' 21 U.S.C. 823(f), and the only evidence in the record relevant to these issues is Reynolds' letter to the DI.

Therein, Reynolds stated that he has closed his practice and would not re-open it; that he has taken 55 hours of continuing education in ethics, boundaries, pharmacology and pain; and offered to take ''other training'' to ensure the public safety and his ''compliance with DEA standards.'' GX 42, at 2. Even were I to give weight to Reynolds's unsworn statement regarding the remedial measures he has undertaken, I would still deny his application because he has presented no evidence that he acknowledges his misconduct. To the contrary, the multiple material false statements Reynolds made in his letter establish that he does not accept responsibility for his misconduct in prescribing to N.S. and others. Thus, I conclude that Reynolds has not refuted the Government's *prima facie* showing that granting his application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). So too, because there is no evidence that either Stout or Killebrew has accepted responsibility for his/her misconduct, nor any evidence that either Stout or Killebrew has undertaken remedial measures to ensure that he/she will not re-offend in the future, I also conclude that neither one has refuted the Government's *prima facie* showing. Accordingly, I will order that the registration issued to Stout be revoked, and that the applications of Reynolds, Stout, and Killebrew [24] be denied.

Orders

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration MS0443046 issued to David R. Stout, N.P., be, and it hereby is, revoked. I further order that the application of David R. Stout, N.P., to renew his registration, be, and it hereby is, denied. This Order is effective June 18, 2015.

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Bobby D. Reynolds II, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Tina L. Killebrew, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

Dated: April 30, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015–12038 Filed 5–18–15; 8:45 am]

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[24] While compared to Reynolds and Stout, Killebrew issued substantially fewer illegal prescriptions, her misconduct still involved the knowing diversion of controlled substances, and as such, is sufficiently egregious to support the denial of her application. *See Jayam Krishna-Iyer,* 74 FR at 464 (''[E]ven where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant [an application for] registration unless [she] accepts responsibility for [her] misconduct.''); *see also MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011) (sustaining agency order revoking practitioner's registration based on proof physician knowingly diverted drugs to two patients).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–35]

JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp; Decision and Order

On October 24, 2013, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, ALJ), issued the attached Recommended Decision. Neither the Government nor the Respondents filed exceptions to the Recommended Decision.[1]

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact including his credibility determinations except as discussed below.[2] I also adopt the ALJ's

[1] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[2] In the Recommended Decision, the ALJ observed that his factual findings ''are entitled to significant deference.'' R.D. at 34 (citing *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951)). To make clear, the Agency is the ultimate factfinder and considers an ALJ's factual findings ''along with the consistency and inherent probability of testimony. The significance of [the ALJ's] report, of course, depends largely on the importance of credibility in the particular case.'' *Universal Camera,* 340 U.S. at 496. *See also Reckitt & Colman, Ltd.,* v. *Administrator,* 788 F.2d 22, 26–27 (D.C. Cir. 1986).

For reasons I have previously explained, *see Top Rx Pharmacy,* 78 FR 26069, 26069 n.1 (2013), I do not adopt the parenthetical following the ALJ's citation to *Paul Weir Battershell,* 76 FR 44359, 44368 n.27 (2011). *See* R.D. at 36.

In his discussion of factor two (''the applicant's experience in . . . dispensing controlled substances''), the ALJ explained that this factor manifests Congress's ''acknowledgment that the qualitative manner and *the quantitative volume* in which an applicant has engaged in the dispensing of controlled substances may be [a] significant factor'' in determining ''whether an applicant should be (or continue to be) entrusted with a DEA'' registration. R.D. at 37 (emphasis added).

It is certainly true that evidence as to the volume of dispensings (whether by a prescriber or a pharmacy) has been admitted in these proceedings, by both the Government to show the extent of practitioner's unlawful activities, and by practitioners to show the extent of their lawful activities. That being said, neither the text of factor two, nor the legislative history of the 1984 amendments which gave the Agency authority to consider the public interest in determining whether to grant an application or revoke (or suspend) an existing registration, compel the conclusion that Congress considered ''the quantitative volume'' of an applicant's or registrant's dispensings to be a significant factor in the public interest analysis.

The word ''experience'' has multiple meanings. Among those most relevant in assessing its meaning as used in the context of factor two are: (1) The ''direct observation of or participation in events as a basis for knowledge,'' (2) ''the fact or state of having been affected by or gained knowledge through direct observation or participation,'' (3) ''practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,'' and (4) ''the length of such participation.'' *See Merriam-Webster's Collegiate Dictionary* 409 (10th ed. 1998); *see also The Random House Dictionary of the English Language* 681 (2d ed. 1987) (defining experience to include ''the process or fact of personally observing encountering, or undergoing something,'' ''the observing, encountering, or undergoing of things generally as they occur in the course of time,'' ''knowledge or practical wisdom gained from what one has observed, encountered, or undergone'').

None of these meanings compels the conclusion that Congress acknowledged that ''the quantitative volume'' of a practitioner's dispensing activity may be a significant consideration under this factor, and certainly none suggest that the Agency is required to count up the number of times an applicant or registrant has dispensed controlled substances in making factual findings under this factor as suggested by another ALJ. *See Clair L. Pettinger,* 78 FR 61592, 61597 (2013) (rejecting reasoning in ALJ's recommended decision that factor two ''requires evidence of both the qualitative and quantitative volume of the Respondent's experience'' and that ''[w]here evidence of the Respondent's experience . . . is silent with respect to the quantitative volume of the Respondent's experience, and requires speculation to support an adverse finding under Factor Two, this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with public interest.'').

Prior to the 1984 amendment of section 823(f), the Agency's authority to deny an application or revoke a registration was limited to cases in which a practitioner: (1) Had materially falsified an application, (2) had been convicted of a State or Federal felony offense related to controlled substances, or (3) had his State license or registration suspended, revoked, or denied. *See* S. Rep. No. 98–225, at 266 (1983), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3448. Finding that the ''[i]mproper diversion of controlled substances'' was ''one of the most serious aspects of the drug abuse problem,'' and yet ''effective Federal action against practitioners ha[d] been severely inhibited by the [then] limited authority to deny or revoke practitioner registrations,'' *id.,* Congress concluded that ''the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.'' *Id.*

The Senate Report thus explained that ''the bill would amend 21 U.S.C. 824(f) [sic] to expand the authority of the Attorney General to deny a practitioner's registration application.'' *Id.* The

Continued

conclusions of law that: (1) Respondents' principal (Mr. Moro Perez) materially falsified each pharmacy's application by failing to disclose that he had previously surrendered for cause each pharmacy's DEA registration, and (2) that Respondents failed to demonstrate that they can be entrusted with a new registration.[3] However, for reasons explained below, I do not adopt the ALJ's conclusions that Respondents and their pharmacists violated their corresponding responsibility when they dispensed controlled substance prescriptions issued by a physician whose registration had expired.

The Material Falsification Allegations

As explained in the ALJ's decision, Mr. Moro Perez asserted that he did not materially falsify the applications because he did not believe that the surrenders were for cause.[4] With respect to this allegation, the evidence showed that on November 30, 2011, the Government executed a search warrant at the two pharmacies and that Mr. Moro Perez, who had been arrested at his residence, was taken to Best Pharmacy, where he was presented with a voluntary surrender form (DEA From 104), and that while the form was in English, its purpose and contents were explained to Mr. Moro Perez by a Special Agent who spoke Spanish. Tr. 175–77.

The evidence further showed that the DI (through the Special Agent who translated for him) explained to Mr. Moro Perez that the form ''dealt with the regulatory matter'' and ''his DEA registration number,'' and that it was ''separate from any criminal allegations that may be levied.'' *Id.* at 177. The DI also told Mr. Moro Perez that ''[i]f he chose not to sign the form, then we would move for an order to show cause proceeding.'' *Id.* Mr. Moro Perez did not dispute this testimony.

The evidence further showed that the DEA Form 104, which was used by the DI to memorialize the surrender, contains two boxes which can be checked with an accompanying statement. The first of these states, in relevant part: ''In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part[.]'' GX 14, at 1. According to the DI, this box had been checked prior to the form's presentation to Mr. Moro Perez. Tr. 176. Mr. Moro Perez signed the form. *Id.; see also* GX 14, at 1.

Thereafter, Mr. Moro Perez was criminally charged with several violations of the Controlled Substances Act including possession with intent to distribute, *see* 21 U.S.C. 841(a)(1), and conspiracy to possess with intent to distribute. *See id.* § 860. However, on March 23, 2012, the charges, on motion of the Government, were dismissed with prejudice. RX 3.

The ALJ took official notice that Respondents were previously the subject of an Order to Show Cause Proceeding, and that either one or both Respondents in this matter requested a hearing on the allegations, which was deemed filed with the Office of Administrative Law Judges on December 6, 2011, and assigned Docket No. 12–16. *See* R.D. at 10. The ALJ also took official notice that the aforesaid proceeding was terminated on June 29, 2012. *Id.*

The evidence further showed that Respondent Farmacia Nueva did not complete a DEA Form 104. Tr. 72–74. However, the Government submitted various emails, which were exchanged between Farmacia Nueva's counsel in proceeding No. 12–16 (and who also represented Respondents in this proceeding) and a DEA attorney, whom the ALJ found, upon taking official notice of the Agency's records, served as the Agency's counsel of record in that proceeding.[5] GX 14, at 2–3; R.D. at 10.

The emails include a June 27, 2012 email, which was sent at 8:52 a.m., by DEA's counsel to Respondent's counsel stating: ''Wondering if you've discussed the surrender issue with your client yet. Please let me know if you have any other questions, thanks.'' GX 14, at 2. Later that day (after exchanging emails as to when they could discuss the matter), Respondent's counsel wrote to DEA counsel: ''Ok, anyway, I discussed the case with my client. I think he will surrender it voluntarily. Let me know where to find a form, or send it to me if you have one.'' *Id.*

DEA counsel then replied: ''We can do it without the form if you'd like, just send me an email stating your client agrees to surrender his registration. I'll then file a joint motion to dismiss the proceeding.'' *Id.*

The next day, Respondent's counsel emailed the following to DEA counsel: ''My client, Farmacia Nueva, has decided to voluntarily surrender its DEA registration at issue in the case Docket No. 12–16. Please prepare a joint motion to dismiss the pending case. Thank you.'' *Id.*

In his testimony, Mr. Moro Perez denied that he had knowingly or intentionally falsified both applications. He testified that he did not believe that the surrenders of either pharmacy's registration were for cause, maintaining that upon the dismissal of the criminal case against him, he believed ''that there was no cause against'' him. Tr. 211. Throughout his testimony he repeatedly adhered to this position. However, as the ALJ explained, at the time he surrendered the Best Pharma registration, the criminal case would not be dismissed for another four months.[6]

Moreover, in signing the voluntary surrender form, Mr. Moro Perez clearly acknowledged that he was doing so ''[i]n view of my alleged failure to

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Report further explained that ''in those cases in which registration is clearly contrary to the public interest, the amendment would allow a swift and sure response to the danger posed to the public health and safety by the registration of the practitioner in question.'' *Id.* at 267, *as reprinted in* 1984 U.S.C.C.A.N. at 3449. Accordingly, section 823(f) was amended to provide the Agency with authority to deny an application based upon a finding that the issuance of a registration ''would be inconsistent with the public interest,'' upon consideration of the five public interest factors, including the experience factor. *Id. See also* 21 U.S.C. 824(a)(4). Nowhere in the Report's discussion of the amendments to sections 823 and 824 is there any support for the notion that Congress deemed the quantitative volume of a practitioner's dispensings to be a significant consideration in making findings under the experience factor.

As in past cases, the parties may continue to introduce evidence as to the extent of both a practitioner's lawful or unlawful dispensing activities. However, under Agency precedent, proof of a single act of intentional or knowing diversion remains sufficient to satisfy the Government's *prima facie* burden and to impose on a respondent, the obligation to produce evidence to show that it can be entrusted with a registration. *See Jayam Krishna-Iyer,* 74 FR 459, 463 (2009); *see also MacKay* v. *DEA,* 664 F.3d 808, 819 (10th Cir. 2011) (''Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.''). I therefore do not adopt the ALJ's statement that Congress acknowledged ''the quantitative volume'' of a practitioner's dispensings to be a ''significant factor'' in assessing a practitioner's experience.

[3] I also adopt the ALJ's legal conclusion that the Government did not sustain the record keeping allegation.

[4] Question 2 on the DEA Application asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' On each application, Mr. Moro Perez answered no. GX 1 & 8.

Question 4 asked, in relevant part: ''If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor . . . ever surrendered or had a federal control substance registration revoked, suspended, restricted, or denied . . . .? GX 1, at 1.

[5] While the ALJ provided Respondent with the opportunity to refute the various facts of which he took official notice, Respondent did not do so. *See* R.D. at 9 n.29.

[6] The record does not establish the date on which the criminal case against Mr. Moro Perez was filed.

comply with the Federal requirements pertaining to controlled substances'' and that he was consenting to the termination and revocation of the Best Pharma ''registration without an order to show cause, a hearing, or any other proceedings.'' GX 14, at 1. Also, as the ALJ found, Mr. Moro Perez was specifically told by the Diversion Investigator that the voluntary surrender form involved his pharmacy's registration and was separate from any criminal allegations that could be levied against him. And most significantly, the Diversion Investigator then told Mr. Moro Perez that if he did not sign the voluntary surrender form, he would seek an Order to Show Cause.

Mr. Moro Perez thus knew that the DI was pursuing the voluntary surrender based on the latter's belief that Best Pharma was engaged in unlawful practices. And finally, in addition to the DI's testimony (which the ALJ found credible) that he repeatedly explained to Mr. Moro Perez that the voluntary surrender form addressed a regulatory matter and was separate from any criminal charges that might be filed, it is noted that the CSA explicitly provides that ''[p]roceedings to deny, revoke, or suspend . . . shall be independent of, and not in lieu of, criminal prosecutions . . . under this subchapter or any other law of the United States.'' 21 U.S.C. 824(c).

As the ALJ recognized, DEA regulations do not define the meaning of the term ''for cause'' as used on the various application for registration forms. Moreover, the application does not define the term. Nonetheless, persons of ordinary intelligence cannot dispute that a surrender which occurs in response to allegations of misconduct raised by the Agency's Special Agents and Diversion Investigators is ''for cause,'' especially when those Agents and Investigators further advise the registrant's principal that if he/she declines to surrender a registration, the Agency will nonetheless initiate proceedings to revoke it.[7]

Beyond this, as the ALJ recognized, if the dismissal of the criminal proceeding transformed the earlier surrender of Best Pharma's registration into a surrender which was no longer ''for cause,'' given that the same allegations were raised with respect to both pharmacies, there would have been no reason for the Agency to continue its pursuit of the Show Cause Proceeding against the registration Mr. Moro Perez held for Farmacia Nueva. Yet the Agency did pursue the Show Cause Proceeding against Farmacia Nueva's registration until its principal agreed to surrender its registration some three months after the dismissal of the criminal case against Mr. Moro Perez. In his testimony, Mr. Moro Perez offered no explanation as to why, if the dismissal of the criminal case against him rendered the surrender of Best Pharma's registration not ''for cause,'' he subsequently agreed to surrender Farmacia Nueva's registration.[8]

In his testimony, Mr. Moro Perez also denied that he knowingly or intentionally falsified the applications because he completed them, ''knowing and recognizing that you, the DEA office, are aware of, [and] had knowledge and everything about me,'' Tr. 218, including his arrest. However, whether Investigators at the local DEA office were aware of Mr. Moro Perez is irrelevant in assessing his scienter; having answered the liability question ''no,'' the only issues that are relevant are whether he knew that he had surrendered his registrations and had done so ''for cause.'' Because Mr. Moro Perez clearly knew that he: (1) Had surrendered his registrations, (2) had done so in response to allegations that his pharmacies had committed violations of the CSA, and (3) did so to avoid proceedings to revoke the registrations, he also clearly knew that he had surrendered ''for cause.''

I thus agree with the ALJ's conclusion that Mr. Moro Perez knowingly and materially falsified[9] the applications he submitted for both Best Pharma and Farmacia Nueva. *Id.* These findings provide reason alone to support the denial of his applications, especially when coupled with the ALJ's findings that Mr. Moro Perez's testimony as to why he falsified the applications ''is simply not credible.'' R.D. at 67.

The Corresponding Responsibility Allegations

The ALJ also found that Respondents' pharmacists violated their corresponding responsibility under 21 CFR 1306.04, when, over the course of some thirty-four months, they filled numerous controlled substance prescriptions which were written by a physician who no longer possessed a valid DEA registration. While I adopt the ALJ's finding that Respondents dispensed the prescriptions at issue when the physician no longer possessed a DEA registration, I reject his legal conclusion that Respondents violated 21 CFR 1306.04(a) because the Government failed to prove that the pharmacists acted with the requisite scienter. However, based on Respondents' admissions, I find that they committed acts inconsistent with the public interest when they failed to verify that the physician remained registered at any time for some thirty-four months.

With respect to this allegation, the evidence showed that a physician named Dr. Hector J. Aguilar-Amieva (hereinafter, Dr. Aguilar) had allowed his registration to expire and that his registration had been retired by the Agency since January 31, 2009.[10] The evidence further shows that between January 30, 2009 and November 30, 2011 (when the search warrants were executed at Respondents), Farmacia Nueva filled 143 controlled substance prescriptions which were purportedly issued by Dr. Aguilar (and which used his DEA registration) and that Best Pharmacy filled thirty-two controlled substance prescriptions. GXs 5 & 10.

Under 21 CFR 1306.03, a controlled substance prescription ''may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) [e]ither registered or

[7] In its post-hearing brief, Respondents note that on the application, the phrase ''for cause'' is in parentheses. Resp. Br. 22–23. Respondents then argue that ''[i]t must be in parenthesis [sic] for some reason [and] [t]he idea cannot be and should not be that any time an applicant who had surrendered his registration for some reason answers 'no' to this question, that applicant is automatically falsifying facts.'' *Id.* at 23.

That is certainly true, as a pharmacy registrant may have surrendered its registration previously because it went out of business but has since reopened, just as a physician registrant may have done so because he/she ceased professional practice but has since resumed practicing medicine. The argument ultimately takes Respondents nowhere because Mr. Moro Perez surrendered Best Pharmacy's registration after he was accused of having violated the CSA and was told that if he did not surrender the registration, the Agency would pursue a proceeding to revoke its registration; as for Farmacia Nueva's registration, the Agency was continuing to pursue a Show Cause Proceeding to revoke its registration when Mr. Moro Perez agreed to surrender its registration.

[8] Respondent makes no claim that Mr. Moro Perez was unaware that its attorney had surrendered Farmacia Nueva's registration. Even if it had, '' 'a principal is chargeable with the knowledge of, or notice to, his agent that is received by the agent in the due course of his employment and is related to the matters within his authority.' '' *McMillan* v. *LTV Steel, Inc.,* 555 F.3d 218, 230 (6th Cir. 2009) (quoting *Aetna Cas. & Sur. Co.* v. *Leahey Constr. Co.,* 219 F.3d 519, 541 (6th Cir. 2000)).

[9] Respondents do not contend that the falsifications were immaterial.

[10] According to the DI, Dr. Aguilar's registration expired after he was convicted of a federal criminal offense; the record does not, however, establish the offense of which he was convicted nor the date of his conviction. Moreover, while there was evidence that Dr. Aguilar's office was only a three to four minute walk from Farmacia Nueva, Tr. 250, and that it was the closest pharmacy to his office, the Government provided no evidence that Respondents' pharmacists were aware of any enforcement actions that were brought against Dr. Aguilar.

exempted from registration [under] this chapter.'' Thus, Dr. Aguilar's prescriptions were unlawful.[11]

Mr. Moro Perez testified that there were ''many times'' when Respondents' pharmacists refused to fill Dr. Aguilar's controlled substances prescriptions because ''we knew that that patient didn't require the use of the medication.'' Tr. 252; *see also id.* at 254. When questioned by the ALJ as to whether he thought it was suspicious that many of Dr. Aguilar's patients were presenting controlled substance prescriptions that he (and his pharmacists) would not fill, Mr. Moro Perez testified that ''we have been very careful with the dispensing'' and ''the amount of medications that were dispensed, the percentage [was] very low.'' *Id.* at 253. Mr. Moro Perez then testified that he never called Dr. Aguilar, and when asked why, claimed that he and his pharmacists reviewed the patient's history and used their professional judgment to evaluate whether a particular prescription was legitimate. *Id.*

When questioned further as to why he did not call Dr. Aguilar, Mr. Moro Perez testified: ''Because I understood, I was aware that the doctor's license were [sic] up-to-date.'' [12] *Id.* at 254. Mr. Moro-Perez and his pharmacists never attempted to verify whether Dr. Aguilar held a registration, *id.* at 193–94, even though, according to the DI, they could have done so simply by calling the local DEA office.[13] *Id.* at 20.

Instead, Mr. Moro-Perez testified that he and his pharmacists relied on the patients' insurance carriers (to which they submitted claims for payment of medications) to determine whether a physician had valid licenses and registrations by seeing if the claim was paid. *Id.* at 200–1. Mr. Moro-Perez conceded that the insurance companies continued to pay claims for prescriptions issued by Dr. Aguilar until the date on which the search warrant was executed, which was nearly three years after the latter's registration had been retired. *Id.* at 202. However, no evidence was adduced as to whether any claim for payment was rejected by a patient's insurer, and there was obviously no evidence as to whether in the event an insurer rejected a claim, it would disclose the reason it did so.[14]

As the ALJ recognized, under DEA's longstanding regulation, a pharmacist has a corresponding responsibility to fill only those prescriptions which are ''issued for a legitimate medical purpose by [a] practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Continuing, the regulation states that ''the person *knowingly* filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*[15] (emphasis added).

DEA has long interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ''knows or *has reason to know* that the prescription was not written for a legitimate medical purpose.'' *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990) (emphasis added); *see also Frank's Corner Pharmacy,* 60 FR 17574, 17576 (1995); *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980). Thus, proof of actual knowledge is not necessary to establish that a pharmacist has violated his/her corresponding responsibility to dispense only lawful prescriptions.

However, in finding violations of the corresponding responsibility where actual knowledge has not been proved, the Agency has explained that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid positive knowledge of the real purpose of the prescription,'' and thereafter fill the prescription ''with impunity.'' *Bertolino,* 55 FR at 4730 (citing *United States* v. *Kershmann,* 555 F.2d 198 (8th Cir. 1977); *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979)); *accord Liberty Discount Drugs, Inc.,* 54 FR 30116, 30117 (1989). *See also Medic-Aid Pharmacy,* 55 FR at 30044 (''The administrative law judge concluded that it is not necessary to find that [the pharmacist] in fact knew that many prescriptions presented to him were not written for a legitimate medical purpose, for there is no question that a conscientious pharmacist would have been suspicious of these prescriptions and would have refused to fill them.''). Thus, both *Bertolino* and *Medic Aid Pharmacy* applied the standard of deliberate ignorance or willful blindness in assessing whether a pharmacist acted with the requisite scienter. *See Seelig,* 622 F.2d at 213 (''the element of knowledge may be inferred from proof that appellants deliberately closed their eyes to what would otherwise be obvious to them''); *Kershmann,* 555 F.3d at 200 (''the element of knowledge may be shown by deliberate ignorance'').

In addition to the obligation imposed by 21 CFR 1306.04(a), ''[a] prescription for a controlled substance may only be filled by a pharmacist, *acting in the usual course of his professional practice. . . .*'' 21 CFR 1306.06 (emphasis added). Thus, the Agency has also repeatedly held that ''a pharmacist must exercise professional judgment [and common sense] when filling a prescription.'' *Bertolino,* 55 FR at 4730; *see also Medicine Shoppe-Jonesborough,* 73 FR 363, 381, *pet. for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. App'x 409, 412 (6th Cir. 2008); *Trinity Health Care Corp.,* 72 FR 30849, 30854 (2007); 21 CFR 1306.06. Accordingly, the Agency has held that ''when a customer presents a suspicious prescription, at a minimum, a pharmacist has a duty to verify the prescription with the prescriber.'' *Medicine Shoppe-Jonesborough,* 73 FR 364, 381; *see also Medicine Shoppe,* 300 Fed. App'x at 412.

Moreover, even if a prescriber tells a pharmacist that a prescription has been issued for a legitimate medical purpose, a pharmacist cannot ignore other evidence that the prescription has not been issued for a legitimate medical purpose or that the prescriber acted outside of the usual course of his or her

[11] Respondents do not claim that Dr. Aguilar was exempt from registration, and under the CSA, had they claimed as much, they (and not the Government) would have had the burden of proof on the issue. *See* 21 U.S.C. 885(a) (1).

[12] The ALJ was not impressed by this testimony, finding it to be ''the obvious fruit of intentional equivocation.'' R.D. at 20. That being said, the ALJ's finding does not establish that Moro-Perez knew that Dr. Aguilar was no longer registered (as opposed to simply being unaware of the status of Aguilar's license) when his pharmacies filled the prescriptions and the ALJ made no such finding. Moreover, it is not even clear on the record whether Moro-Perez was testifying regarding Dr. Aguilar's DEA registration rather than his state license.

[13] The evidence also showed that since 2008, DEA has provided a Web page, at which a DEA registrant can verify the registration status of another person or entity. Tr. 22. However, other than vague testimony suggesting that during an inspection an investigator would tell a registrant that the Web site is available, *id.* at 90, no evidence was put forward that this information was conveyed to Respondents. Nor did the Government provide any evidence as to what efforts have been made to notify the community of registrants as to the Web page's availability.

It is noted that in publishing its Interim Final Rule on Electronic Prescriptions for Controlled Substances, the Agency explained that ''[i]f a pharmacy has doubts about a particular DEA registration, it can now check the registration through DEA's Registration Validation Tool'' which is available at the Agency's Web site. *See* 75 FR 16236, 16266 (2010).

[14] Nor was any evidence put forward as to how many of the Aguilar prescriptions were actually paid for with cash.

[15] As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 (1975)).

professional practice and dispense the prescription. As one court of appeals has explained:

> Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.

United States v. *Hayes,* 595 F.2d 258, 260 (5th Cir. 1979). *See also Medicine Shoppe,* 300 Fed. App'x at 412 (quoting *Bertolino,* 55 FR at 4730) (" 'When [pharmacists'] suspicions are aroused as reasonable professionals,' they must at least verify the prescription's propriety, and if not satisfied by the answer they must 'refuse to dispense.' "); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR 62316, 62341 (2012); *East Main Street Pharmacy,* 75 FR 66149, 66163–64 (2010).

Under an Agency regulation, every controlled substance prescription must contain "the name, address and registration number of the practitioner" who issued it. 21 CFR 1306.05(a). However, the Agency's regulation does not require that a practitioner provide the expiration date of his registration on a prescription. *See id.*

Moreover, no Agency regulation requires that a pharmacist ascertain that each prescription presented to him/her has been issued by a practitioner who possesses a valid DEA registration. Indeed, the Agency recognized this much in 2010, when it promulgated its Interim Final Rule on Electronic Prescriptions for Controlled Substances. *See* 75 FR 16236, 16266 (2010). Therein, the Agency noted that it had proposed requiring pharmacies "to confirm that the [prescriber's] DEA registration . . . was valid at the time" the prescription was signed. *Id.* However, several commenters objected "that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription." *Id.*

In its response (which appears to be missing pertinent text), the Agency stated that it "agrees with those commenters that expressed the view that, when filling a paper prescription, it is not necessary for a pharmacist who receives an electronic prescription for a controlled substance to check the CSA database in every instance to confirm that the prescribing practitioner is properly registered with DEA." *Id.* The Agency thus removed the requirement from the Interim Final Rule, but "made clear that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered." *Id.*

As this pronouncement makes clear, a pharmacist is not obligated to verify whether every prescription he fills has been issued by a practitioner who holds a valid DEA registration. Of course, if a pharmacist has actual knowledge that a prescriber does not hold a valid registration, or acts with willful blindness to this fact, a pharmacist violates the Controlled Substances Act if he proceeds to dispense that prescription. 21 U.S.C. 843(a)(2). Thus, in *United Prescription Services,* I held that a pharmacy violated its corresponding responsibility by dispensing prescriptions issued by a physician, whose registration had expired, where the pharmacy had on file a copy of the physician's registration and thus, its pharmacists clearly knew, or were willfully blind to the fact, that the physician was issuing prescriptions on an expired registration and that the prescriptions were therefore illegal.[16] 72 FR at 50408.

More recently, in *Holiday CVS, L.L.C.,* 77 FR 62316 (2012), two pharmacies continued to fill prescriptions written by two physicians whose registrations had expired. Moreover, the registration of one of the physicians had been revoked following a proceeding under 21 U.S.C. 824(a)(4) and the Agency's Decision and Order had been published in the **Federal Register** (as well as on the DEA Office of Diversion Control's public Web site) approximately one month before the Order became effective. *Id.* Yet both pharmacies continued to dispense prescriptions issued by this physician, including some which were issued more than five months after the Order became effective. *Id.* Finally, the evidence also showed that the pharmacies used a company wide information management system which obtained updated registration data from a third party aggregator (which obtained it from DEA) on a weekly basis and that a prescribing physician's registration status was displayed to the pharmacist when entering the prescription into the pharmacy's dispensing software. *Id.* Thus, the pharmacists at each store had knowledge that the physicians' registrations had expired at the time they filled most of the prescriptions.[17] *Id.* Here again, liability was imposed on the pharmacies consistent with the corresponding responsibility imposed on their pharmacists.[18]

As the ALJ found, the Government put forward no evidence that Mr. Moro-Perez or any of his pharmacists had actual knowledge that Dr. Aguilar's registration was no longer valid at any point during the thirty-four month period in which they filled his prescriptions. R.D. 51 n.86. The ALJ nonetheless concluded that the requisite knowledge could be imputed to Respondents because their pharmacists entirely failed to investigate whether Dr. Aguilar held a valid registration and thus were willfully blind to the fact that Aguilar was no longer registered and could not write a controlled substance prescription. R.D. at 53 (citing *United*

[16] In *United Prescription Services,* this particular physician's registration had expired on February 28, 2003, and yet the pharmacy was still dispensing prescriptions written by him in September and October 2004. *See* 72 FR at 50408.

[17] I also noted that as participants in a highly regulated industry, the pharmacies were required to keep abreast of regulatory developments which affect their industry and that with respect to the physician whose registration was revoked, publication of the Decision and Order in the **Federal Register** "provided [the pharmacies] with reason to know" that upon the effective date, the physician "would no longer be authorized to issue controlled substance prescriptions." 77 FR at 62317 (citations omitted).

[18] In the Show Cause Order, the Government cited *Medicine Shoppe—Jonesborough,* 73 FR 364 (2008), as authority for the violation. In *Medicine Shoppe—Jonesborough,* a pharmacy was found to have filled over 124 controlled substances prescriptions which were written by a veterinarian who no longer possessed either a state license or a DEA registration. *Id.* at 381. However, I did not decide whether the pharmacy violated its corresponding responsibility because it dispensed the prescriptions when the veterinarian lacked either state authority or a DEA registration. *Id.* Rather, I found that even if the pharmacy's pharmacist-in-charge was unaware that the veterinarian no longer possessed a DEA registration and state license, it violated its corresponding responsibility based on the expert testimony that the pharmacy had ignored various circumstances that provided knowledge to its pharmacists that the prescriptions were not issued for legitimate medical purposes (including that the prescriptions were presented on a daily basis by the veterinarian's brother and were for drugs, which according to the expert, would be toxic for certain animals). *Id.*

However, in a footnote, I explained that "[a] pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance." *Id.* at n.45. Because of the evidence that the pharmacy had violated 21 CFR 1306.04(a), I deemed it unnecessary to decide whether the pharmacy had violated this duty. However, I noted my agreement with the ALJ's reasoning that failing "to do so could threaten public health and safety because there is usually a good reason for why a practitioner has lost his or her state license and DEA registration." *Id.*

States v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006)).[19]

Recently, however, the Supreme Court made clear that ''a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can *almost be said to have actually known the critical facts.'' Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 131 S.Ct. 2060, 2070–71 (2011) (emphasis added) (citing and quoting G. Williams, *Criminal Law* § 57, p.159 (2d ed. 1961) (''A court can properly find willful blindness only where it can almost be said that the defendant actually knew.'')); *see also id.* at 2069 (quoting with approval American Law Institute, *Model Penal Code* § 202(7) (Proposed Official Draft 1962) (''defining 'knowledge of the existence of a particular fact' to include a situation in which 'a person is aware of a high probability of [the fact's] existence, unless he actually believed that it does not exist'''')).

In *Global-Tech,* the Supreme Court further explained that even proof that a defendant was reckless in that he knew ''of a substantial and unjustified risk of wrongdoing'' does not establish willful blindness. *Id.* at 2071. Rather, to establish willful blindness, proof is required that: ''(1) the defendant must *subjectively believe* that there is high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.'' *Id.* at 2070 (emphasis added).

Here, the Government offered no evidence to establish that Mr. Moro-Perez, or any other of Respondents' pharmacists, subjectively believed that there was a high probability that Dr. Aguilar was issuing prescriptions on an expired registration. Moreover, notwithstanding that Respondents put forward no evidence that it was objectively reasonable to determine if Dr. Aguilar possessed a valid registration by relying on whether the patients' insurance companies paid for their prescriptions, there is no evidence that a claim for payment of any of Dr. Aguilar's prescriptions was ever rejected by a patient's insurer. Indeed, notwithstanding the ALJ's finding (with which I agree) that this was an ''irresponsible practice'' and ''illogical manner'' of determining a physician's registration status, he made no finding that Moro-Perez (or any other pharmacist) ''subjectively believe[d] that there was a high probability'' that Dr. Aguilar was writing on an expired registration.

To be sure, in his testimony, Mr. Moro-Perez admitted that his pharmacists had rejected controlled substance prescriptions issued by Dr. Aguilar ''many times,'' because based on the patients' histories, they did not consider the prescriptions to be legitimate for the respective patients. This admission might well have established willful blindness with respect to whether the Aguilar prescriptions which Respondents filled lacked a legitimate medical purpose—had the Government challenged the dispensing of any of the post-January 31, 2009 prescriptions on this basis. But it did not. Most importantly, it does not establish that Moro-Perez or any of his pharmacists subjectively believed that there was a high probability that Aguilar no longer had a registration.[20]

As for whether Respondents' pharmacists violated their obligation to act within the usual course of professional practice, *see* 21 CFR 1306.06, because their suspicions as to Dr. Aguilar's lack of registration should have been aroused as reasonable pharmacists and they failed to investigate, the evidence is simply insufficient to establish a violation. Notably, the Government does not cite to any statute, Board regulation, or decision of either the Board or the courts which requires a pharmacist to verify the status of a DEA registration (or medical license) upon being presented with a prescription which he/she suspects lacks a legitimate medical purpose.[21] Nor, notwithstanding the abundance of agency case law applying the reasonable pharmacist standard, did the Government call an expert to testify that the standards of professional pharmacy practice require that a pharmacist who is confronted with prescriptions from a particular physician which he/she suspects lack a legitimate medical purpose, must also determine whether the physician possesses a valid DEA registration.[22]

In its post-hearing brief, the Government argues for the first time that Respondents' pharmacists also violated their corresponding responsibility because the prescriptions they filled also lacked a legitimate medical purpose. As the Government argues, ''Mr. Moro-Perez's most egregious conduct involves filling prescriptions for Dr. Aguilar-Amieva despite the fact that he had previously flagged prior prescriptions as being illegitimate.'' Gov. Post-Hrng. Br. at 22. The Government then argues that ''Respondent[s] deliberately ignored their own internal warnings when they continued to fill other prescriptions for Dr. Aguilar-Amieva,'' that ''Moro-Perez failed to conduct any investigation to resolve this flag,'' and that ''[a]ny reasonable and prudent pharmacist would not have continued to fill prescriptions without further investigation.'' *Id.* at 23.

Even ignoring that raising this theory for the first time in its post-hearing brief is too late to provide fair notice (given that the testimony did not occur until Moro-Perez was cross-examined by his own counsel), the Government did not put on any evidence to show that any of the Aguilar prescriptions filled by

[19] *See also United States* v. *Lawson,* 682 F.2d 480, 482 (4th Cir. 1982); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980); *United States* v. *Kershmann,* 555 F.2d 198, 200–01 (8th Cir. 1977).

[20] Although both the Government and ALJ made much of Moro-Perez's admission, ''many'' is an indefinite term and the record does not clarify just how many prescriptions were rejected by Respondents, and as of what date their pharmacists were aware of this.

[21] The ALJ also reasoned that ''[t]he absence of Dr. Aguilar's [registration] is the most glaring of red flags that could and should have been recognized by the Respondent upon the exercise of even the most minimal due diligence. Conclusively resolving such a fundamental red flag was a mandatory condition precedent to the legal dispensing of a control substance. . . .'' R.D. at 52.

The term ''red flag'' is not defined in either the CSA or DEA regulations. However, in the context of a pharmacy, a red flag is simply a circumstance arising during the presentation of a prescription, which creates a reasonable suspicion that the prescription is not valid and which imposes on a pharmacist the obligation to conduct further inquiry into whether the prescription is valid or to not fill it all. *See Holiday CVS,* 77 FR at 62332.

Here, there was no evidence that Respondents' pharmacists ever received any information that Dr. Aguilar was no longer registered such as through a tip, the grapevine, or having seen media coverage of Aguilar's putative arrest or trial. Moreover, while a red flag includes additional facts developed during the investigation of other red flags, here, the red flag was the illegality of the prescriptions Respondents declined to fill. Because there is no regulation which required Respondents to the check the registration status of Dr. Aguilar, nor any testimony that the accepted standards of professional practice required that they do so, I do not adopt the ALJ's discussion that Dr. Aguilar's lack of a registration was ''the most glaring of red flags'' which should have been discovered.

[22] As found above, in the Interim Rule on Electronic Prescribing, the Agency noted that several commenters had objected to the proposal that the DEA registration must be verified for all electronic prescriptions, noting ''that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription.'' 75 FR at 16266. While this may reflect the accepted standards of professional pharmacy practice, the Interim Rule did not explain who the commenters were and whether they speak for the profession as a whole. Moreover, absent proof of either: (1) That a dispensing was simply a drug deal, or (2) that the pharmacy violated an explicit duty set forth in a statute, regulation, or case law, the standards of professional practice must generally be established on the record in any case. Accordingly, I place no weight on the statement suggesting that a pharmacist is required to check a prescriber's registration if he/she suspects there is something wrong with a prescription.

Respondents also lacked a legitimate medical purpose.[23] Indeed, there is no evidence to refute Moro-Perez's testimony (which the ALJ apparently found credible) that he and his pharmacists declined to fill many prescriptions and thus complied, (at least with respect to those prescriptions), with their corresponding responsibility.

As for its contention that no reasonable and prudent pharmacist would have filled the prescriptions, here again, there is no evidence as to what a reasonable and prudent pharmacist would have done when confronted with this information. Nor is there any expert testimony as to at what point (*i.e.,* after how many prescriptions), this information would have prompted further investigation.[24]

In their post-hearing brief, Respondents nonetheless concede that by dispensing the Aguilar prescriptions they committed acts inconsistent with the public interest, Resp. Post-Hrng. Br. 18, because ''it was wrong for him [Moro-Perez] and [the] pharmacies to rely on [an] insurance company's system to notify [them] if a doctor's license is expired, suspended, or revoked.'' *Id.* at 19. Respondents further concede that doing so constitutes ''such other conduct which may threaten public health and safety.'' *Id.* at 25.

I agree. As the ALJ found (and given Respondent's concession), it was not objectively reasonable for Respondents' pharmacist to rely on whether insurance companies rejected a claim for payment of a prescription to determine whether a physician held a valid registration. And as explained above, more than a year prior to the conduct at issue here, I explained (albeit in a dictum) that ''[a] pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance.'' *Medicine Shoppe-Jonesborough,* 73 FR at 381 n.45. However, because it was not necessary to decide the case, *Medicine Shoppe—Jonesborough* did not set forth the specific parameters of this duty. *See id.*

I nonetheless conclude that Respondents breached this duty because their pharmacists failed to verify that Dr. Aguilar remained registered at any time during the thirty-four month period between the expiration of his registration and the execution of the search warrants. However, I place only nominal weight on this aspect of Respondents' misconduct. The Government did not prove that Respondents' misconduct was intentional or knowing. Moreover, while Respondents do not dispute that their failure to verify Dr. Aguilar's registration at any time during the aforesaid period constitutes conduct which may threaten the public health and safety, the lack of specific guidance as to what steps are necessary to comply with this duty diminishes its egregiousness to some degree. Finally, Mr. Moro-Perez's material falsification of the applications and failure to accept responsibility for the falsifications, provide reason alone to deny the applications.

While it is indisputable that failing to verify a controlled-substance prescriber's credentials at any time during a three year period is a breach of the duty set forth in *Medicine Shoppe—Jonesborough,* I conclude that if the Agency intends to enforce this duty in other cases, it must provide the regulated community with guidance as to its scope. However, while such guidance can be announced in an adjudicatory proceeding, the process of adjudication is not well suited for doing so. *See* I Richard J. Pierce, Jr., *Administrative Law Treatise* § 6.8, at 368–74 (4th ed. 2002). Accordingly, I decline to set forth how frequently a pharmacy must verify that a prescriber is registered.

In sum, I reject the allegations that Respondents violated Federal law and DEA regulations when they dispensed controlled substance prescriptions ''issued by a medical doctor who did not possess a valid DEA registration.'' Show Cause Order (ALJ Ex. 1), at 2 ¶¶ 4 & 8 (citing 21 U.S.C. 843(a)(2); 21 CFR 1306.04).[25] However, I find that Respondents breached their duty to periodically verify Dr. Aguilar's registration status. *See Medicine Shoppe-Jonesborough,* 73 FR at 381 n.45.

Most significantly, I also adopt the ALJ's findings that Mr. Moro-Perez materially falsified the application of each Respondent by failing to disclose that he had previously surrendered each pharmacy's registration for cause, as well as the ALJ's findings that Mr. Moro-Perez has not acknowledged his misconduct in doing so. *See* R.D. at 53 (finding that Mr. Moro-Perez ''insistence that his false response to an application query regarding whether each pharmacy had ever surrendered a [registration] for cause was some sort of reasonable

[23] Notably, in this portion of its brief, the Government makes no reference to the status of Dr. Aguilar's registration. *See* Gov. Post-Hrng. Br. 22–23.

While the Government obtained the prescriptions during its investigation, it did not raise this theory in the Show Cause Order, which, with regard to Respondents' dispensings, rested entirely on the allegations that they dispensed ''prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration.'' ALJ Ex. 1, at 2. Moreover, in neither of its pre-hearing statements, did the Government provide notice that it was challenging the dispensings of the Aguilar prescriptions on the ground that they were issued for other than a legitimate medical purpose. *See* ALJ Exs. 4 & 8.

[24] Even were I to apply the ''reason to know'' standard of the common law, *see Novicki* v. *Cook,* 946 F.2d 938, 941 (D.C. Cir. 1991), which requires proof of something less than either actual knowledge or willful blindness, the Government would not prevail on its contention that Respondents violated 21 CFR 1306.04(a) because the prescriptions were issued under an expired registration. In *Novicki,* the D.C. Circuit looked to the Restatement (Second) of Agency (1958) and the Restatement (Second) of Torts (1965) to give meaning to the term. *See id.* (quoting Restatement (Second) of Agency § 9 cmt. d (1958) and citing Restatement (Second) of Torts § 12(1)). As the Restatement of Agency explains,

A person has reason to know of a fact if he has information from which a person of ordinary intelligence, or of the superior intelligence which such person may have, would infer that the fact in question exists or that there is such a substantial chance of its existence that, if exercising reasonable care with reference to the matter in question, his action would be predicated upon the assumption of its possible existence. The inference drawn need not be that the fact exists; it is sufficient that the likelihood of its existence is so great that a person of ordinary intelligence, or of the superior intelligence which the person in question has, would, if exercising ordinary prudence under the circumstances, govern his conduct as if the fact existed, until he could ascertain its existence or non-existence. . . . A person of superior intelligence or training has reason to know a fact if a person with his mental capacity and attainments would draw such an inference from the facts know to him. On the other hand, ''reason to know'' imports no duty to ascertain facts not to be deduced as inferences from facts already known; one has reason to know a fact only if a reasonable person in his position would infer such fact from other facts already known to him.

Restatement (Second) of Agency § 9 cmt. d (1958); *see also* Restatement (Second) of Torts § 12, cmt. a (''Reason to know' means that the actor has knowledge of facts from which a reasonable man of ordinary intelligence or one of the superior intelligence of the actor would either infer the existence of the fact in question or would regard its existence as so highly probable that his conduct would be predicated upon the assumption that the fact did exist.'').

Because he is a licensed pharmacist (as are presumably his other pharmacists), Mr. Moro-Perez is a ''person of superior intelligence or training.'' Thus, it would be appropriate to consider whether a person possessing the mental capacity and attainments of Mr. Moro-Perez and his pharmacists would, based on the knowledge that Dr. Aguilar was issuing prescriptions which lacked a legitimate medical purpose, draw the further inference that he was no longer registered. Here again, because the Government did not sponsor any expert testimony, there is no evidence as to whether, based on the prescriptions that he/she was rejecting, a reasonable pharmacist would have inferred that Aguilar was not registered or would have regarded the existence of this fact ''as so highly probable'' that he would have refused to dispense the prescriptions.

[25] I also do not adopt the ALJ's discussion in the Recommendation section of his decision regarding the egregiousness of Respondents' conduct in filling the Aguilar prescriptions and the Agency's interest in deterring similar misconduct. Nor do I adopt the ALJ's discussion rejecting Respondents' arguments which were offered in mitigation of this violation.

misunderstanding is simply not credible and defeats the Respondents' efforts to meet the Government's case''). Accordingly, I will deny each Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of JM Pharmacy Group Inc., d/b/a Farmacia Nueva, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. I further order that the application of Best Pharma Corp, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This Order is effective immediately.

Dated: April 29, 2015.

Michele M. Leonhart,

Administrator.

Anthony Yim, Esq., for the Government.
Vladimir Mihailovich, Esq., for the Respondent.

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Chief Administrative Law Judge John J. Mulrooney, II. On June 19, 2013, the Deputy-Assistant Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause (OSC) proposing to deny applications for two DEA Certificates of Registration (COR) submitted on behalf of two pharmacies [1] (collectively, the Respondents). In its OSC and its prehearing statements, the Government avers that the applications should be denied because they were submitted with material falsifications,[2] and because granting the applications would be inconsistent with the public interest as that term is defined under the Controlled Substances Act (CSA). 21 U.S.C. 823(f) (2006). On July 18, 2013, the Respondents, through counsel, filed a timely request for hearing, which was conducted in Arlington, Virginia, on September 3, 2013.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that the Respondents' applications for registrations with the DEA should be denied on the grounds alleged by the Government.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

In its OSC,[3] the Government alleges that the COR applications filed on behalf of both registrants should be denied as contrary to the public interest.[4] In its subsequently filed Prehearing Statement,[5] the Government supplemented its theory in support of denial with additional allegations that the COR applications filed on behalf of each Respondent contained material falsifications [6] in that each application stated that the respective registrant had never surrendered a COR for cause, when, in fact, both had.

In support of the denial it seeks regarding an application for a COR filed by JM Pharmacy Corp., d/b/a Farmacia Nueva (Farmacia Nueva or FN), based on the public interest, the Government avers that this Respondent: (1) ''filled approximately 160 prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration in violation of'' 21 U.S.C. 843(a)(2) and 21 CFR 1306.04 (2013); and (2) ''failed to keep records of approximately twenty-seven (27) prescriptions for controlled substances'' from November 2009 through November 2011 in violation of 21 U.S.C. 827(b)(1) and 21 CFR 1304.04.[7]

The Government alleges that the granting of the COR application filed by Best Pharma Corp. (Best Pharma or BP) is inconsistent with the public interest in that this Respondent: (1) ''filled approximately thirty-two (32) prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration, in violation of'' 21 U.S.C. 843(a)(2) and 21 CFR 1306.04; and (2) ''failed to keep records of approximately seven (7) prescriptions for controlled substances'' from November 2009 through November 2011 in violation of 21 U.S.C. 827(b)(1) and 21 CFR 1304.04.[8]

Additionally, the Government alleges that both Farmacia Nueva and Best Pharma ''materially falsified'' their applications for DEA CORs.[9]

The Stipulations of Fact

The Government and the Respondents, through counsel, have entered into stipulations [10] regarding the following matters:

1) The owner of Farmacia Nueva and Best Pharma is Mr. Julio E. Moro-Perez (Moro-Perez).

2) Farmacia Nueva previously held DEA COR BF9534187 as a retail pharmacy in Schedules II–V.

3) Best Pharma previously held DEA COR FB1971565 as a retail pharmacy in Schedules II–V.

4) Neither Farmacia Nueva nor Best Pharma currently possesses a DEA COR.

5) On October 10, 2012, Moro-Perez applied on behalf of Farmacia Nueva for a DEA COR as a retail pharmacy in Schedules II–V at URB Raholisa #3, San Sebastian, Puerto Rico 00685.

6) On October 10, 2012, Moro-Perez applied on behalf of Best Pharma for a DEA COR as a retail pharmacy in Schedules II–V at Carr 111 KM 5.2 Bo. Pueblo, Ave La Moca 300, Moca, Puerto Rico 00685.

7) A COR previously issued to Dr. Hector J. Aguilar-Amieva, M.D. (Dr. Aguilar) was retired by DEA on January 31, 2009.

8) A criminal case against Moro-Perez, case no. 3:11–CR–00532–006, was dismissed with prejudice by the United States District Court for the District of Puerto Rico on March 23, 2012, upon petition from the United States Attorney's Office for the District of Puerto Rico.[11]

The Evidence

The Government's Evidence

The Government's case-in-chief rested on the testimony of four witnesses: DEA Diversion Investigator (DI) Ghensy Antoine, DEA Digital Forensic Examiner (DFE) Amy L. Herrmann, DI George Taylor, and Moro-Perez, the owner/president of Farmacia Nueva and Best Pharma.

DI Ghensy Antoine testified that in the course of his duties as a DI in the Ponce, Puerto Rico DEA field office, he was assigned as the lead investigator for the COR applications filed by Moro-Perez on behalf of the Respondents. Tr. 13–14, 76. Antoine explained that these COR applications were designated for investigation because the Respondents had a history of ''some issues with some minor violations.'' Tr. 15. Specifically, regarding Farmacia Nueva, Antoine stated that his application [12] investigation preliminarily revealed that on

[1] The two registrants were jointly captioned on a single OSC, and neither party petitioned for severance.

[2] 21 U.S.C. 824(a)(1) (2006) (providing a statutory basis for discretionary revocation).

[3] ALJ Ex. 1.

[4] 21 U.S.C. 824(a)(4).

[5] ALJ Ex. 4.

[6] 21 U.S.C. 824(a)(1).

[7] ALJ Ex. 1, at 2.

[8] *Id.*

[9] ALJ Ex. 8, at 1.

[10] On August 28, 2013 (three business days prior to the commencement of the hearing in this matter), a telephonic status conference (Status Conference) was conducted with the parties, wherein, *inter alia,* the Government concurred with Best Pharma's position that several prescription events initially alleged by the Government as involving controlled substances actually described substances that were not controlled. The next day, the Government filed a document styled ''Joint Stipulations'' (Joint Stipulations) wherein the parties mutually agreed to the substitution of previously-noticed versions of Proposed Government Exhibits 7(ID) and 12(ID), and stipulated that six prescription events purportedly detailed in Proposed Government Exibit 7(ID) and one prescription event purportedly detailed in Proposed Government Exhibit 12(ID) do not refer to controlled substances. ALJ Ex. 11. Notwithstanding the purported exhibit substitution set forth in the Joint Stipulations, at the hearing, the Government (errantly) represented that it had withdrawn Proposed Government Exhibit 12(ID). Tr. 97–98. Regrettably, the record is further confounded by the fact that none of the seven non-controlled prescription events referenced in the Joint Stipulations are depicted in the substituted Government Exhibits 7 or 12(ID). The parties also agreed to forego objections to numerous proposed exhibits. ALJ Ex. 11.

[11] The parties stipulated to this after the issuance of the Prehearing Ruling in this matter. The Respondents, through counsel, telephonically communicated their assent to this stipulation on August 26, 2013, the business day after the Government proposed it in its Supplemental Prehearing Statement. ALJ Ex. 8.

[12] Farmacia Nueva's COR application was received into the record. Gov't Ex. 1.

November 30, 2011, the pharmacy had been the subject of a DEA-executed federal criminal search warrant,[13] which resulted in an immediate suspension order.[14] Tr. 14, 16. DI Antoine testified that he learned that, between January 30, 2009 and November 30, 2011, Farmacia Nueva had dispensed 143 controlled substances [15] based on prescription scrips issued by Dr. Aguilar,[16] and that, during that period of time, Dr. Aguilar did not possess a valid COR. Tr. 17–18. DI Antoine stated that Dr. Aguilar's registration number had been retired by DEA since January 31, 2009, following an investigation and a federal criminal conviction, and that the status of his COR would have been uploaded to the DEA Diversion Web site on the date it was retired. Tr. 53–55. According to DI Antoine, there were multiple, readily-available means for Farmacia Nueva personnel to have ascertained that Dr. Aguilar lacked federal authorization to prescribe controlled substances at the time the prescriptions were filled. Tr. 20. Antoine related that Farmacia Nueva personnel could have checked Dr. Aguilar's COR status by accessing a link that is ''clearly visible'' [17] on the DEA Diversion Web site,[18] by consulting a list of registrants updated regularly by the Department of Commerce, by contacting the local DEA field office directly, or by contracting with a private company. Tr. 20–21.

Antoine testified that he also learned that, in 2008, DEA had issued a letter admonishing Farmacia Nueva ''for failure to comply with federal requirements of the [CSA]'' (Letter of Admonition). Tr. 19. The Letter of Admonition, which was received into evidence,[19] presents as having been sent on April 3, 2008, from the DEA Caribbean Division to Moro-Perez regarding Farmacia Nueva and, on its face, purports to have been sent via certified mail. Gov't Ex. 3. The Letter of Admonition informs Moro-Perez that DEA investigators discovered numerous record-keeping discrepancies during a March 2008 investigation, *to wit:* (1) Failure to take a biennial inventory; (2) failure to record on DEA Form 222 the number of containers received and date on which such containers were received; (3) failure to record the date of receipt of controlled substances on commercial invoices; and (4) failure to submit DEA Form 41. *Id.* Each noticed violation is accompanied by a corresponding statutory and/or regulatory basis. *Id.* Although the Letter of Admonition directs Farmacia Nueva to ''[p]lease advise this office in writing within thirty (30) days, the action taken or planned, to correct [the listed] violations,'' Antoine testified that, although DEA has no record of any further correspondence related to this admonition, the matter was closed without further action. Tr. 82–86.

On the issue of Farmacia Nueva's records, DI Antoine testified that he was furnished with data from the pharmacy's computer and hard copies of prescriptions seized from Farmacia Nueva at the time of a November 30, 2011 search warrant execution. Tr. 23–24. Although Antoine's testimony was by no means a model of clarity, it appears that when the DI compared the Dr. Aguilar-authorized controlled substance dispensing events in the computer data with copies of the seized hard-copy scrips, he was unable to match twenty-two dispensing events in the data with corresponding hard-copy scrips. Tr. 23–25, 91. Antoine added that, in the course of his investigation, he also sent Moro-Perez a January 30, 2013 letter (Administrative Request for Information), over the signature of his DEA supervisor, requesting ''[c]opies of [p]rescriptions issued by [Dr. Aguilar] within the period of January 31, 2009 to November 30, 2011, including any information related to the dispensing of such prescriptions.'' Tr. 31–33; Gov't Ex. 4. Moro-Perez responded to the Administrative Request for Information in a letter,[20] dated March 4, 2013 (Response to Administrative Request for Information), which included copies of additional prescription scrips. Tr. 36. The Response to Administrative Request for Information represented that ''all of the requested prescriptions'' were included with the correspondence. Gov't Ex. 4, at 3. DI Antoine presented a document (Government FN Aguilar Scrips) that he described as copies [21] of controlled substance scrips obtained by the search warrant and later supplemented by Moro-Perez in the Response to Administrative Request for Information. Tr. 36–39; Gov't Ex. 5. Antoine testified that when he compared the Aguilar dispensing events recorded in the Farmacia Nueva computer data (FN Computer Data) to the Government FN Aguilar Scrips, he was unable to locate twenty-two Aguilar scrips that, based on the FN Computer Data, should have been there. Tr. 48. Antoine testified that he used a sorting function to create a spreadsheet from the FN Computer Data that listed every transaction from the scrips contained in the Government FN Aguilar Scrips package, or as he put it, ''exactly a mirror of what's included [in the Government FN Aguilar Scrips].'' Tr. 44–47; Gov't Ex. 6. Thus, the spreadsheet (Government FN Aguilar Scrips Spreadsheet) [22] contains every dispensing event transaction depicted in the Government FN Aguilar Scrips [23] document created by the seized scrips and supplemented by Moro-Perez pursuant to the Request for Information. DI Antoine testified that he used the sorting feature to tease out the dispensing events in the Government FN Computer Data that did not have a corresponding scrip in the Government FN Aguilar Scrips and made a spreadsheet (Government FN Aguilar No-Scrip List).[24]

[13] From the outset of the Government's case as detailed in the OSC and its Prehearing Statement, the Government signaled its intention to rely upon a theory of incomplete recordkeeping at Farmacia Nueva, and made known that its case in this regard would be principally established by an evaluation of records seized during the course of a search warrant executed at the pharmacy on November 30, 2011 and supplemented by an administrative request for information. ALJ Exs. 1, 4, at 4. Although it could hardly be a surprise that details surrounding the adequacy of the execution of the Farmacia Nueva search warrant could be an issue, instead of presenting testimony from anyone present when the warrant was executed, the Government elected to present hearsay testimony about the details of the operation from only DI Antoine, who was not present during the execution. Tr. 113–18. Over Respondents' timely (and ultimately correct) objection, the Government elicited details of conversations that occurred between DI Antoine and DIs Rosa Smith and Jose Rodriguez, who apparently were present at Farmacia Nueva when the search warrant was executed. DI Antoine was not certain about when the conversation(s) took place. Tr. 119–20; *see also* ALJ Ex. 24, at 7 n.1. The Government offered no indication that DIs or other personnel present at the search warrant execution were in any way unavailable and tendered no indicia of reliability that would merit consideration of this hearsay testimony in support of a substantial evidence finding. *See Mireille Lalanne, M.D.,* 78 FR 47750, 44752 (2013) (holding that the proponent of a hearsay statement in DEA administrative proceedings bears the burden to demonstrate sufficient reliability to warrant consideration as substantial evidence); *see also Kevin Dennis, M.D.,* 78 FR 52787, 52796 (2013) (''[H]earsay may be substantial evidence depending on its truthfulness, reasonableness, and credibility; hearsay statements are highly probative where declarants are disinterested witnesses, statements are essentially consistent, and counsel had access to the statements prior to the agency hearing.''). DEA applies the law in the relevant Circuit. *Lalanne,* 78 FR at 47751 & n.4. Precedent in the applicable Circuits are in accord. *Echostar Commc'ns Corp.* v. *FCC,* 292 F.3d 749, 753 (D.C. Cir. 2002) (holding that hearsay evidence at an administrative hearing may be used to support substantial evidence finding where it bears sufficient indicia of reliability and is reliable and trustworthy); *Hoska* v. *U.S. Dep't of the Army,* 677 F.2d 131, 138 (D.C. Cir. 1982) (holding that hearsay statements admitted at an administrative hearing that were tested for reliability and found wanting were thus insufficient to support a substantial evidence finding); *NLRB* v. *Serv. Wood Heel Co.,* 124 F.2d 470, 472 (1st Cir. 1941) (finding hearsay evidence adduced at an administrative hearing sufficiently trustworthy to be considered in a substantial evidence finding where corroborated and consistent with attendant circumstances). Inasmuch as the Government did not even attempt to demonstrate any indicia of reliability regarding the hearsay statements from DIs Smith and Rodriguez received through DI Antoine, those statements cannot be properly considered here, and were not considered in support of substantial evidence.

[14] An indictment issued against Moro-Perez was ultimately dismissed with prejudice. Stip. 8; Tr. 76–77.

[15] Tr. 78.

[16] DI Antoine testified that documentary references to Dr. Aguilar and Dr. Hector Aquilar refer to the same individual. Tr. 19.

[17] Tr. 87–89.

[18] DI Antoine testified that he was unable to recall the name of the database, but was sure that it was free and available to registrants and accessible as a link on the DEA Diversion Web site and that it has been up and running continuously since 2008. Tr. 21–22. A registrant must sign into the system to review the available information. *Id.*

[19] Tr. 34.

[20] The Government presented a copy of the Response to the Administrative Request for Information in a translated format as well as a copy of the original Spanish-language version. Gov't Ex. 4, at 2–3.

[21] DI Antoine testified that hard-copy scrips seized from Farmacia Nueva during the execution of the search warrant were photocopied. Tr. 37.

[22] Gov't Ex. 6.

[23] Gov't Ex. 5.

[24] Although not explained during the course of the hearing, the three pages that comprise the Government FN Aguilar No-Scrip List must be placed side-by-side and read across. Gov't Ex. 7. Needless to say, this format is not optimal.

Gov't Ex. 7. Thus, the Government FN Aguilar No-Scrip List reflects twenty-four [25] Aguilar-authorized controlled substance dispensing events at Farmacia Nueva where the combined efforts of DI Antoine's seized records and Moro-Perez's supplemented records still did not yield a copy of a scrip.

DI Antoine testified that he also conducted the COR application [26] investigation of Best Pharma. Tr. 52. According to Antoine, Best Pharma was also the subject of an executed criminal search warrant on November 30, 2011, and prescription scrips were likewise seized from its pharmacy, scanned into DEA computers, and returned. Tr. 50, 52, 60–61; Gov't Ex. 10. As was the case at Farmacia Nueva, data from the Best Pharma computers was extracted by DEA, and the data was queried by DI Antoine to yield controlled substance dispensing events on scrips authorized by Dr. Aguilar from the time his COR was retired up to and including the date the search warrant was executed. Tr. 65–69; Gov't Ex. 11. Antoine testified that an examination of the seized documents revealed that, like Farmacia Nueva, Best Pharma dispensed controlled substances on prescriptions issued by Dr. Aguilar during a time when the doctor did not possess a COR. Tr. 52–53. In his testimony, DI Antoine re-affirmed the aforementioned methods that Best Pharma staff members had at their disposal to ascertain Dr. Aguilar's COR status. Tr. 55.

Antoine also indicated that when he compared the Best Pharma computer-stored dispensing events with the controlled substance prescription scrips seized in connection with the search warrant, he was unable to identify ''four or five'' scrips that corresponded to dispensing events. Tr. 96.

Government-supplied declarations from the DEA Registration and Program Support Section Chief reflect that a COR was issued to Farmacia Nueva in 2005 and to Best Pharma in 2010. Gov't Exs. 2, 9. The DEA Best Pharma Declaration indicates that Best Pharma surrendered its COR for cause on December 14, 2011. Gov't Ex. 9. The Government also submitted a DEA Form 104 (Best Pharma Surrender Form) that indicates that Moro-Perez executed a voluntary surrender for cause on November 30, 2011.[27] Gov't Ex. 14, at 1. On the Best Pharma Surrender Form, Moro-Perez signed below a checked box, which provides: ''In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part . . . I hereby voluntarily surrender my Drug Enforcement Administration Certificate of Registration. . . .'' *Id.*

The DEA Farmacia Nueva Declaration states that Farmacia Nueva surrendered its COR for cause on June 28, 2012. Gov't Ex. 2, at 2. Also offered in support of the proposition that Farmacia Nueva surrendered for cause in 2012 was a copy of what purports to be email correspondence (printed out under DI Antoine's email header) between the Respondents' present counsel and an individual to whom counsel was seeking to surrender its COR. Gov't Ex. 14, at 2–4. Although the Government presented no explanation or context regarding the email traffic or any witness testimony regarding the participants, the exhibit (which was received in the absence of objection), on its face, includes this unambiguous statement:

> My client, Farmacia Nueva, has decided to voluntarily surrender its DEA registration at issue in the case Docket No. 12–16. Please prepare a joint motion to dismiss the pending case.

Id. at 2. Official notice is taken that the same Respondents captioned in this matter were also the subject of DEA administrative proceedings under Docket Number 2012–16 (Case 2012–16), an action that was commenced with a request for hearing filed on December 6, 2011, and which culminated in a termination order dated June 29, 2012.[28] Further notice is taken that the records of the Agency reflect that the recipient of the email served as the Government counsel of record in Case 2012–16. DEA has no record of a DEA Form 104 executed on behalf of Farmacia Nueva, but Antoine testified that it is his understanding that the email surrender occurred while the case was in active administrative enforcement proceedings. Tr. 72–74. In his testimony, DI Antoine explained that while it is his ''practice [to] always get a [DEA Form] 104,'' and that he has procured a DEA Form 104 in all but one case where he has accepted a registrant's surrender for cause, it was his understanding of the law that the email correspondence offered by the Government in this case was sufficient to memorialize the event. Tr. 73–74.

DI Antoine stated that he visited Farmacia Nueva and Best Pharma on August 14, 2013 (twenty days prior to the commencement of the hearing in this matter), and spoke with Nelson Vale and Miriam Castro Andujar, the respective pharmacists-in-charge (PICs).[29] Tr. 106–11. According to Antoine, in response to his query of them on the subject, both PICs indicated that they were aware of no written procedures issued for their respective pharmacies on the subject of the handling of controlled substances. Tr. 107. The PICs did, however, relate to DI Antoine that they believed that the owner planned to install a computer monitor in each pharmacy to facilitate some measure of access to verify the COR status of prescribing practitioners, and that there was also a plan to check prescriber statuses once per month. Tr. 112. PIC Castro told Antoine that she had recommendations for the handling of controlled substances that she would like to make to the pharmacy owner. *Id.*

DI Antoine's testimony was, at times, difficult to understand and not always clear. That said, his testimony was sufficiently detailed, plausible, and internally consistent to be deemed credible in this recommended decision.

The Government also presented the testimony of DFE Amy Herrmann, a digital forensic examiner employed by DEA. DFE Herrmann has been a DFE at the DEA Digital Evidence Laboratory since March 2008, and holds degrees in Information Technology, Network Security-Computer Forensics, and Financial Services. Tr. 122–25; Gov't Ex. 13. DFE Herrmann is certified as a Global Information Assurance Forensic Examiner and as an Information Systems Security Professional. Gov't Ex. 13. In the absence of objection, DFE Herrmann was accepted as an expert in the field of digital forensics.[30] Tr. 126.

DFE Herrmann stated that she was assigned to the investigations concerning the Respondent pharmacies that were conducted in November 2011. *Id.* She explained that another DFE who works in her office, Ryan Gladieux,[31] extracted the information from the Farmacia Nueva computer by imaging the computer to a wiped and sterile DEA hard drive. Tr. 128–29. Herrmann testified that the

[25] Although DI Antoine described twenty-two Aguilar dispensing events without corresponding scrip copies, the Government FN Aguilar No-Scrip List sets forth twenty-four dispensing events. *Id.* While no explanation regarding this disparity was offered at the hearing, the extra two entries appear to be refills of previously-filled prescriptions. In any event, the variance, whatever its genesis, was inconsequential to the resolution of the ultimate issues presented in this case.

[26] The Best Pharma COR application was received into the record. Gov't Ex. 8.

[27] Although no explanation has been tendered to explain this disparity, the anomaly does not impact any issue dispositive to a resolution of the ultimate issues in this case.

[28] The Administrative Procedure Act and the DEA regulations authorize the identification, recognition, and inclusion of material facts in the administrative record by the taking of official notice. 5 U.S.C. 556(e); 21 CFR 1316.59(e); *Attorney General's Manual on the Administrative Procedure Act* § 7(d) (1947). To the extent either party seeks to challenge the factual predicate of the official notice taken in this matter, it may file an appropriate motion no later than fifteen days from the issuance of this recommended decision.

[29] *See* Fed. R. Evid. 801(d)(2)(E).

[30] DFE Herrmann's CV was received into the record. Gov't Ex. 13.

[31] During the Direct Examination of DFE Herrmann, the Government offered into evidence a declaration from DFE Ryan Gladieux. Tr. 133–37; Gov't Ex. 15. In his declaration, Gladieux states that he made complete copies of the hard drives seized during the investigations of Farmacia Nueva and Best Pharma on November 30, 2011. Gov't Ex. 15. Gladieux declares that the copies of the hard drives are complete and accurate. *Id.* In objecting to the admission of the declaration, the Respondents raised the (fair) point that in contrast to the declarant, who had actual knowledge as to how the evidence was extracted, DFE Herrmann, ''has testified only to the things she has heard from someone that that happened.'' Tr. 135–36; *see also* Tr. 149–50. In explaining its election to present a declaration in lieu of testimony from Gladieux, the Government acknowledged that Gladieux was available, but stated ''[t]he reason was that the [G]overnment felt that a declaration would have been sufficient insofar as that it was properly noticed in the prehearing statement and that an indicia of reliability would have been given during this hearing [sic].'' Tr. 135. Regarding the Government's proposed transcript errata correction (ALJ Ex. 20, at 2) in this regard, the version set forth in the official transcript is consistent with my recollection. Gladieux's declaration was received into the record over the Respondents' hearsay objection, and although all parties were granted leave to present his live testimony, none did. Tr. 136. As explained more fully, *infra,* the Respondents' objection more correctly reflected on the weight to be afforded the content of the exhibit than it did on the document's admissibility.

technique employed by Gladieux[32] for imaging the computer makes a complete copy of all data contained therein and provides an alert to indicate if certain files are unreadable.[33] Tr. 139–41. DFE Gladieux then provided the hard drive to the DEA office in Ponce where it was checked in as non-drug evidence. Tr. 131. From there it was forwarded to the DEA laboratory in Lorton, Virginia, and checked into the digital evidence vault. Tr. 122–23, 131. Herrmann stated that she then created a virtual machine with which to run Farmacia Nueva's RX30 program,[34] enabling her to access the program as if she were accessing it from Farmacia Nueva's own computer at the moment the data was extracted.[35] Tr. 141–42. Herrmann testified that she generated a report of all prescriptions dispensed by the pharmacy from January 1, 2009 to December 31, 2011, and converted the report into an Excel file. Tr. 142–43. According to Herrmann, she ran another report of the same data, but excluded any prescriptions that were noted as ''on hold'' (no-holds run). Tr. 143–44. The no-holds run generated fewer dispensing events than the first report, but she never attempted to run a report to isolate the dispensing events in the ''on hold'' status. Tr. 145–47. Some of the dispensing event transaction numbers in the no-holds run are preceded by the letter ''H.'' *See* Gov't Ex. 7. When Herrmann was queried about whether the ''H'' indicated that these events really were ''on hold,'' she conceded that she did not understand what the ''H'' meant and that she did not know why some transaction numbers bore that designator. Tr. 152–53, 161–62. Whatever ''H'' meant, DFE Herrmann testified that the report she ran on the data from the Farmacia Nueva computer excluded any dispensing event that was in an ''on hold'' status. Tr. 143–44, 151–52, 160–61.

DFE Herrmann testified that she used ''essentially the same steps''[36] employed on the Farmacia Nueva computer data to analyze the information extracted from Best Pharma's RX30 program. Tr. 147. Regarding those matters of which she did have first-hand knowledge, her testimony was sufficiently detailed, plausible, and internally consistent to be fully credited in this recommended decision.

George Taylor, a DI stationed at the DEA Des Moines Resident Office, was called as a witness for the Government regarding his role as the team leader in charge of executing the search warrant at Best Pharma on November 30, 2011. Tr. 168–69. DI Taylor testified that his team of seven to nine federal and local agents and analysts seized all prescription records, controlled substances, and other specific items listed on the warrant. Tr. 170, 172. DI Taylor stated that the search warrant team was assisted by a Best Pharma pharmacist[37] who directed them where to find the items listed on the warrant. Tr. 170. Controlled substances were seized and inventoried on the premises, and hard copies of controlled substance scrips and other records were collected and transported back to the staging area and then to the DEA Ponce Resident Office. Tr. 170–71, 187. Taylor testified that, with the guidance of the Best Pharma pharmacist (who he assessed as cooperative), it is his opinion that the team seized all controlled substance prescription scrips that were on hand at the pharmacy, including paperwork from the prescription counter. Tr. 186–88.

DI Taylor also testified that he was with Moro-Perez at the time the latter signed the Best Pharma Surrender Form. Tr. 175; Gov't Ex. 14, at 1. On November 30, 2011, DI Taylor, accompanied by DEA Special Agent Juan Hernandez, signed the form as a witness and presented it to Moro-Perez while the latter was in custody.[38] Tr. 175; Gov't Ex. 14, at 1. DI Taylor directed Special Agent Hernandez to explain, in Spanish, to Moro-Perez that the form was a voluntary surrender of his controlled substances privileges. Tr. 176, 184. Special Agent Hernandez also read the entire form to Moro-Perez in Spanish. Tr. 178. DI Taylor testified that Moro-Perez questioned him regarding the nature of the surrender and whether it was related to the criminal charges against him. Tr. 179. DI Taylor stated that he explained that the surrender specifically related to the DEA registration number and was separate from any criminal allegations, and he testified that he dealt only with the regulatory matter. DI Taylor explained to Moro-Perez that if he did not sign the form, the DEA would move for an OSC proceeding. Tr. 176–77. DI Taylor stated that in his conversations with Moro-Perez, he never linked the voluntary surrender to the ongoing criminal investigation. Tr. 177.

Moro-Perez also testified at the hearing.[39] He stated that he is the president and original owner of both Farmacia Nueva and Best Pharma. Tr. 192, 219, 222, 238. He stated that he has been a pharmacist since he completed his training at medical school in Puerto Rico in 1999, worked as a pharmacist at another pharmacy, and served as chief pharmacist at Farmacia Nueva. Tr. 194, 202, 223–24. He acknowledged that he had received training regarding the prevention of the unauthorized distribution of controlled substances, and that he learned in his training that the pharmacy is ''ultimately responsible for ensuring the integrity and the veracity of the prescription.'' Tr. 194. He also acknowledged that, from February 2009 to October 2011, both Respondent pharmacies filled prescriptions for (the un-registered) Dr. Aguilar. Tr. 193. Farmacia Nueva filled approximately 143 prescriptions, and Best Pharma filled approximately 32 prescriptions. *Id.* Moro-Perez conceded that at no point during that time period did any of the pharmacies attempt to verify the COR status of any of the doctors for whom they filled prescriptions. Tr. 194.

During the course of Moro-Perez's testimony, he described the physical layout and operational procedures utilized at the Respondent pharmacies. Regarding Farmacia Nueva, Moro-Perez explained that the three-story establishment is manned by twenty-two employees and that Nelson Vale is and has been the pharmacist-in-charge (PIC) since 2010. Tr. 224–25. According to Moro-Perez, Best Pharma is located in a two-story building with sixteen employees. Tr. 240–41. The departments in each store are divided between the various floors. Tr. 224, 240. Moro-Perez testified that his role as a pharmacist and company president requires that he ensure that every prescription has a regular and legal use; that all administrative duties are carried out; and that each prescription is dispatched faithfully to the patient as the doctor prescribed it. Tr. 226–27. He then explained the following procedure for when a patient enters the FN pharmacy with a prescription: The patient, first, turns in his prescription at the pharmacy's receiving area. Tr. 227. Next, a pharmacy employee verifies the prescription, the name on the prescription, the address of the patient, the date, the medication, the quantity to be dispatched, the instructions on how to use the medication, the doctor's signature, and, if it is a prescription for a controlled substance, the DEA license, the AMSSCA license,[40] and the state medical registration or license as found on the pharmacy's RX30 program. Tr. 227–28, 230. The employee then verifies if the prescription and medication are bioequivalent. Tr. 228. If the patient accepts the medication, the back of the prescription is stamped and signed, and then the patient signs the document to acknowledge acceptance of the exchange of medication. *Id.* Next, pharmacy personnel enter the patient's name, phone number, address, driver's license, and medical plan information into

[32] Herrmann acknowledged that she had no personal knowledge of exactly what Gladieux did and/or how well he did it beyond reading reports he prepared. Tr. 149–50.

[33] The imaged files copy each piece of data from the original, and a DEA program creates something called a ''hash'' for every file. Tr. 128. The hash is an algorithm that uniquely fits a piece of data and creates a certain value. Tr. 132. If a piece of data is altered in any way from the original data extracted from the computer, the hash value will change, notifying the DEA of the alteration. Tr. 132, 148. Herrmann testified that she verified that all hash values matched when she commenced her analysis of the data extracted from the computer. Tr. 133. Herrmann clarified that although error is always a possibility, the software she utilized is designed to alert the examiner if the reports generated do not match the amount of records contained in the data. Tr. 154–56.

[34] RX30 appears to be a software program that enables pharmacies to manage and record their dispensing events. Tr. 91, 138, 142.

[35] Herrmann acknowledged that the reports could have been run using Farmacia Nueva's computer instead of from an image of the data extracted from the computer. Tr. 163–65.

[36] There is no indication in the record why Herrmann characterized the steps as ''essentially'' the same.

[37] DI Taylor testified that a female Best Pharma pharmacist assisted his team in the execution of the search warrant, but he was unable to recall her name. Tr. 170.

[38] It is clear from DI Taylor's testimony that Moro-Perez was in custody in the rear of a government vehicle when he signed the Best Pharma Surrender Form. Tr. 179–83. The Respondents have raised no issue related to the voluntariness of the Surrender Form execution, and no genuine issue in this regard is supported by the record evidence.

[39] Although Moro-Perez was noticed as a witness by the Respondents, his testimony was elicited by the Government as part of its case-in-chief. Tr. 190–191, 268.

[40] Regrettably, neither side provided any additional details as to what this organization is, or what the letters stand for.

the RX30 system. Tr. 228–29. The prescription is then scanned, and the pharmacy enters the doctor's information. Tr. 229. The pharmacy staff verifies that all of the prescriber's information (including COR and license numbers) is found in the system, and enters the medication, including the amount to be dispensed and the dosage instructions. *Id.* After obtaining and entering all this information, the pharmacy staff submits the information to the appropriate insurance carrier, which will determine whether it will reimburse based on the information submitted. *Id.* The pharmacy staff then counts out the medication, puts it in a basket, and presents it to a pharmacist for verification. *Id.* Upon successful verification, the prescription is placed in dispatch, and the pharmacy contacts the patient who signs for the prescription, collects the medication, receives instructions on use, and pays any applicable deductible. Tr. 229–30.

Moro-Perez stated that Best Pharma uses the same process of dispensing prescriptions as Farmacia Nueva. Tr. 245. He testified that Farmacia Nueva dispenses 500 prescriptions per day, with controlled substances accounting for approximately 10–15% of those sales. Tr. 244–45. Best Pharma dispenses 200–300 prescriptions per day, with approximately 10–15% of those sales derived from controlled substances. Tr. 245.

Moro-Perez testified that, for prescriber COR verification, his Respondent pharmacies have relied upon a system of entering information into their internal computers, submitting the information to medical insurance providers through pharmacy software, and basing the assumption of up-to-date doctor licensing on the receipt of insurance provider ''confirmation'' [41] of payment approval. Tr. 195–96, 230–32. Moro-Perez represented that both pharmacies purchased the RX30 system for their computers from a company named Ontime Soft, Inc. Tr. 196–97, 244. Pharmacy staff inputted a list of prescribing doctors and the doctors' information into the program. Tr. 199–200. Moro-Perez then explained that, when a patient visits one of the pharmacies with a prescription, the following information is entered into the system and then transmitted to the insurance providers: the patient, the patient's information, the doctor's information, the medication, the amount of medication, the directions for using the medication, and the amount of days that the medication will be supplied. Tr. 201. Moro-Perez eventually admitted that the pharmacies' method of ensuring the validity of the prescribing doctors' DEA licenses was to check, prior to dispensing, that the insurance company was willing to reimburse based on the electronically-transmitted claim. Tr. 200–01. He even conceded that although this was the method they employed to verify the prescribers' registration status,[42] the insurance companies never represented that reliance upon the benefits claim determination was an appropriate method to check COR status.[43] Tr. 202. Moro-Perez stated that he does not know why the insurance companies kept reimbursing based on Dr. Aguilar's controlled substance prescriptions when he no longer had a COR, and he even agreed that the Respondent pharmacies would likely never have stopped dispensing (unregistered) Dr. Aguilar's prescriptions if the DEA had not executed its search warrant on November 30, 2011. Tr. 202–03. Moro-Perez acknowledged that the Respondents made a mistake and that they erred in not calling the DEA to verify Dr. Aguilar's COR. Tr. 201–02.

When questioned regarding the Government's list of purportedly missing prescriptions from Farmacia Nueva,[44] Moro-Perez insisted that, when he was told that the DEA identified those scrips as missing, he queried the system by medication name and was able to locate and identify all but one of the missing scrips in the Farmacia Nueva Computer and found a hard copy of the single missing (apparently unscanned) scrip in the pharmacy.[45] Tr. 203–05. Copies of the imaged Dr. Aguilar scrips he purportedly printed from the pharmacy computer and supplemented with the single hard-copy scrip were received into the record (Moro-Perez FN Aguilar Scrips). Resp't Exs. 1, 2. Also received into evidence was a package of imaged prescription scrips that Moro-Perez testified he produced by querying the dispensing event numbers corresponding to the Dr. Aguilar controlled substance scrips that DEA alleged as missing (Moro-Perez FN Aguilar Found Scrips).[46] Resp't Ex. 4; Tr. 263. The Moro-Perez FN Aguilar Found Scrips document contains nine scrips that, according to Moro-Perez, he was able to create by querying the Farmacia Nueva RX30 system with the dispensing event numbers that DEA told him they were unable to match with Government FN Aguilar Scrips.[47]

Although, in a prehearing motion,[48] Farmacia Nueva averred that multiple dispensing events set forth in the Government FN Aguilar No-Scrip List document were the result of typographical errors, an analysis of the documents does not bear this out. Both of the purportedly mistyped dispensing events (00735388 & 00784686) were actually supplied by the Respondent in the Moro-Perez FN Aguilar Found Scrips document.[49]

A detailed analysis of the dispensing event exhibits from both sides presents a nuanced and initially confusing picture that would have benefitted greatly from explanation at the hearing. An examination of the Moro-Perez FN Aguilar Scrips [50] and the Moro-Perez FN Aguilar Found Scrips [51] documents reveals that they contain all but two of the dispensing events depicted in the Government FN Aguilar No-Scrip List [52] that was created by DI Antoine.[53] This testimony was offered by Farmacia Nueva in support of its contention that Moro-Perez, with some level of diligence, was able to retrieve all of the scrips that DEA identified to him as missing.

One of the two unaccounted-for dispensing events bears a dispensing event number preceded by an ''H'' (H00751567). Gov't Ex. 7. No witness who testified at the hearing explained the significance of an ''H'' affixed to a dispensing event number, but since a second ''H''-designated number (H00784094) was eventually paired with a scrip [54] by Moro-Perez, it seems unlikely that the ''H'' presents a reasonable explanation for the scrip's absence. DFE Herrmann testified that ''hold'' was a status setting available within the RX30 software structure, but she did not

[41] The witness never made clear what information was actually being transmitted or confirmed in the ''confirmation.''

[42] Moro-Perez also said that pharmacy staff checked prescriber licenses in the RX30 system. Tr. 230–31. However, since the pharmacies' internal systems were only updated by pharmacy staff, who relied exclusively on payment approvals from insurance companies, this step added little to the aggregate safeguards in place.

[43] Actually, the record contains no evidence that would objectively support a decision to rely on this approach or even support a conclusion that this method would be an effective manner to garner this information.

[44] Gov't Ex. 7.

[45] The supplemented scrip was identified by Moro-Perez as page 143 of Respondents Exhibit 2. According to Moro-Perez, the computer automatically affixes identifier information at the top of each prescription image it produces. Tr. 235. The scrip that Moro-Perez added to the package does not have the identifier heading on it. Resp't Ex. 2, at 143.

[46] The witness testified that the first five pages of the package contain Best Pharma scrips (identified by 5-digit dispensing event numbers) and the balance reflects Farmacia Nueva scrips (identified by 6-digit dispensing event numbers). Tr. 260–65.

[47] However, only two of the nine scrips (Resp't Ex. 4, at 191, 192) contained in the Moro-Perez FN Aguilar Found Scrips document correspond to Aguilar Farmacia Nueva dispensing events listed by the Government as missing scrips in its Government FN Aguilar No-Scrip List. Gov't Ex. 7. This is likely the result of a pre-hearing motion submitted by the Respondents (ALJ Ex. 10) wherein they pointed out that numerous scrips noticed by the Government (apparently including seven of the nine FN scrips contained in the Moro-Perez FN Aguilar Found Scrips document (Resp't Ex. 4, at 184–90)) refer to non-controlled substances. As a result of the Respondents' motion, the Government substituted the current version of Government Exhibit 7, which evidently omits reference to the non-controlled substances.

[48] ALJ Ex. 10, at 2. In their motion, the Respondents represented that when the typographical errors are factored into the equation, ''no prescription is missing.'' *Id.* at 3.

[49] Resp't Ex. 4, at 191, 192.

[50] Resp't Ex. 1–2.

[51] Resp't Ex. 4.

[52] Gov't Ex. 7.

[53] The following is a list of each entry found in the Government FN Aguilar No-Scrip List (Gov't Ex. 7), which listed the prescriptions missing from Farmacia Nueva. After each listed prescription event number entry, a corresponding citation to where that prescription can be found in the Respondents' exhibits (if at all) is provided: #00581227: Resp't Ex. 2, at 165; #00592053: Resp't Ex. 2, at 167; #00594763: Resp't Ex. 2, at 168; #00603582: Resp't Ex. 2, at 169; #00615341: Resp't Ex. 2, at 170; #00680204: Resp't Ex. 2, at 143–44; #00696609: Resp't Ex. 1, at 49; #00735388: Resp't Exs. 1, at 52, 4, at 191; #00739096: Resp't Ex. 1, at 28; #00740774: Resp't Ex. 1, at 29; #00748164: Resp't Ex. 1, at 31; #00750564: Resp't Ex. 1, at 92; #H00751567: no record; #00760079: Resp't Ex. 1, at 93; #00760079: Resp't Ex. 1, at 93; #00784105: Resp't Ex. 2, at 123; #00784686: Resp't Ex. 4, at 192; #00785359: Resp't Ex. 2, at 124; #00785837: Resp't Ex. 2, at 125; #00785837: Resp't Ex. 2, at 125; #00798150: Resp't Ex. 2, at 126; #00805523: no record; #00806899: Resp't Ex. 2, at 127; #H00784094: Resp't Ex. 4, at 190.

[54] Resp't Ex. 4, at 190.

know what it signified. Tr. 144–46. Moro-Perez likewise offered no explanations about the significance of an ''H'' before a dispensing event number, or ''hold'' status.[55] The second missing dispensing event (00805523) was never matched up with a corresponding scrip.

Moro-Perez testified that DEA personnel left the Respondent pharmacies in considerable disarray after the simultaneous execution of the search warrants, and that the agents left ''a lot of controlled [substance] prescriptions'' in drawers at ''both pharmacies.'' Tr. 243–44. At the hearing, when Moro-Perez was shown the Government's Administrative Request for Information to Farmacia Nueva[56] in which DEA requested the pharmacy to supply copies of all prescriptions issued by Dr. Aguilar during the period in question and dispensed by the pharmacy, he responded that he ''provided [DEA] everything that the system provided and all the prescriptions were submitted.'' Tr. 206–08.

Moro-Perez explained that RX30 creates a separate number for each dispensing event, and that once that number is created, it cannot be altered or manipulated manually.[57] Tr. 235. He offered his assurance that he has not nor would ever attempt to do so. *Id.* Moro-Perez indicated that Farmacia Nueva has had the same computer for about five years and that it has never left the pharmacy except for when the DEA took possession of it for about five days at the time the search warrant was executed. Tr. 232–33. Best Pharma's computers have also been in the business since it opened, and inasmuch as DEA extracted data from them on the date of the search warrant execution, these computers have never left the pharmacy. Tr. 242.

Moro-Perez testified that Farmacia Nueva dispensed approximately two to three prescriptions authorized by Dr. Aguilar every two weeks and that there was sometimes a few months between prescriptions. Tr. 250. He also explained that Farmacia Nueva was about a three-to-four minute walk from Dr. Aguilar's office.[58] Tr. 250–51. Stunningly, Moro-Perez testified that personnel at Farmacia Nueva ''many times'' declined to fill controlled substance prescriptions authorized by Dr. Aguilar because they were deemed illegitimate. Tr. 252. Moro-Perez explained that, quite often, ''many'' patients brought controlled substance prescriptions issued by Dr. Aguilar where the Farmacia Nueva pharmacists ''knew that that patient didn't require the use of that medication [and] we told them that we were not going to dispense the prescription.'' *Id.* Notwithstanding the close proximity of Dr. Aguilar's practice to Farmacia Nueva (three to four minutes on foot), and the frequency with which the pharmacy declined to dispense controlled substances he prescribed, Moro-Perez provided the astonishing revelation that he never contacted Dr. Aguilar about any of his (bad) prescriptions. Tr. 252–54. When pressed as to why Dr. Aguilar's routine prescribing misconduct did not arouse any heightened scrutiny on the part of his pharmacies, Moro-Perez offered that ''if you analyze the amount of medications that were dispensed, the percentage is very low.'' Tr. 253. In other words, the Respondents knew Dr. Aguilar was regularly providing illegal controlled substance prescriptions to Respondents' customers, but no one on staff checked his registration in any serious way or even took the minimal step of reaching out to speak with him about his prescribing practices because ''the percentage [was] very low.'' *Id.* Moro-Perez stated that he never contacted Dr. Aguilar because ''I was aware that the doctor's license was up to date.'' Tr. 253–54. In addition to the fact that Dr. Aguilar was not, in fact, ''up to date'' on his DEA registration, Moro-Perez's answer is patently illogical and presents as intentional equivocation.

At the hearing, Moro-Perez identified a printed copy of the online registration application that he submitted on behalf of Farmacia Nueva. Tr. 210; Gov't Ex. 1; *see also* Stip. 5. He confirmed that he understood the application and Question 2 (asking whether the applicant had ever surrendered a COR for cause), agreed that he entered a ''no'' response, and explained that his reason for doing so was because he understood that, ''in relation to the criminal case, there was no cause against me.''[59] Tr. 211. Moro-Perez conceded that no one from DEA told him that his former criminal case (which was actually dismissed three months prior to the surrender) was linked in any way to the surrender,[60] but he insisted that he believed that Farmacia Nueva's surrender was associated with his criminal case because ''all this is a consequence of the dispatch of the medications of Dr. Aguilar.'' Tr. 212–13. The witness persisted in this answer, even when pressed by the Government about how he could think that the nature of the Farmacia Nueva surrender could be affected by an event (the indictment dismissal) that preceded it. Tr. 212–13, 215. In response to a question asked by the Government, Moro-Perez responded that if Question 2 did not contain the words ''for cause,'' he would have answered ''yes'' to the question. Tr. 216–17, 219. Moro-Perez explained that he never wanted to lie to DEA because ''[t]hey are aware of the arrest that they executed.'' Tr. 216. Later in his testimony, Moro-Perez offered this:

> Really in relation to this particular case I'll repeat again. I answered no knowing and recognizing that you, the DEA office, are aware of, had knowledge and everything about me. Therefore, I have never had intentions [sic] to lie. I'm going to say the truth, and that's the truth.

Tr. 218–19. Moro-Perez clarified that the rationale he used for answering Question 2 in the negative on the Farmacia Nueva application was the same approach employed by him when answering the same question in the Best Pharma application. Tr. 222.

Although Moro-Perez acknowledged at the hearing that Question 2 was erroneously answered,[61] he expressed no remorse. In like manner, he stood by his ability to retrieve required records from the Respondent pharmacies' computers and questioned the thoroughness of DEA's search warrant execution, *see* Tr. 243–44. On the other hand, he readily accepted that the procedure previously employed for ensuring that controlled-substance prescribers had valid CORs was a ''mistake.'' Tr. 236. He offered that if the Respondent pharmacies are granted CORs, they would take several preventative steps to ensure that the doctors who wrote prescriptions for dispensing at the pharmacy had the requisite authority to do so.[62] *Id.* Moro-Perez represented that if the pharmacies were again registered, an employee would verify the registration status of prescribing physicians with the appropriate DEA Web site every month. Tr. 236–37. He also represented that he is ''establishing a new system of computers so the pharmacy will be able to study the patient file and the doctor's file'' and ''demand'' documentation that the patient is being treated by a specialist ''mostly on the narcotic medications, the pain medications and any other that we understand that is being used for alleged medical use [sic].'' Tr. 237–38. Moro-Perez also offered that the current PICs of both Farmacia Nueva and Best Pharma have spent a significant number of years practicing in the field. Tr. 241–42.

The testimony of Moro-Perez cannot be deemed entirely credible. There were times during his testimony where he offered answers that were intentionally equivocal and made no sense. For example, when asked why no increased scrutiny or contact resulted from ''many'' instances where Dr. Aguilar's patients attempted to fill bad prescriptions at the pharmacies and were refused, Moro-Perez responded that no action was taken because the percentages were very low and because he knew Aguilar's licenses were current.[63] These answers were inconsistent with his earlier recognition that the responsibility for accurate dispensing rests with the

[55] To the extent that the Respondents' closing brief avers that the ''H'' described in the record refers to a dispensing event being in a ''hold'' status (ALJ Ex. 24, at 8, 17), that assertion is simply not supported in the record. This record does not contain an explanation of the meaning of an ''H'' before a dispensing event transaction number.

[56] Gov't Ex. 4.

[57] Although the relevance of this testimony was likely linked to dispel any notion that Moro-Perez or other pharmacy personnel could have manually placed an ''H'' before certain dispensing event numbers, the lack of any witness to explain what an ''H'' signifies greatly diminishes the utility of this testimony. Stated differently, since the record never says what the ''H'' signifies, it does not much matter whether anyone could have manually added it to the transaction numbers or anywhere else.

[58] Moro-Perez testified that, of the dozen or so pharmacies in San Sebastian that dispensed controlled substances, Farmacia Nueva was the pharmacy located closest to Dr. Aguilar's office. Tr. 251.

[59] A copy of the March 28, 2012 federal criminal indictment dismissal where Moro-Perez was a defendant was received into the record (Resp't Ex. 3) and was also the subject of testimony (Tr. 212) and a stipulation between the parties (Stip. 8).

[60] Tr. 213, 218–19.

[61] Tr. 216.

[62] Although he directed his initial comments regarding remedial steps to Farmacia Nueva, Moro-Perez testified that the same measures would be taken at Best Pharma. Tr. 245–46.

[63] Tr. 250–54.

pharmacy,[64] bear little relation to the question, and are the obvious fruit of intentional equivocation. In like manner, Moro-Perez initially testified that when claims were submitted to insurance carriers, the pharmacies would receive a ''confirmation'' that the prescribers had valid licenses. Tr. 196. Later in his testimony, it became apparent that the ''confirmation'' from the insurance providers informed the pharmacy staff only that the reimbursement claim would be approved. Tr. 200–01. It was the same sort of equivocation employed when Moro-Perez testified that pharmacy staff would check prescriber licenses through RX30, a system that depended exclusively on input from staff who depended exclusively on the fact that claims were being approved.[65] When questioned as to why, at the hearing, he was able to produce scrips that were apparently not forwarded to DEA as part of his compliance with the Request for Information, Moro-Perez never explained why the new scrips were so late in coming or suggested that DEA did not have the complete set he forwarded, but merely continued to insist that he ''provided them everything that the [RX30] system provided, and all the prescriptions were submitted.'' Tr. 208. These answers presented inconsistencies, were less than complete, and were certainly less than candid. Similarly, when explaining his rationale for answering ''no'' to application Question 2, Moro-Perez adhered to the position that the nature of the June 2012 Farmacia Nueva surrender was somehow altered by the dismissal of a criminal indictment against him (not the pharmacies) that occurred three months earlier. It is inescapably illogical to insist that an event which occurred prior to the surrender would somehow alter its characterization from ''for cause'' to otherwise. Inasmuch as Moro-Perez is an educated and experienced pharmacist, to suggest that this *non sequitor* was the result of naiveté or inexperience is patently unreasonable. The answer was deceitful, intentionally so, and he well knew it. Similarly, when explaining his position on the negative response entered on Question 2, Moro-Perez qualified his testimony by twice adding that DEA knew about his arrest. Tr. 216, 218–19. Again, this is a non-answer, since the arrest, the indictment dismissal, and DEA's knowledge about those events do not bear any relation to the issue he was addressing, *to wit,* the ''no'' response to the question of whether the Respondents' registrations had been surrendered for cause. Thus, Moro-Perez tendered testimony that was at times implausible and inconsistent, and he substituted intentional equivocation for detail. His testimony, then, cannot be deemed fully credible in this recommended decision. That is not to say that all of his testimony is not worthy of belief, but in those places where his testimony conflicts with other record evidence, it must be considered with heightened vigilance.[66]

The Respondents' Evidence

In addition to the testimony from Moro-Perez that was elicited on cross examination, the Respondents' presented the testimony of Mr. Nelson Vale. Tr. 268. Mr. Vale testified that he has worked at Farmacia Nueva since February 2009 and has served as the chief pharmacist since August 2010. Tr. 272. Vale acknowledged that he was employed at the pharmacy during the time period when it was dispensing controlled substances on Dr. Aguilar's expired COR. Tr. 281. Before working at Farmacia Nueva, he worked as a pharmacist and chief pharmacist at two Walgreens pharmacies. Tr. 272–73. Vale testified that his role at Farmacia Nueva requires ensuring ''that the medication is dispensed properly'' and that the pharmacy maintains a correct inventory. Tr. 273. Consistent with other witnesses who have testified on the subject, Vale stated that the pharmacy uses the RX30 program, that the system automatically assigns dispensing event numbers to each prescription, and that the program cannot be manipulated to change the dispensing event numbers once they have been assigned. Tr. 273–74. Vale testified that a prescription dispensing event can be looked up on the RX30 program by its dispensing event number, by the type of medication, or by the doctor's name. Tr. 276. Further, Vale indicated that he could identify all prescriptions in the system that were authorized by Dr. Aguilar. Tr. 277. He also stated that, ''to the best of his knowledge,'' no one has ever tried to manipulate the numbers for Farmacia Nueva's RX30 program, that he has never tried to do so, and that he was never directed to do so. Tr. 276–77.

Vale described the dispensing process at Farmacia Nueva. Tr. 274. Vale's account of FN pharmacy operations was in substantial accord to the explanation provided by his boss, Moro-Perez. Tr. 274–75.

Vale also testified that he and Moro-Perez have discussed remedial improvements they intend to implement if Farmacia Nueva is granted its COR. Tr. 278. Among their plans is the future pursuit of a strict policy regarding dispensing controlled substances, a ''program''[67] that will alert pharmacy personnel when a physician's license is expired in real time, and a plan to have staff access the DEA Web site at least once a month to ascertain prescriber COR status. Tr. 278–79.

Vale conceded that these safety measures could have been implemented before the execution of the search warrant on November 30, 2011. Tr. 280. He also admitted that, since November 30, 2011, he has not asked DEA whether they provide training against illegal distribution and he has not taken any training regarding anti-diversion efforts or anti-illegal distribution efforts. Tr. 281–82. Vale likewise acknowledged that the planned remedial measures stem from enforcement actions already taken by DEA as well as a desire to avoid the specter of future sanctions. Tr. 282.

Mr. Vale's testimony was sufficiently plausible, detailed, and internally consistent to be deemed credible in this recommended decision.

Additional facts required for a disposition of this case are set forth below.

The Analysis

The Government alleges two bases for denial of the Respondents' applications: (1) that Respondents' owner/president, Moro-Perez, materially falsified the Respondents' applications for CORs; and (2) that the granting of the Respondents' applications would be inconsistent with the public interest. These bases are addressed below, *in seriatim.*

Material Falsification

The Government has alleged that the Respondents' respective applications for CORs should be denied because each application contains a material falsification,[68] which, under the CSA, is a ground for a sanction against an existing COR. 21 U.S.C. 824(a)(1). The Agency may revoke or suspend a DEA COR upon a finding that the registrant has materially falsified any application filed to obtain it. *Id.* Under the theory that the law would not require issuance of a COR that should be revoked *ab initio,* a long line of Agency precedent has consistently held that the grounds for the revocation or suspension of an existing registration are also properly considered in adjudicating an application for a COR. *The Lawsons, Inc.,* 72 FR 74334, 74335 (2007); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23852 (2007); *Dan E. Hale, D.O.,* 69 FR 69402, 69405–06 (2004); *Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman, M.D.,* 63 FR 45260, 45260 (1998); *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993). Thus, in the same way that materially falsifying an application provides an independent basis for revoking an existing registration without proof of any other misconduct, it also provides an independent and adequate ground for denying an application for a new COR. *The Lawsons,* 72 FR at 74338. It is settled Agency precedent that ''[s]ince DEA must rely on the truthfulness of information supplied by applicants in registering them to handle controlled substances, falsification cannot be tolerated,'' *Bobby Watts, M.D.,* 58 FR 46995, 46995 (1993), and that a ''cavalier attitude toward the importance of accurately executing [a registration] application suggests a lack of concern for the responsibilities inherent in a DEA registration.'' *Chen,* 58 FR at 65402.

To serve as a basis for an adverse application determination, it is incumbent upon the Government to establish that an applicant has provided false information in his or her application, and that the false

[64] Tr. 194.

[65] Tr. 229–31.

[66] The Government has argued in its closing brief that Moro-Perez ''frequently gave evidence that directly conflicted with the Government's evidence.'' ALJ Ex. 23, at 27. This misses the point. It is not that his testimony is lacking in credibility because it is incongruous with testimony elicited by the Government, but, rather, it is worthy of diminished credibility based on a dispassionate review of its own merits.

[67] No further explanation was offered as to what sort of a ''program'' is contemplated, how it would work, or how it would alert pharmacy staff when a prescriber's COR expires. This proposal was described by the witness in terms that seemed more ethereal than concrete.

[68] ALJ Ex. 4, at 3–5.

information provided is material. 21 U.S.C. 824(a)(1). The Government must prove that the false information is material by ''clear, unequivocal, and convincing'' evidence. *Hoi Y. Kam, M.D.,* 78 FR 62694, 62696 (2013) (quoting *Kungys* v. *United States,* 485 U.S. 759, 772 (1988)). A material falsification requires a showing that a statement tendered in a COR application is one that '' 'has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.' '' *The Lawsons,* 72 FR at 74338 (citing *Kungys,* 485 U.S. at 770); *see also Robles* v. *United States,* 279 F.2d 401, 404 (9th Cir. 1960), *cert. denied,* 365 U.S. 836 (1961). Proof that any Government decision, including the decision regarding the registration application, was actually influenced is not required. *The Lawsons,* 72 FR at 74339. The touchstone is whether the statement had the *capacity* to influence. *See United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985), *cert. denied,* 475 U.S. 1086 (1986); *Alvin Darby, M.D.,* 75 FR 26993, 26998 (2010). Since a materiality determination turns on an analysis of the relevant substantive law, *Kungys,* 485 U.S. at 772, the allegedly false statement must be analyzed in the context of the application requirements sought by DEA and provided by the applicant. The falsification must relate to a ground that could affect the decision, not merely a basis upon which an investigation could be initiated. *Darryl J. Mohr, M.D.,* 77 FR 34998, 34998 n.2 (2012); *Harold Edward Smith, M.D.,* 76 FR 53961, 53964 (2011); *Scott C. Bickman, M.D.,* 76 FR 17694, 17701 (2011). The entire application will be examined to determine whether there was an intention to deceive the agency. *See Jackson,* 72 FR at 23852–53.

Furthermore, the correct analysis hinges on whether the applicant knew or should have known that he or she submitted a false application. *Hale,* 69 FR at 69406; *The Drugstore,* 61 FR 5031, 5032 (1996); *Watts,* 58 FR at 46995. Although even an unintentional falsification can serve as a basis for adverse action regarding a registration, lack of intent to deceive and evidence that the falsification was not intentional or negligent are all relevant considerations. *Funches,* 64 FR at 14268.

The Government has alleged that each of the Respondent pharmacies surrendered a COR for cause and that, when Moro-Perez stated otherwise on their COR applications, he knew or should have known that his statement in this regard was untrue. In their closing brief, the Respondents assert that ''the Government did not submit any evidence to prove that Farmacia Nueva's registration was revoked or surrendered (for cause).'' ALJ Ex. 24, at 22. Although the record evidence tells a story somewhere between the parties' contentions, it is the Government's view that is better supported.

The DEA regulations related to COR termination provide, in pertinent part, that:

> In the case of a surrender, termination shall occur upon receipt by any [DEA employee] of a duly executed DEA Form 104 or any signed writing indicating the desire to surrender a registration.

21 CFR 1301.52(a).

The evidence of record here clearly demonstrates that Best Pharma surrendered its registration through the execution of a DEA Form 104. Gov't Ex. 14, at 1. However, with respect to Farmacia Nueva, the Government has tendered neither a DEA Form 104 nor ''any *signed* writing indicating a desire to surrender a registration.'' 21 CFR 1301.52(a) (emphasis supplied). The Government tendered an unsigned email exchange and brought no witness with any personal knowledge about the circumstances underlying the exchange or even one able to identify the participants. However, the existence and validity of the Farmacia Nueva surrender was never challenged at the hearing. Additionally, the identification (through official notice regarding Government counsel and notice of appearance of FN's current counsel) of the names on the face of the email traffic, coupled with the fact that Farmacia Nueva filed an application for a new COR, provide a sufficiently reliable basis upon which to conclude that the COR was surrendered and that Farmacia Nueva accepts that as fact. In any event, the language employed in the surrender/termination provision [69] cited above appears more focused on fixing an effective date for when a surrender ripens into a termination than on circumscribing the exclusive means to surrender a COR.[70]

Whether the surrenders were ''for cause'' is yet even more nuanced. Neither the Best Pharma Surrender Form nor Farmacia Nueva's email exchange contain the words ''for cause.'' Gov't Ex. 14. In fact, the only mention of a surrender ''for cause'' is set forth in two regulatory sections devoted to security matters, each of which provides that:

> For purposes of [the two security subsections], the term ''for cause'' means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of [a current or prospective employee's] handling of controlled substances. . . .

21 CFR 1301.76(a), 1309.72(a). There is no ''for cause'' definition set forth in the regulations related to COR surrender. 21 CFR 1301.52.

Agency precedent has looked into the circumstances surrounding a surrender to determine whether it was properly characterized as being ''for cause'' and whether a registrant is properly charged with understanding that characterization. *See, e.g., Shannon L. Gallentine, D.P.M.,* 76 FR 45864, 45866 (2011) (holding that the signing of a DEA Form 104 during a search warrant execution where the investigator was asking questions about prescribing practices and lack of documentation to justify prescriptions constituted circumstances sufficient to establish that COR applicant knew or should have known that his COR surrender, which occurred two years earlier, was ''for cause''); *see also Robert M. Brodkin, D.P.M.,* 77 FR 73678, 73679 (2012) (holding that an executed DEA Form 104 and subsequent federal and state disciplinary proceedings were circumstances sufficient to characterize a surrender as ''for cause''). The Best Pharma Surrender Form was executed by Moro-Perez while the investigators were executing a search warrant at the pharmacy, and they explained to him that the Form 104 ''dealt with the regulatory matter [and that i]f he chose not to sign the form then [DEA] would move for an order to show cause proceeding.'' Tr. 177. Thus, unrefuted testimony establishes that DI Taylor, through an interpreter, told Moro-Perez that the surrender related only to the administrative proceedings, and not any criminal case. There was no evidence as to why Moro-Perez would not take the DI at his word that the surrender related only to administrative issues, not a criminal case. The Farmacia Nueva surrender was effected by counsel via email while administrative revocation proceedings were apparently underway before the Agency. Gov't Ex. 14, at 2–4. The circumstances surrounding each surrender provided sufficient notice to Moro-Perez that DEA was intent upon seeking revocation based on what its agents perceived to be serious regulatory violations. While the record is not optimal in this regard, there is sufficient, unrefuted evidence [71] to establish that the BP and FN CORs were surrendered for cause and that Moro-Perez had reason to know this was the case.[72]

The COR surrenders for cause that were errantly denied in Question 2 of the Respondents' applications were founded in controlled substance recordkeeping and corresponding responsibility violations

[69] 21 CFR 1301.52(a).

[70] The Agency Final Rule promulgating the modification stated that the language is designed to ''clarify that a voluntary surrender of a registration signed by a registrant using any format has the legal effect of immediately terminating the registrant's registration without any further action by DEA.'' *Voluntary Surrender of Certificate of Registration,* 76 FR 61563, 61563 (Oct. 5, 2011). Thus, the primary focus appears to have been on providing clarity regarding the date upon which the surrender became effective, not the nature of the instruments required to make the surrender valid.

[71] In their closing brief, the Respondents argue that DI Antoine testified that he did not know what ''for cause'' meant. ALJ Ex. 24, at 13, 23. Even the record citation (Tr. 105–06) provided by the Respondents makes clear that Antoine testified that he did not know why the words ''for cause'' were in parentheses, not that he did not know what the phrase meant. In any event, highlighting this point does nothing to further the Respondents' position. If placement of the phrase ''for cause'' somehow renders it optional or diminishes its import, that would leave Question 2 as asking whether a COR had ever been surrendered (for any reason). A ''no'' answer tendered in response to a question interpreted thus would be false here irrespective of the Respondents' illogical association of the ''for cause'' clause to his indictment dismissal.

[72] In its brief, the Government points out that Moro-Perez ''never contacted [DI Antoine] to inquire as to what 'for cause' meant.'' ALJ Ex. 23, at 6. To be clear, there was no burden on Moro-Perez to contact DEA to ascertain the meaning of the language in the BP voluntary surrender form or the consequences of the surrender effected by counsel during the FN administrative proceedings. The language and circumstances of the voluntary surrender were sufficiently clear to find that the surrender here was ''for cause'' and that Moro-Perez knew it, whether he made inquiry or not. If the language and circumstances were not sufficiently clear, the absence of any efforts by Moro-Perez to contact DI Antoine would not advance the Government's case in any measure.

uncovered by DEA in the course of a criminal search warrant execution, and those violations would have supported the denial of the Respondents' applications. *See Kam,* 78 FR at 62697 & n.7 (holding that a material falsification, to be material, must be such that the truthful disclosure of the facts would have supported the denial of the Respondent's application). One of the CORs was surrendered during the course of DEA administrative hearing procedures. As discussed more fully, *infra,* allegations that the dispensing of controlled substance prescriptions authorized by an unregistered physician that resulted in their surrender for cause provided ''actionable grounds'' sufficient to merit a COR sanction. *Kam,* 78 FR at 62697. Hence, it is beyond argument that the alleged falsifications, if established, ''had the capacity to influence the Agency's decision to grant [the] application[s]'' and, thus, were material. *Id.*

Regarding Moro-Perez's position that he was confused about the whether the surrenders retained their ''for cause'' character based on his indictment dismissal, the timeline of events is key. Moro-Perez testified that he has owned Farmacia Nueva and Best Pharma since each establishment was opened. Tr. 192, 222, 238. A COR was issued to Farmacia Nueva in 2005 and to Best Pharma in 2010. Gov't Exs. 2, 9. The Best Pharma Surrender Form was executed by Moro-Perez [73] on November 30, 2011.[74] Gov't Ex. 14, at 1. The DEA COR applications that are the subject of these proceedings include four liability questions that require the applicant to choose a ''yes'' or ''no'' answer. The second liability question (Liability Question 2) contains the following language:

Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?

Gov't Exs. 1, 8. Moro-Perez included a ''no'' response to Liability Question 2 on the online application he submitted for each Respondent. Gov't Exs. 1, 8. Notwithstanding the less-than-ideal sentence structure in Liability Question 2, since both CORs were surrendered for cause by Moro-Perez prior to the filing of the applications, the ''no'' response in each application is indisputably untrue. The principal issue remaining is whether the negative response entered by Moro-Perez on each application was objectively reasonable.

Moro-Perez testified that, while he now acknowledges that he should have answered the surrender for cause questions in the affirmative, he misunderstood the question at the time, and there was never an intention on his part to deceive DEA. Tr. 216–17. Specifically, Moro-Perez posits that the dismissal of an indictment against him led him to believe that the surrenders of the two CORs by the Respondents were not for cause. Tr. 211–13. When viewed against a backdrop of the timeline of events delineated in the evidence of record, Moro-Perez's explanation makes no sense.

As set forth in the table below, Moro-Perez surrendered the Best Pharma COR at the time of his arrest during the early morning hours of November 30, 2011. Tr. 72, 175, 181; Gov't Exs. 2, at 2, 14, at 2–4. The indictment referenced by Moro-Perez was dismissed on March 23, 2012, some four months later. Stip. 8; Resp't Ex. 3; Tr. 212. The Farmacia Nueva COR was surrendered for cause by counsel on June 28, 2012, three months after the indictment dismissal and seven months following the Best Pharma surrender for cause. Gov't Exs. 2, 14. The online COR applications that are the subject of these proceedings were submitted by Moro-Perez on October 10, 2012, eleven months after the for-cause surrender of Best Pharma's COR, four months following the Farmacia Nueva for-cause surrender, and (most significantly) seven months following the dismissal of the indictment against Moro-Perez. Gov't Exs. 1, 8; Stips. 5, 6.

Date	Event
November 30, 2011	Best Pharma COR Surrender Form Executed by Moro-Perez.
March 23, 2012	Indictment Against Moro-Perez Dismissed.
June 28, 2012	Farmacia Nueva COR Surrendered by Counsel via Email.
October 10, 2012	Respondents' COR Applications Submitted by Moro-Perez.

As is apparent in the table above, the indictment dismissal, the single event to which Moro-Perez ascribes the confusion that spawned his false answers on the COR applications, occurred between the for-cause surrenders of Best Pharma and Farmacia Nueva. The Farmacia Nueva surrender happened *after* the indictment dismissal [75] and was effected through counsel. In effect, Moro-Perez testified that he believed that the dismissal of the criminal charges (against himself) somehow washed away the sins of Best Pharma, resulting in what had previously been a surrender *for cause* being transformed into a surrender *not for cause.* Then, as if this gift was not good enough, he also asserted that not only did the dismissal of the indictment (against himself) forgive the sins of one of his pharmacies, but somehow it preemptively pardoned another pharmacy that surrendered for cause after the date of dismissal by characterizing that surrender as ''not for cause.'' But this cannot be. If the dismissal of indictment really cleaned up all issues surrounding Moro-Perez *and* his pharmacies, why would there even need to be a subsequent surrender of Farmacia Nueva's COR? And, in light of the subsequent surrender of Farmacia Nueva's COR, why would it be reasonable to believe that the dismissal of the criminal charges against Moro-Perez magically deemed a subsequent surrender *for cause* as a surrender *not for cause*?

There is simply no logical manner in which a rational person (much less an educated, experienced registrant holder) would or could reason that a surrender that was ''for cause'' when effected, could somehow morph into one that was not ''for cause'' by an action (the dismissal) that preceded it. Even if it were assumed, *arguendo,* that Moro-Perez's account that he subjectively believed the dismissal of an indictment against him (not the Respondents) could somehow change the character of the surrender for cause, no indictment dismissal or other operative fact occurred after the surrender of Farmacia Nueva's COR that could alter its character. Thus, even if credit were afforded to Moro-Perez's account that it was the dismissal of the indictment against him that led him to believe that the surrenders of the CORs were not for cause, this theory of ignorance, even in its best (most naïve) light, only covers the Best Pharma surrender that was signed before the indictment dismissal, not the Farmacia Nueva surrender, which occurred three months after the dismissal. Even putting aside the reality that, as a veteran registrant holder, Moro-Perez had the experience and bore the responsibility to understand the meaning of his answers to the applications he was filing, he failed to present a logical theory of subjective ignorance that corresponds with the facts. At the hearing, Moro-Perez acknowledged that he understood the question concerning the surrender for cause and his response to it. Tr. 210–11. The indictment dismissal occurred prior to the surrender for cause, and there is simply no rational view of the facts that could lead any reasonable person, much less an experienced COR holder, to believe that the surrender was suddenly no longer ''for cause'' due to a dismissal that came first. It is not insignificant that Moro-Perez (not the Respondents) was captioned in the indictment, and, given the timeline of events, the dismissal added no level of cognizable confusion here. Moro-Perez's assertions to the contrary are simply not credible. The ''provision of truthful information is absolutely essential to effectuating th[e] statutory purpose'' of determining whether the granting of an application is consistent with the public interest. *Darby,* 75 FR at 26998 (quoting *Peter A. Ahles, M.D.,* 71 FR

[73] Moro-Perez testified at the hearing with the benefit of a Spanish-language interpreter. Tr. 191. Uncontroverted record evidence establishes that the Best Pharma Surrender Form was read and explained to Moro-Perez in Spanish at the time it was executed. Tr. 175–78. At the hearing, the Respondents raised no issue regarding any impediment presented by language regarding Moro-Perez's execution of the Best Pharma Surrender Form or the COR applications he filed on their behalf. The Farmacia Nueva COR surrender was effected via email by its present counsel, who possessed sufficient command of the Spanish language to communicate with Moro-Perez throughout these proceedings and to offer numerous challenges during the hearing to translations supplied by the official hearing interpreter. *See, e.g.,* Tr. 195–96, 200, 206, 214–15, 220, 224. Thus, this record does not support any level of cognizable confusion on the part of Moro-Perez borne of a language barrier in understanding the COR surrenders or the filed applications.

[74] The Government also provided a certification by the Chief of the DEA Registration and Program Support Section (Farmacia Nueva Certification) that the same voluntary surrender took place on December 14, 2011. Gov't Ex. 9, at 2. Although no explanation was offered for the disparity, the date variance does not impact the outcome of the case.

[75] Gov't Ex. 14, at 2.

50097, 50098 (2006)); *see VI Pharmacy,* 69 FR 5584, 5585 (2004); *Terrence E. Murphy, M.D.,* 61 FR 2841, 2846 (1996). This finding, standing alone, is sufficient to recommend denial of both applications. *Cf. Gallentine,* 76 FR at 45866. It is clear that the Respondents, through their common owner, Moro-Perez, knew or should have known [76] that the answers provided to Question 2 were false, and that their COR applications contained material falsifications. The absence of any logical basis for confusion and the past experience of Moro-Perez as a registrant holder and pharmacist preponderantly support a finding that the misrepresentations were intentional, not negligent.[77] The Respondents are accountable for the actions of Moro-Perez as their owner/president,[78] and, even standing alone, the denial of the Respondents' COR applications is adequately supported on this record based on the material falsifications set forth in the filed applications.

Public Interest Determination: The Standard

The Government also seeks denial of the Respondents' respective COR applications based on a theory that each has committed acts inconsistent with the public interest. Pursuant to 21 U.S.C. 823(f), the Administrator [79] is permitted to deny an application for a COR if persuaded that an applicant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' [80] The following factors have been provided by Congress in determining ''the public interest'':

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f) (2006 & Supp. III 2010).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *Id.; David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest. . . .'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009).

In the adjudication of an application for a DEA COR, the DEA has the burden of proving that the requirements for registration are not satisfied. 21 CFR 1301.44(d). Where the Government has sustained its burden and established that an applicant has committed acts inconsistent with the public interest, that applicant must present sufficient mitigating evidence to provide assurance that it can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Jackson,* 72 FR at 23853. Where the Government has met this burden, the registrant must show an acceptance of responsibility for its misconduct and a demonstration that corrective measures have been undertaken to prevent the re-occurrence of similar acts. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38364, 38385 (2013).

Normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration. *Linda Sue Cheek, M.D.,* 76 FR 66972, 66972–73 (2011); *Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009). The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct, *Hoxie,* 419 F.3d at 483; *see also Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. While '''the possibility of drawing two inconsistent conclusions from the evidence''' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989) (quoting *Trawick,* 861 F.2d at 77), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered, *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys* v. *DEA,* 96 F.3d 658, 663 (3d Cir. 1996). The ultimate disposition of the case ''must be 'in accordance with' the weight of the evidence, not simply supported by enough evidence 'to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.''' *Steadman,* 450 U.S. at 99 (quoting *Consolo* v. *Fed. Mar. Comm'n,* 383 U.S. 607, 620 (1966)).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* 555 U.S. 1139 (2009). It is well settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Agency's final decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

Factors 1, 3, and 5: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority; Any Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances; Such Other Conduct Which May Threaten the Public Health and Safety

Regarding Factor 1, the record contains no evidence of a recommendation by any state

[76] *See Hale,* 69 FR at 69406; *The Drugstore,* 61 FR 5031, 5032 (1996); *Watts,* 58 FR at 46995.

[77] *See Funches,* 64 FR at 14268.

[78] *See Top Rx Pharmacy,* 78 FR 26069, 26081–82 (2013); *EZRX, LLC,* 69 FR 63178, 63181 (2004); *Plaza Pharmacy,* 53 FR 36910, 36911 (1988); *Syncon Pharm., Inc.,* 53 FR 15155, 15156 (1988); *see also Neil Labs., Inc.* v. *Ashcroft,* 217 F. Supp. 2d 80, 87–88 (D.D.C. 2002).

[79] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

[80] 21 U.S.C. 824(a)(4).

licensing board, body, or authority related to the Respondent pharmacies. However, the fact that a state has not acted against a registrant's state authority is not dispositive in this administrative determination as to whether continuation of its registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that ''state [authority] is a necessary, but not sufficient condition for registration.'' *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006) (quoting *Leslie,* 68 FR at 15230). DEA bears an independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 8209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* 555 U.S. 1139 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 FR at 20735 n.31. Thus, on these facts, the absence of a recommendation by a state licensing board does not weigh for or against a determination as to whether granting the Respondents' applications would be consistent with the public interest. *See Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011) (''[T]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'').

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondents, their owner, or any pharmacist or key employee of either pharmacy has been convicted of (or charged with) a crime related to any of the controlled substance activities designated in the CSA.[81]

The standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest. Still, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 FR 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 FR 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.''), *aff'd, Mackay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009). Therefore, on the present record, the absence of criminal convictions (Factor 3), like the absence of a recommendation from any state licensing authorities (Factor 1), militates neither for nor against the COR denials sought by the Government.

The fifth statutory public interest factor directs consideration of ''[s]uch *other conduct* which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5) (emphasis added). Existing Agency precedent has long held that this factor encompasses ''conduct which creates a probable or possible threat (and not only an actual [threat]) . . . to public health and safety.'' *Dreszer,* 76 FR at 19434 n.3; *Michael J. Aruta, M.D.,* 76 FR 19420, 19420 n.3 (2011); *Beau Boshers, M.D.,* 76 FR 19401, 19402 n.4 (2011); *Jacobo Dreszer,* 76 FR 19386, 19386 n.3 (2011). Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese, Inc.,* 76 FR 46843, 46848 (2011); *Tony T. Bui, M.D.,* 75 FR 49979, 49989 (2010) (stating that prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); *cf. Paul Weir Battershell, N.P.,* 76 FR 44359, 44368 n.27 (2011) (noting that although a registrant's non-compliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent's future compliance with the CSA).

Similar ''catch-all'' language is employed by Congress in the CSA related to the Agency's authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider ''such *other factors* as are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(5) (emphasis added). In *Holloway Distributing,* the Agency held this catch-all language to be broader than the language directed at practitioners under ''other conduct which may threaten the public health and safety'' utilized in 21 U.S.C. 823(f)(5). 72 FR 42118, 42126 n.16 (2007). Regarding the List I catch-all language, the Administrator, in *Holloway,* stated:

[T]he Government is not required to prove that the [r]espondent's conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young,* 71 [FR] at 60572 n.13. Rather, the statutory text directs the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* § 823(f)(5) (directing consideration of ''[s]uch other conduct which may threaten the public health and safety'').

Id.[82] Thus, the Agency has recognized that, while the fifth factor applicable to List I chemical distributors—21 U.S.C. 823(h)(5)—encompasses all ''factors,'' the Factor Five applied to practitioners—21 U.S.C. 823(f)(5)—considers only ''conduct.'' However, because § 823(f)(5) only implicates ''such *other* conduct,'' it necessarily follows that conduct considered in Factors One through Four may not be considered in Factor Five.

The Government has not alleged any conduct against either Respondent in these proceedings that implicates Factor Five. Indeed, those portions of each party's closing briefs dedicated to Factor Five are exclusively (and mistakenly) devoted to a discussion of the burdens established under Agency precedent and the exercise of some of the appropriate discretionary considerations. Accordingly, consideration of the record evidence under Factors One, Three, and Five weigh neither for nor against the Governments' petition to deny the Respondents' COR applications.

Factors 2 and 4: The Respondents' Experience in Dispensing Controlled Substances, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government's public-interest-factors case seeking COR application denials for both Respondents is based exclusively on conduct properly considered under Factors Two and Four. The Government alleges and relies on recordkeeping and dispensing activity conducted by the Respondent pharmacies' pharmacists, staff, and management.

Regarding Factor Two, in requiring an examination of an applicant's experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which an applicant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether an applicant should be (or continue to be) entrusted with a DEA COR. In some (but not all) cases, viewing an applicant's actions

[81] The parties stipulated that Moro-Perez was indicted, but that the indictment was ultimately dismissed. Stip. 8; Resp't Ex. 3. The indictment itself was not offered into the record. The mere fact that Moro-Perez was the subject of a criminal indictment does not establish culpability for the acts charged by the indictment, and the dismissal in this matter has been considered only under the narrow *mens rea* theory upon which the Respondents offered it. *See Paul Weir Battershell, N.P.,* 76 FR 44359, 44364 n.17 (2011) (concluding that an indictment is an instrument containing accusations, not proof of a respondent's actions).

[82] In *Bui,* the Agency clarified that ''an adverse finding under [Factor Five did not require a] showing that the relevant conduct actually constituted a threat to public safety.'' 75 FR at 49988 n.12.

against a backdrop of how its regulated activities have been performed within the scope of its registration can provide a contextual lens to assist in a fair adjudication of whether registration is in the public interest. In this regard, however, the Agency has applied principles of reason, coupled with its own expertise, in the application of this factor. For example, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest, and will be afforded scant weight in the face of proven allegations of intentional diversion. *Krishna-Iyer,* 74 FR at 463; *see also Hassman,* 75 FR at 8235 (acknowledging Agency precedential rejection of the concept that conduct inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities that occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 FR 51592, 51560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). Similarly, in *Cynthia M. Cadet, M.D.,* the Agency determined that existing List I precedent [83] clarifying that experience related to conduct within the scope of the COR sheds light on a practitioner's knowledge of applicable rules and regulations would not be applied to cases where intentional diversion allegations were sustained. 76 FR 19450, 19450 n.3 (2011). The Agency's approach in this regard has been sustained on review. *Mackay,* 664 F.3d at 819.

Regarding Factor Four (compliance with laws related to controlled substances), to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Under the regulations, ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a). Under this language, a pharmacist has a duty ''to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered.'' *Electronic Prescriptions for Controlled Substances,* 75 FR 16236, 16266 (Mar. 31, 2010). In short, a pharmacist has a ''corresponding responsibility under Federal law'' to dispense only lawful prescriptions. *Liddy's Pharmacy, L.L.C.,* 76 FR 48887, 48895 (2011). ''The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR 62316, 62341 (2012) (citing *Medicine Shoppe,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50397, 50407–08 (2007); *EZRX, LLC,* 69 FR 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61613, 61617 (Oct. 16, 2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64921, 69424 (Nov. 19, 2007)). Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy ''knows or has reason to know'' that the prescription is invalid. *E. Main St. Pharmacy,* 75 FR 66149, 66163 (2010); *Bob's Pharmacy & Diabetic Supplies,* 74 FR 19599, 19601 (2009) (citing *Medicine Shoppe,* 73 FR at 381); *see also United Prescription Servs.,* 72 FR at 50407–08 (finding a violation of corresponding responsibility where the pharmacy ''had ample reason to know'' that the practitioner was not acting in the usual course of professional practice). The pharmacy registrant's responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but is, rather, a *corresponding* one. 21 CFR 1306.04(a). The Government has averred that for a period of over two years, the Respondents filled controlled substance prescriptions for Dr. Aguilar, a physician who did not possess a valid COR. These allegations impact both Factor 2 [84] and Factor 4.

To show a violation of a pharmacy registrant's corresponding responsibility, ''the Government must establish three elements: (1) the registrant dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.'' *Holiday CVS,* 77 FR at 62341. ''The steps necessary to resolve the red flag conclusively will *perforce* be influenced by the nature of the circumstances giving rise to the red flag.'' *Id.* (emphasis added). When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the *entity,* not the pharmacist, can be charged with the requisite knowledge. *See United Prescription Servs.,* 72 FR at 50407 (finding that the Respondent pharmacy violated its corresponding responsibility because ''an *entity* which voluntarily engages in commerce [to] other States is properly charged with knowledge of the laws regarding the practice of medicine in those States'' (emphasis added)); *see also Pharmboy Ventures Unlimited, Inc.,* 77 FR 33770, 33771 n.2 (2012) (''DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.''' (quoting *Carriage Apothecary,* 52 FR 27599, 27599 (1987))); *S & S Pharmacy, Inc.,* 46 FR 13051, 13052 (1981) (holding that the corporate pharmacy acts through the agency of its PIC). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself. *See United States* v. *7326 Highway 45 N.,* 965 F.2d 311, 316 (7th Cir. 1992) (''Only knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation.''). Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employees. *Holiday CVS,* 77 FR at 62340; *EZRX,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR 36910, 36911 (1988). Thus, it is necessary and appropriate to analyze the relevant conduct of each pharmacy's personnel, including Moro-Perez, who serves as the owner/president of each.[85]

The DEA regulations provide that a controlled substance prescription may only be issued by a practitioner with state and federal authority to do so. 21 CFR 1306.03(a). For a controlled substance prescription to be effective, it must be issued by a practitioner. 21 CFR 1306.04(a). To be a ''practitioner'' under the CSA in this context, an individual must possess authority to prescribe controlled substances. 21 U.S.C. 802(21). Thus, a controlled substance prescription issued by one who lacks authority to prescribe is issued by a non-practitioner and is ineffective. A pharmacy registrant who dispenses a controlled substance based on an ineffective prescription, in the face of a red flag that was recognized or should have been recognized, has violated its regulatory corresponding responsibility. 21 CFR 1306.14; *Holiday CVS,* 77 FR at 62341. The question then devolves to whether Dr. Aguilar's lack of a COR is a red flag that should have been recognized. As discussed, *infra,* this question must be answered in the affirmative.

On the present record, it is beyond argument that controlled substances were dispensed by the Respondent pharmacies on scrips issued by (unregistered) Dr. Aguilar (Element 1). The remaining issues concern whether this was done in the face of an unresolved red flag that should have been recognized [86] before the prescriptions were filled (Elements 2 & 3).

The unrefuted evidence of record establishes that, for over two years, the Respondent pharmacies filled controlled substance prescriptions without checking COR status beyond insurance payment confirmation. From Antoine's testimony, it appears that, from the period of January 31, 2009 to November 30, 2011, Dr. Aguilar's lack of a DEA COR had no perceptible impact on either the enthusiasm with which he issued controlled substance prescriptions,

[83] *See, e.g., Volusia Wholesale,* 69 FR 69409, 69410 (2004).

[84] This case contained no allegation (or evidence) of intentional diversion, but the Respondents offered no evidence or argument regarding the length and character of their experience in dispensing controlled substances. ALJ Ex. 24, at 24–25. Thus, it is unnecessary to determine whether such evidence would have been relevant to a disposition of the case. *See Cadet,* 76 FR at 19450 n.3; *Krishna-Iyer,* 74 FR at 463.

[85] Tr. 192, 219, 222, 223, 226, 238.

[86] The Government has not alleged or proved actual knowledge on the part of Moro-Perez or the staff at the Respondent pharmacies that Dr. Aguilar lacked a valid COR at the time the dispensing events in issue occurred.

nor the Respondents' willingness to fill them. Tr. 17. As acknowledged by Moro-Perez during his testimony, during that thirty-four month period, Farmacia Nueva and Best Pharma made no attempt (that was reasonably calculated for success) to ascertain whether Dr. Aguilar (or apparently any other physician for whom they were filling controlled substance prescriptions) had a valid COR. Tr. 194. Moro-Perez testified that his pharmacy staff assumed the validity of all prescriber CORs if insurance carriers provided notification that the patients were covered and the claims related to the prescription would be paid. Tr. 196. He indicated that the pharmacies would only have had reason to know that a doctor's COR had expired if, regarding a particular scrip, the insurance company signaled its intent to decline payment. Tr. 201. At no point during the hearing did Moro-Perez give any basis to establish that insurance providers would know whether medical practitioners were authorized to prescribe controlled substances, much less why insurance companies would have a legal or contractual duty (or even an inclination) to pass on COR information to dispensing pharmacies. Moro-Perez testified that his pharmacies relied on the approvals they received from insurance providers, but he did not even attempt to describe why such a practice was rational or supported by any level of common sense, much less why such a practice could be a responsible discharge of the authority of a registrant. The only notification apparently provided by the insurance companies' notifications is that the claim would be paid—and that is apparently the point at which these registrants' interest in the subject waned.

The responsibility for ensuring the authority of the practitioner writing the controlled substance prescription is abjectly integral to the pharmacy registrant's corresponding responsibility. The uncontroverted evidence of record establishes that, as DEA pharmacy registrants, the Respondents could have checked the COR status of Dr. Aguilar (and all prescribing doctors) by accessing a link on the DEA Diversion Web site, by consulting a list of current registrants that is regularly updated by the Department of Commerce, by contacting the local DEA office, or by contracting with a private company to perform due diligence in this regard. Tr. 20–21. The Respondents' irresponsible practice of ending their COR inquiry at the moment an insurance company agrees to remit payment speaks volumes on the subject of whether these Respondents should be entrusted with the responsibility of a controlled substance registrant. That the Respondents chose a patently ineffective and illogical manner to check COR statuses cannot absolve them of their responsibility to ensure this most basic of requirements. The Agency has never been, and cannot be, persuaded by a policy of ''see no evil, hear no evil.'' *Cf. Gonzalez,* 76 FR at 63142. Even in a criminal context regarding prescriptions illegitimately issued, the courts have held that a factfinder ''may consider willful blindness as a basis for knowledge.'' *United States* v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006). The absence of Dr. Aguilar's COR is the most glaring of red flags that could and should have been recognized by the Respondents upon the exercise of even the most minimal due diligence. Conclusively resolving such a fundamental red flag was a mandatory condition precedent to the legal dispensing of a controlled substance, and the Respondents' failure to do so (on multiple occasions) was a clear breach of their corresponding responsibility under the regulations. 21 CFR 1306.04(a). ''It would be difficult to imagine a duty of a pharmacy registrant that is more fundamental to the law and spirit of the CSA than the obligation to ensure that controlled substance prescriptions are issued only on the authority of those empowered to prescribe by the DEA.'' *Holiday CVS,* 77 FR at 62341; *see also Liddy's Pharmacy,* 76 FR at 48895. Absent confirmation of a COR, a prescription written by one without COR authority would authorize the routine distribution of dangerous narcotics on the approval of anyone from the uninformed to the malevolent. The DEA's *Pharmacist's Manual* specifically provides that controlled substance prescriptions may only be issued by a practitioner who is, *inter alia,* ''[r]egistered with DEA or exempted from registration.'' DEA, *Pharmacist's Manual* § IX (2010).

It is hardly insignificant that more than serving merely as the owner/president of both pharmacies, Moro-Perez has been a trained pharmacist since 1999. He acknowledged at the hearing that he had received training regarding the lawful procedures for handling controlled substances. Tr. 194. In addition to the readily available means for checking COR statuses outlined by DI Antoine, it is worthy of note that, with minimal effort, Aguilar's office could have been contacted or even (in light of its close proximity to FN) visited.[87] The Respondent pharmacies knowingly pursued a course of deliberate ignorance, satisfying themselves in a sort of collective shrug that if there was ever a problem with a physician's COR, the insurance company would deny the claim. Tr. 201. Passively waiting to receive an insurance carrier claim rejection is not a responsible manner to discharge the duties of a registrant, and it certainly does not satisfy a registrant's obligation to ensure the authority of the issuer of the prescription. It is merely an effective manner to ensure payment.

The practice of relying on insurance carrier claim rejections as the principal means of due diligence is particularly egregious here. Moro-Perez testified that both pharmacies denied ''many'' of the controlled substance prescriptions written by Dr. Aguilar based on a review of the scrips submitted by his patients. Tr. 252–53. The pharmacies declined to fill these prescriptions based on the (repeated) professional judgment of the pharmacists that the scrips were invalid. Tr. 252. Yet, even armed with the knowledge that Dr. Aguilar was engaged in writing ''many'' illegitimate controlled substance prescriptions that could not legally be filled, Moro-Perez testified that his pharmacies never looked into Dr. Aguilar's practice or COR status in any way. Tr. 252–54. Instead, the Respondents blithely continued to fill Dr. Aguilar's prescriptions—and presumably, the pharmacies continued to receive payments. Tr. 250–52. Thus, it is clear on the present record that even though Dr. Aguilar had repeatedly given the professional staff working at both Respondent pharmacies reason to suspect his *bona fides* as a legitimate controlled substance prescriber, none of the Respondents' personnel was inspired to employ even the minimal effort that would have been required to check the status of his registration. Over and over again, the Respondents' pharmacists rendered their professional judgment that Dr. Aguilar was writing unsupported controlled substance prescriptions that were so sufficiently irregular that they were refused, yet they did not check into his authority beyond ensuring insurance carrier approvals for payments. It is a testament to the Respondents' irresponsibility (and exclusive focus on remuneration) that Moro-Perez acknowledged that if the DEA had not executed its search warrant on November 30, 2011, Farmacia Nueva would still be filling Dr. Aguilar's (unauthorized) controlled substance prescriptions. Tr. 202–03.

The Government's evidence established that, for thirty-four months, Farmacia Nueva filled over 140 prescriptions for controlled substances written by Dr. Aguilar on his expired COR. Gov't Ex. 5. Similarly, the Government's evidence demonstrated that during the same period, Best Pharma filled 32 controlled substance prescriptions written by Dr. Aguilar. Gov't Ex. 10. Respondents clearly violated their ''fundamental'' duties under the CSA by failing to ensure that Dr. Aguilar's COR was valid. *Holiday CVS,* 77 FR at 62341. In so doing, they breached their corresponding responsibilities as pharmacy registrants under Federal law to dispense only lawful prescriptions. *Liddy's Pharmacy,* 76 FR at 48895.

Thus, in addition to Element 1, the Government's evidence preponderantly established that the absence of a valid COR is a ''red flag'' that should have been known prior to dispensing (Element 2), and that (inasmuch as the deficiency revolved around Dr. Aguilar's lack of a valid registration) it was not and could not have been adequately resolved prior to dispensing controlled substances (Element 3). Having established all three elements, there is no question that each Respondent violated its corresponding responsibility under the regulations.

The record of both pharmacies indicates a clear disregard for following proper legal procedures designed to protect the public from the dangers of the unregulated dispensing of controlled substances. Furthermore, both pharmacies displayed a lack of motivation to follow through even the most basic of procedures, such as verifying a prescribing physician's COR. The Government's evidence that the Respondent pharmacies continued, for thirty-four months, to recklessly fill Dr. Aguilar's controlled substance prescriptions when he was unregistered and when they had actual knowledge that he was writing ''many'' illegitimate prescriptions negatively impacts

[87] Tr. 250–51.

both Factor 2 (experience in dispensing) and Factor 4 (compliance with federal controlled substance laws) and militates strongly in favor of the application denial sought by the Government.[88]

The Government's allegations regarding missing records/poor recordkeeping also relate to considerations under Factor Four. It is beyond argument that accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system designed by Congress. *See Gonzales* v. *Raich,* 545 U.S. at 13. ''Recordkeeping is one of the central features of the CSA's closed system of distribution. . . . 'A registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.' '' *Satinder Dang, M.D.,* 76 FR 51424, 51429 (2011) (internal punctuation and citations omitted) (quoting *Paul H. Volkman,* 73 FR 30630, 30644 (2008)). There is no question that the maintenance of accurate records by registrants is key to DEA's ability to fulfill its obligations to regulate controlled substances. *See Volkman,* 73 FR at 30644, *aff'd, Volkman* v. *U.S. DEA,* 567 F.3d 215, 224 (6th Cir. 2009) (specifically upholding the DEA Administrator's reliance on recordkeeping violations in denying a COR application). Thus, where established by reliable evidence, recordkeeping deficiencies may provide a reason—''which is sufficient by itself''—to find that the granting of a registration would be inconsistent with the public interest. *Id.* DEA has also held that non-compliance with recordkeeping obligations can lend ''substantial credence'' to allegations that a registrant is engaged in ''massive diversion.'' *Grider Drug #1 & Grider Drug #2,* 77 FR 44069, 44101 (2012). However, the Agency has also held that where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required. *Terese,* 76 FR at 46848.

In *Terese,* substantial evidence established that the registrant had failed to conduct an initial inventory as required under 21 CFR 1304.11(b), failed to execute a power of attorney form as required by 21 CFR 1305.05(a), and failed to include dates on DEA Forms 222 as required by 21 CFR 1305.13(e). *Id.* In declining to revoke Terese's registration, the Agency, emphasizing that the registrant had accepted responsibility for its violations and had instituted corrective actions, determined that, under the circumstances, the three recordkeeping violations did not render its continued registration inconsistent with the public interest. *Id.* at 46848. In *Ideal Pharmacy Care, Inc.,* an audit of the registrant's records showed a shortage of 150,000 dosage units of hydrocodone, 83,000 dosage units of alprazolam, and 1.6 million milliliters of promethazine with codeine. 76 FR 51415, 51416 (2011). However, in contrast to *Terese,* the Agency found[89] that Ideal Pharmacy's failure to maintain accurate records constituted an act that rendered its continued registration inconsistent with the public interest. *Id.* at 51416. Taken together, *Ideal* and *Terese* indicate that, when considering recordkeeping violations, the Agency has coupled consideration of the degree of severity of the non-compliance with an analysis of whether the registrant has both acknowledged culpability and demonstrated credible efforts aimed at correction. The current state of the Agency's precedent, thus, provides a logical framework upon which the current evidence can be evaluated.

DEA regulations provide that ''[e]very registrant required to keep records pursuant to § 1304.03[90] shall maintain on a current basis a complete and accurate record of each substance . . . imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.'' 21 CFR 1304.21(a). The regulations also mandate that ''every . . . record[] required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such . . . records, for inspection and copying by authorized employees of the [DEA].'' *Id.* § 1304.04(a). Pharmacy registrants, such as the Respondents used to be, are required to maintain separate records of Schedule II controlled substances, and to maintain records of controlled substances listed in Schedules III–V ''either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from the ordinary business records of the pharmacy.'' *Id.* § 1304.04(h). Readily retrievable is defined in the regulations as records kept ''in such a manner that they can be separated out from all other records in a reasonable time . . . .'' 21 CFR 1300.01(b).

On this record, the Government's allegations regarding alleged infirmities in the Respondents' recordkeeping are simply not supported by the presentation it made at the hearing. It is uncontroverted that both pharmacies used a computer program called ''RX30'' to manage and record prescriptions and corresponding dispenses. Tr. 234, 244. While DI Antoine testified that, consistent with the Government's allegations, there were missing records from the computer systems of both pharmacies,[91] the Government only offered exhibits relating to the missing records at Farmacia Nueva. Gov't Exs. 5–7.

Exhibits supplied by both the Government and Farmacia Nueva purport to constitute copies of all controlled substance prescription scrips filled for Dr. Aguilar's patients between January 31, 2009 to November 30, 2011. Gov't Ex. 5; Resp't Exs. 1, 2. It is uncontroverted that the RX30 system employed at Farmacia Nueva automatically affixes an informational heading at the top of each copy of a scrip that has been scanned into the system. Tr. 263. Both the Government's version and Farmacia Nueva's version contain scrip copies that display the informational heading and copies that do not.[92] DI Antoine testified that he assembled the Government's version of Dr. Aguilar's Farmacia Nueva scrips from material seized at the search warrant execution and from material forwarded by Moro-Perez in response to DEA's Supplemental Information Request. Tr. 23–25.

Moro-Perez, for his part, testified that he was able to generate a copy of all but one of every Aguilar controlled substance prescription scrip through a query of the Farmacia Nueva RX30 program. Tr. 203–04, 248; Resp't Exs. 1, 2. While it strains credulity that Moro-Perez would intentionally hold back material that could have conceivably cleared up the issue of missing scrips until the hearing process commenced, the Government (who bears the burden on this issue) presented no testimony or other evidence that would explain why its version should be deemed the more complete one. The Government presented no testimony from anyone who was present at the search warrant execution at Farmacia Nueva. Likewise, instead of calling DFE Gladieux, who extracted the digital information, the Government presented a terse, barebones declaration.[93] Gov't Ex. 15.

On the state of the present record, there is no way to determine which party has presented the more persuasive set of the Aguilar prescription scrips maintained at Farmacia Nueva. DFE Herrmann, the DEA digital forensic examiner who analyzed the data pulled from FN's RX30 program, acknowledged the possibility of a ''margin for error,''[94] but testified that she was able to create a duplicate of the Farmacia Nueva computer as it existed on the day the data was extracted from it. Tr. 141–42. The Government initially alleged that Best Pharma and Farmacia Nueva did not maintain controlled substance scrips authorized by Dr. Aguilar, but withdrew and/or did not proceed on all of the Best Pharma scrips[95] and many of the Farmacia Nueva scrips when the Respondents pointed out in a prehearing motion[96] that the noticed scrips included non-controlled substances. Farmacia Nueva was able to produce purported copies of scrips for all but two (H00751567 & 00805523) of the (reduced number of) Aguilar scrips that the Government alleged as missing.[97] Resp't Exs.

[88] In view of the lengthy (34-month) period of time during which the scrips of (unregistered) Dr. Aguilar were filled, it is not necessary to discern exactly when the duty to re-check COR credentials emerges. A more precise divination of that issue may require resolution on different facts in another case.

[89] The registrant in *Ideal* waived its right to a hearing and presented no evidence to the Agency on its behalf. *Ideal,* 76 FR at 51415.

[90] Section 1304.03(a) provides that ''[e]ach registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.'' 21 CFR 1304.03(a). The record contains no contention that any of the § 1304.03 exemptions apply in this case.

[91] Tr. 23–25, 96.

[92] Resp't Ex. 2, at 143–44; Gov't Ex. 5, at 1–6.

[93] At the hearing, Government counsel represented that Gladieux was local and available, but not called as a witness because he felt that the declaration was sufficient. Tr. 135–37.

[94] Tr. 155.

[95] In its closing brief, the Government made no mention of the Best Pharma recordkeeping allegations. ALJ Ex. 24, at 25.

[96] ALJ Ex. 10.

[97] So much of the Government's evidence in this regard was withdrawn or readily contradicted by

Continued

1–2, 4. While admittedly true that Farmacia Nueva did little to explain the origin, structure, or reliability of its own scrip-related exhibits, the Government produced no credible challenge to Farmacia Nueva's purported scrip copies and declined to challenge their admission into evidence. Tr. 249, 257, 264–65. Even though he was not unavailable, DFE Gladieux, the technician who imaged the Farmacia Nueva computer, was not called as a witness to explain the data extraction process or defend its integrity and completeness. It is also worth noting here that Moro-Perez never explained why, if the FN scrips in question did exist and were available from the outset, they were not forwarded to the Government with his Response to Government Administrative Request for Information,[98] wherein he provided the assurance that ''all of the requested prescriptions'' were included—a position he re-affirmed during his testimony. Tr. 206–08. Still, the Government presented no evidence whatsoever in support of its BP recordkeeping allegations, and, with respect to Farmacia Nueva, its evidence was confusing and wholly unpersuasive. It would be virtually impossible on the present record to assign one party's batch of copied, purported prescriptions more credibility than the other party's batch in any manner that could be logically defended on appeal. In this mutually confusing contest of admitted evidence, it was the Government that bore the burden to establish the violations of the laws it had alleged. Regarding the recordkeeping allegations, its burden was simply not carried.

Accordingly, to the extent the Government alleged that the Respondents violated 21 U.S.C. 827(b)(1) and 21 CFR 1304.04 by failing to maintain controlled substance scrips authorized by Dr. Aguilar, those allegations are not sustained.

That said, the Respondents' actions in filling Dr. Aguilar's controlled substance prescriptions over the course of over two and a half years without checking his (expired) COR status in any logical manner, even though pharmacy personnel had rejected ''many'' of his prescriptions as illegitimate, balance powerfully in favor of denying both COR applications under Factors Two and Four.

Recommendation

Based on the foregoing, the Government has established that the Respondents have submitted COR applications that bear material falsifications [99] and have committed acts that are inconsistent with the public interest. 21 U.S.C. 823(f). Accordingly, the Government has sustained its *prima facie* burden to establish that the Respondents' COR applications should be denied. Hence, under established Agency precedent, the burden is shifted to the Respondents to demonstrate that each can be entrusted with a DEA registration.

''[T]o rebut the Government's *prima facie* case, [the Respondents are] required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Hassman,* 75 FR at 8236; *see Hoxie,* 419 F.3d at 483; *Lynch,* 75 FR at 78754 (holding that a respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Mathew,* 75 FR at 66140, 66145, 66148; *Aycock,* 74 FR at 17543; *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387. The acceptance of responsibility is a condition precedent for the Respondents to prevail once the Government has established its *prima facie* case. *Mathew,* 75 FR at 66148. This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Mackay,* 664 F.3d at 822. In determining whether and to what extent a sanction, such as denial of an application, is appropriate, consideration must be given to both the egregiousness of the offenses established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Ruben,* 78 FR at 38364, 38385.

The issue of acceptance of responsibility presents something of a mixed bag for the Respondents. Moro-Perez, the owner/president of both Respondent pharmacies, spoke on their behalf and, through counsel, represented their interests. As discussed in more detail, *supra,* the pharmacies are responsible for his actions. *See EZRX,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR at 36911. Moro-Perez acknowledged that he and his staff substituted what was essentially affirmative payment notification by insurance carriers in place of their responsibility to ensure that prescribing physicians, such as Dr. Aguilar, have valid CORs. The representations rendered by Moro-Perez and echoed by Farmacia Nueva PIC Nelson Vale regarding their intent to be more careful and purchase computer screens in the future were too amorphous to provide evidence sufficient to engender enough confidence that the pharmacies should be entrusted with CORs in the future. The Farmacia Nueva and Best Pharma PICs told DI Antoine that, as recently as two weeks prior to this hearing, no written controlled substance handling procedures had been promulgated by either pharmacy.[100] Tr. 107. Even if the tacit admissions of wrongdoing by Moro-Perez were embraced as sufficient acceptance of responsibility to carry the pharmacies' burden (a dubious proposition), the showing of remedial measures is too weak to carry the day. In like manner, the intentional decision by an experienced registrant to have his staff substitute insurance approvals for COR checks over the course of over two years is bad enough, but when coupled with the actual knowledge by the Respondent pharmacies that Dr. Aguilar had written ''many'' bad controlled substance prescriptions, it elevates the level of egregiousness to a point where it militates powerfully in favor of denial of the CORs. While true that the Government's failure to sustain its recordkeeping allegations substantially diminishes the gravity to be attached to the 2008 Letter of Admonition,[101] it is still relevant that Moro-Perez had been counseled once by the Agency to exercise an appropriate level of care, and that the Agency's warning did not inspire sufficient vigilance to check the COR status of a prescribing physician who was engaged in writing ''many'' bad controlled substance prescriptions. To grant registrations in the face of such conduct would be a statement to the regulated community of pharmacy registrants that employing a patently infirm system of COR checks for prescribing physicians can serve as an effective shield to the consequences of failure to exercise due care. Thus, the Agency's interests in deterrence also weigh in favor of denial of the requested registrations.

In their closing brief, the Respondents argue that mitigation is found in: (1) what they posit as a relatively modest number of dispensed prescriptions issued by (unregistered) Dr. Aguilar; (2) ''minimal'' pecuniary gain to the registrants that resulted in filling Dr. Aguilar's scrips; (3) their continuing representation that the Respondents' pharmacists actually turned down ''many'' of Dr. Aguilar's controlled substance prescription that were illegitimate; (4) the fact that forty employees working at the Respondent pharmacies stand to lose their jobs upon an unfavorable decision by the Agency on the applications; and (5) that the Government offered no evidence that any of the scrips in question were for other than a legitimate medical purpose. ALJ Ex. 24, at 20–21, 26. None of these arguments, all but one of which are offered under an apparent theory that ''it could have been worse,'' are persuasive on the present record.

While the Respondents characterize the number of the Dr. Aguilar scrips during the relevant period as modest in comparison to the pharmacies' other business, their numbers (even if assumed as accurate) do not further their cause. These dispensing events were executed during a time when the pharmacies had no rational system for checking the COR status of any of the prescribers whose scrips they were filling. To compare the Dr. Aguilar scrips with the scrips of other physicians while the pharmacy was not checking anyone's COR

evidence offered by the Respondent that it would be difficult to assign persuasive weight to even the two instances where the Respondent did not produce corresponding scrips. Stated differently, the Government's evidentiary presentation in this regard was simply too shaky and shifting to merit sufficient confidence to sustain the allegations. But even if the Government's evidence was deemed sufficiently reliable to believe that two Aguilar scrips were not maintained in accordance with the regulations, Agency precedent provides support for the proposition that, standing alone, these two missing scrips would not have been a sufficient violation to merit the application denial the Government seeks. *See Terese,* 76 FR at 46848 (determining that three recordkeeping violations that were acknowledged and timely corrected were insufficient to warrant COR revocation).

[98] Gov't Ex. 4, at 2–3.

[99] 21 U.S.C. 824(a)(1).

[100] While Moro-Perez made a fleeting reference to a ''continuing education'' that he participated in after the execution of the search warrant (Tr. 203), there was no evidence as to what the class covered or whether it was in any way related to controlled substance diversion issues.

[101] Gov't Ex. 3. Indeed, none of the deficiencies cited in the Letter of Admonition are the basis of any allegation in these proceedings.

status confounds logic. Stated differently, the level of care exercised on Dr. Aguilar's scrips was the same as every other controlled substance scrip issued during the relevant period. The Agency has revoked based on as few as two acts of intentional diversion, and it held that one such act can be sufficient. *MacKay,* 75 FR at 4997; *Krishna-Iyer,* 74 FR at 463. While the dispensing acts proven on this record may not have been intentional, there were certainly well more than one or two.

Similarly, that the Respondents argue (without specific figures) that they have made ''minimal'' pecuniary gain due to their lack of care helps their respective causes not at all. A reduced profit margin is no more persuasive evidence in the context of a registrant pharmacy as it would be in the case of a street dealer in illicit drugs. The focus is on maintaining a closed regulatory system that protects the public from the unlawful distribution of controlled substances. *Gonzales,* 545 U.S. at 13. A registrant's voluntary decision to abandon the most basic of its registrant obligations should not result in any profit. Further, as is true with the Respondents' argument regarding the relative percentage of scrips that can be attributed to Dr. Aguilar, in an environment where no serious COR checking was employed, there is no basis in reason for evaluating the money Moro-Perez's pharmacies made from prescriptions authorized by Dr. Aguilar as compared to those by other practitioners. Who knows which of the issuing prescribers were actually registered? Hence, that the ''pecuniary benefits gained'' from dispensing controlled substances on Dr. Aguilar's scrips ''is minimal'' [102] means nothing and mitigates nothing.

As discussed in detail, *supra,* the Respondents argument that they turned down ''many'' of Dr. Aguilar's prescriptions they thought to be illegitimate actually exacerbates the pharmacies' positions. Turning down ''many'' prescriptions from Dr. Aguilar that pharmacists determined to be illegitimate should have caused increased circumspection about dispensing on Aguilar's scrips. Instead, even by their own account, the pharmacies identified Dr. Aguilar as a problematic prescriber, never checked his COR status, and kept dispensing many of the prescriptions he authorized.

In their closing brief, the Respondents ask that, in making its decision on the COR applications, the Agency consider that ''[t]here are . . . more than 40 employees among two pharmacies whose welfare depend on their jobs at the pharmacies [and that in] small towns like San Sebastian and Moca in Puerto Rico, this means a lot.'' ALJ Ex. 24, at 21 (internal transcript citations omitted). Even setting aside for a moment Moro-Perez's testimony that controlled substances account for only 10–15% of the prescription medications dispensed at each of the Respondent pharmacies,[103] any blame for the lost jobs must properly be laid at the feet of the Respondents themselves, and Moro-Perez in particular. It is settled Agency precedent that normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration in determining whether status as a COR registrant is in the public interest within the meaning of the CSA. *Cheek,* 76 FR at 66972–73; *Owens,* 74 FR at 36757; *Abbadessa,* 74 FR at 10078.

Finally, insofar as the Respondents point to the fact that the Government's theory of the case and its evidence have never relied on the absence of a legitimate medical purpose (LMP) for any of the scrips in question, it is certainly true that the Agency has looked at the LMP issue where prescriptions were issued by a prescriber who lacked proper authorization. *Kam,* 78 FR at 62698. However, that the Government has advanced no LMP evidence does not mitigate the evidence that was received regarding the Respondents' breach in their respective duties of due care in ensuring that controlled substance prescriptions were authorized by a practitioner with a valid COR.

Regarding the material false misrepresentations intentionally placed into the COR applications, Moro-Perez doggedly adhered to his illogical position that he was reasonable in representing on the COR applications that neither pharmacy had ever surrendered a registration for cause. By Moro-Perez's intractable logic, the dismissal of an indictment against him (not either pharmacy) that occurred after the for-cause surrender of Best Pharma's COR, but before the for-cause surrender of Farmacia Nueva's COR, rendered both surrenders no longer ''for cause.'' Moro-Perez is an experienced COR holder and an educated, veteran pharmacist. His insistence that his false response to an application query regarding whether each pharmacy had ever surrendered a COR for cause was some sort of reasonable misunderstanding is simply not credible and defeats the Respondents' efforts to meet the Government's case. The false misrepresentation regarding the errant denial of the Respondents' prior surrenders for cause are sufficiently egregious on their face to warrant sanction, and the denial of the Respondents' applications here serve the Agency's interest in deterring false statements on the applications that it depends upon in its decisionmaking.

The Respondents have, thus, failed to rebut the Government's *prima facie* case regarding either material falsification of their applications or a balancing of the public interest factors. Further, consideration of the egregiousness of the offenses, coupled with the Agency's interest in both specific deterrence regarding these pharmacies, and general deterrence among the regulated community, supports the denial of both COR applications. Accordingly, the Respondents' respective applications for DEA Certificates of Registration should be DENIED.

Dated: October 24, 2013.

s/JOHN J. MULROONEY, II,

Chief Administrative Law Judge.

[FR Doc. 2015–12043 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

[102] ALJ Ex. 24, at 21.

[103] Tr. 244–45.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–27]

Maryanne Phillips-Elias, M.D.; Decision and Order

On October 23, 2014, Administrative Law Judge (ALJ) Christopher McNeil issued the attached Recommended Decision. Therein, the ALJ found that it was undisputed that Respondent's Nevada Controlled Substance Registration had been revoked and that she does not possess authority to dispense controlled substances in Nevada, the State in which she holds her DEA registration. R.D. at 6; *see also id.* at 2. The ALJ thus concluded that Respondent is no longer a practitioner within the meaning of the Controlled Substances Act and is therefore not entitled to be registered. He therefore recommended that I ''deny Respondent's application for a DEA Certificate of Registration.'' R.D. at 9.

There is, however, no evidence that an application is currently pending before the Agency. Rather, the Government seeks the revocation of Respondent's registration, which does not expire until March 31, 2017, and authorizes her to dispense controlled substances in schedules II through V, at registered premises located in Henderson, Nevada. Order to Show Cause, at 1.

Pursuant to 21 U.S.C. 824(a)(3), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had [her] State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' This Agency has further held that notwithstanding that this provision grants the Agency authority to suspend or revoke a registration, other provisions of the Controlled Substances Act ''make plain that a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.'' *James L. Hooper,* 76 FR 71371, 71372 (2011), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012).

These provisions include section 102(21), which defines the term ''practitioner'' to ''mean[ ] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which [s]he practices . . . to distribute, dispense, [or] administer . . . a

controlled substance in the course of professional practice,'' 21 U.S.C. 802(21), as well as section 303(f), which directs that ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which [s]he practices.'' *Id.* § 823(f). Based on these provisions, the Agency has long held that revocation is warranted even where a state order has summarily suspended a practitioner's controlled substances authority and the state agency's order remains subject to challenge in either administrative or judicial proceedings.[1] *See Gary Alfred Shearer,* 78 FR 19009 (2013); *Carmencita E. Gallora,* 60 FR 47967 (1995).

Respondent argues that she ''should be given a hearing to present evidence to refute the legitimacy of the revocation'' of her state registration by the Nevada Pharmacy Board. Respondent's Reply to the Govt.'s Mot. for Summary Judgment, at 2. According to Respondent, the Nevada Board's Order is invalid ''because the Board never identified the specific grounds for which [her] license should be revoked in Nevada.'' *Id.* at 3.

Respondent thus seeks to collaterally attack the Nevada Board's Order. However, '''DEA has repeatedly held that a registrant cannot collaterally attack the results of a state criminal or administrative proceeding in a proceeding brought under section 304 [21 U.S.C. 824] of the CSA.''' *Calvin Ramsey,* 76 FR 20034, 20036 (2011) (quoting *Hicham K. Riba,* 73 FR 75773, 75774 (2008) (other citations omitted)); *see also Shahid Musud Siddiqui,* 61 FR 14818 (1996); *Robert A. Leslie,* 60 FR 14004 (1995). Respondent must therefore seek relief from the State Board's Order in those administrative and judicial forums provided by the State. Her various contentions as to the validity of the Nevada Pharmacy Board's order are therefore not material to this Agency's resolution of whether she is entitled to maintain her DEA registration.

As for her argument that the Agency's use of summary disposition to revoke her DEA registration has denied her ''fundamental fairness'' because DEA regulations provide that she is entitled to a hearing, Resp. Reply at 3; ''summary judgment has been used for more than 100 years to resolve legal 'actions in which there is no genuine issue as to any material fact' and has never been deemed to violate Due Process.'' *Ramsey,* 76 FR at 20036 (citing Fed. R. Civ. P. 56 (Advisory Committee Notes—1937 Adoption) and *Codd* v. *Velger,* 429 U.S. 624, 627 (1977)). Respondent was provided with the opportunity to dispute the material fact which is dispositive of the Government's allegation that she lacks authority to dispense controlled substances in the State in which she is registered and therefore cannot remained registered. I thus reject her contention that the use of summary disposition denied her fundamental fairness.

Accordingly, for reasons explained above and with the caveat that there is no application pending before the Agency, I adopt the ALJ's factual finding that Respondent's Nevada controlled substance registration has been revoked and therefore she does not possess authority under Nevada law to dispense controlled substances. I further adopt the ALJ's legal conclusion that Respondent is no longer a practitioner within the meaning of the CSA and is therefore not entitled to be registered. However, because there is no application currently pending before the Agency, I do not adopt those portions of his opinion which discuss whether Respondent's application should be granted or denied, including his Recommendation that I deny her application. Instead, for reasons explained above, I will order that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 28 CFR 0.100(b) I order that DEA Certificate of Registration FP2501648 issued to Maryanne Phillips-Elias be, and it hereby is, revoked. This Order is effectively immediately.

Dated: May 1, 2015

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq., for the Government.

Michael Khouri, Esq., and *Ashley K. Kagasoff, Esq.,* for the Respondent.

[1] I thus also reject Respondent's contention that because she ''has not acted [in a manner] inconsistent with [the] public interest as laid out in'' section 823(f), ''DEA has discretion to carve out an exception in this case'' to the CSA's requirement that she possess state authority to hold a DEA registration. Resp. Reply, at 4. As explained above, this is a requirement imposed by statute which DEA has no authority to waive.

RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Case and Procedural History

Administrative Law Judge Christopher B. McNeil. Maryanne Phillips-Elias, M.D., the respondent in this case, is registered with the DEA as a practitioner in Schedules II through V under Drug Enforcement Administration (DEA) certificate registration number FP2501648 at 9065 S. Peco Rd., Ste. 250, Henderson, NV 89074.[1] The registration number expires by its own terms on March 31, 2017.[2]

On September 17, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause as to why the DEA should not revoke her current certificate of registration, deny any applications for renewal or modification, and deny any application for any other DEA registration pursuant to 21 U.S.C. 823(f) and 21 U.S.C. 824(a)(3).[3] As grounds for revocation, the Government alleges that Respondent does not have authority to handle controlled substances in Nevada, the State in which Respondent is registered with the DEA.[4]

On September 26, 2014, Respondent, through her Attorneys, Ashley K. Kagasoff, Esq., and Michael Khouri, Esq., filed a timely request for hearing.[5] Respondent does not dispute that her controlled substance registration was revoked by the Nevada State Board of Pharmacy.[6] Instead, Respondent asserts that the Nevada State Board of Pharmacy acted on grounds that did not warrant discipline and that the Board's decision was arbitrary.[7] Respondent has a writ, *Maryanne Phillips* v. *Nevada State Board of Pharmacy,*[8] pending in the First Judicial Court of Carson City County, Nevada to set aside the decision to revoke Respondent's registration.[9] Respondent asks me to delay any hearing until the writ is resolved.[10] Alternatively, if the delay is not granted, Respondent expresses her wish to continue with the hearing as planned.[11]

[1] Order to Show Cause dated Sept. 17, 2014 at 1.

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] Respondent's Request for Hearing dated Sept. 23, 2014 at 1, received by DEA Sept. 26, 2014.

[6] *Id.*

[7] *Id.*

[8] Case No. 14–OC–00064.

[9] Respondent's Request for Hearing at 1.

[10] *Id.*

[11] *Id.*

I received the Government's Motion for Summary Judgment on October 8, 2014, with proof of service upon Respondent, accompanied by supporting documentation.[12] In my Order of September 30, 2014, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances.[13] The factual premise relied upon by the Government in support of its motion is that Respondent does not have a controlled substance registration issued by the Nevada State Board of Pharmacy, the state in which Respondent is registered.[14] Additionally, in the same Order, I provided Respondent the opportunity to respond to the Government's Motion for Summary Judgment.[15] That response was due seven business days after service of the Government's motion on opposing parties.[16] On October 17, 2014, I received Respondent's timely response.[17] The Government exercised its right to reply to the response and submitted a reply on October 22, 2014.[18] Drawing from the motion and briefs submitted, I find as follows:

Issue

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a controlled substance registration issued by the state in which she intends to practice.[19] Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which she maintains DEA registration.[20] Unless from the pleadings now before me there is a material issue regarding Respondent's authority to handle controlled substances in Nevada, the application must be denied summarily, without a hearing.

Respondent's Contentions

In Respondent's Reply to the Motion for Summary Judgment, Respondent never disputes the Government's contention that she is not currently licensed by the State of Nevada to dispense controlled substances.[21] Instead, Respondent asserts three legal arguments. Respondent's first legal argument is that Respondent should be given a hearing to present evidence to refute the legitimacy of the revocation.[22] Respondent states her belief that the matter should be determined following the resolution of Respondent's writ and that the Nevada State Board of Pharmacy relied on insufficient grounds to revoke her state controlled substance registration.[23] Respondent's second argument is that she has been denied fundamental fairness by the DEA.[24] Respondent writes that ''it does not make any sense that Respondent is given the right to a hearing only to get denied one, once the request is made.'' [25] Finally, Respondent asserts that the DEA has discretion to do what is in the best interest of promoting the public interest.[26] After stating the five public interest factors provided by 21 U.S.C. 823(f), Respondent declares that allowing her to retain her license is not inconsistent with the public interest.[27]

Scope of Authority

On September 17, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f).[28]

Respondent believes that she should be given a hearing to present evidence to refute the legitimacy of the revocation following the resolution of Respondent's writ to demonstrate that the Nevada State Board of Pharmacy relied on insufficient grounds to revoke her state controlled substance registration.[29] However, the case before me is presented under a grant of authority to recommend that the Administrator either continue or revoke Respondent's Certificate of Registration for controlled substances. Pursuant to 21 U.S.C. 823(f), the DEA may grant such an application only to a ''practitioner.'' Under 21 U.S.C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to grant a registration to a practitioner if that practitioner is not authorized to dispense controlled substances.[30]

The fact that Respondent is currently in the process of appealing what she views as an unjust decision of the Nevada State Board of Pharmacy does not change this outcome. As the Government notes, the assertion that she might prevail in overturning the Board's revocation order is ''highly speculative.'' [31] Even if Respondent was very likely to succeed on appeal, summary disposition is still appropriate. As the Government notes in its Reply in Support of its Motion for Summary Judgment, ''[a]ll that matters is that Respondent lacks state authority to dispense or distribute controlled substances.'' [32] Under no circumstances is the DEA authorized to provide a doctor, such as Respondent, the ability to dispense controlled substances when the doctor does not possess their state controlled substance registration. This limitation is not without meaning. In the first subchapter of the Controlled Substances Act (CSA), 21 U.S.C. 801,

[12] Government's Motion for Summary Judgment dated Oct. 7, 2014 at 1–18, received by DEA Oct. 8, 2014.

[13] Order for Briefing on Allegations Concerning Respondent's Lack of State Authority dated Sept. 30, 2014 at 1.

[14] Government's Motion for Summary Judgment at 1–3.

[15] Order for Briefing on Allegations Concerning Respondent's Lack of State Authority at 2.

[16] *Id.*

[17] Respondent Maryanne Phillips-Elias, M.D. Reply to the Government's Motion for Summary Judgment and Declaration of Ashley K. Kagasoff in Support Thereof dated Oct. 16, 2014 at 1. Note that the fax was received at 6:00pm E.D.T. on October 16, 2014. As the document was received after normal business hours, the document is treated as if it was received on October 17, 2014. Regardless, the response was timely received.

[18] Government's Reply in Support of its Motion to Summary Judgment dated Oct. 22, 2014 at 1.

[19] Government's Motion for Summary Judgment at 1–2.

[20] *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also House of Medicine,* 79 FR 4959, 4961 (DEA 2014); *Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA November 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA August 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA April 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA April 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA November 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[21] Reply to the Government's Motion for Summary Judgment at 2.

[22] *Id.*

[23] *Id.* at 2–3.

[24] *Id.* at 3.

[25] *Id.*

[26] *Id.* at 4.

[27] *Id.*

[28] Order to Show Cause at 1.

[29] Reply to the Government's Motion for Summary Judgment at 2–3.

[30] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA November 24, 1992), and cases cited therein. In *Chaplan,* DEA Administrator Robert C. Bonner adopts the ALJ's opinion that ''the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances.'' *Id.*

[31] Government's Motion for Summary Judgment at 3.

[32] Government's Reply in Support of its Motion to Summary Judgment at 2.

Congress acknowledged that controlled substances when utilized improperly ''have a substantial and detrimental effect on the health and general welfare of the American people.'' [33] Mandating that a practitioner possess state authority before providing a practitioner the privilege to handle controlled substances lowers the risk of diversion by illegitimate or unqualified practitioners.

Respondent also alleges that she has been denied fundamental fairness by the DEA.[34] Specifically, Respondent cites that fact that the Government's Order to Show Cause provides her notice of the opportunity of a hearing to show cause why the DEA should not revoke her DEA certificate of registration, but later denies her a hearing.[35] Although Respondent may believe it is unfair that the DEA denies her a hearing after issuing an Order to Show Cause, Respondent has failed to show that any disputed material fact is involved regarding her state controlled substance registration. If Respondent through her Reply to Government's Motion for Summary Judgment demonstrated that there was a dispute as to the material fact of whether her state controlled substance registration was revoked, I would not have dismissed this case without a comprehensive hearing. However, the inability for the DEA to grant Respondent a DEA certificate of registration without a valid state controlled substance registration prevents further consideration of this matter.

Respondent's final argument is that the DEA has discretion to act in the public interest to not revoke Respondent's federal certificate of registration.[36] In her Reply to Government's Motion for Summary Judgment, Respondent correctly notes that to determine whether a DEA certificate of registration is in the public interest, a DEA ALJ must consider the factors enumerated under 21 U.S.C. 823(f).[37] Respondent proceeds to apply the factors to her specific situation to make the argument that she should not lose her DEA certificate of registration.[38] Quoting the Declaration of Ashley Kagasoff,[39] Respondent cites statements such as that she has never been convicted of a federal or state crime to support the notion that not revoking her DEA COR is consistent with the public interest.[40] Such statements made by Respondent are unpersuasive. If Respondent is successful in her writ and her state license to dispense controlled substances is restored, she is welcome to immediately apply for a new DEA certificate of registration. If Respondent's application for a new registration is opposed by the DEA and Respondent exercises her right to a hearing, it is at that time—not before that time—that a DEA ALJ will hear evidence from both Respondent and the Government as to whether the registration is consistent with the public interest.

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of Nevada to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.[41] The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes no dispute regarding the Government's contention that the authority of Dr. Phillips-Elias to dispense controlled substances in Nevada was revoked by the Nevada State Board of Pharmacy on June 13, 2014.[42] The reasons for the revocation are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government's Motion for Summary Disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory—even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted).[43]

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, ''it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing.'' [44] Under this guidance, the Government's motion must be sustained unless a material fact question has been presented.

The sole determinative fact now before me is that Respondent lacks a Nevada controlled substance registration. In order for a doctor to receive a DEA registration authorizing her to dispense controlled substances under 21 U.S.C. 823(f), she must meet the definition of ''practitioner'' as found in the Controlled Substances Act.[45] Such a person must be ''licensed, registered, or otherwise permitted by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' [46] Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to ''practitioners'' as defined by the Controlled Substances Act.[47]

As cited by the Government in its Motion for Summary Judgment, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that a doctor's DEA controlled substance registration is dependent upon the doctor having a state license to dispense controlled substances.[48] Under the doctrine before me, the Government meets its burden of

[33] Controlled Substances Act. 21 U.S.C. 801(1). 1970.

[34] Reply to the Government's Motion for Summary Judgment at 3. Respondent's allegation does not directly allege a violation of her constitutional right to due process. Respondent's failure to make a conspicuous claim regarding due process has led to a waiver of this constitutional claim. However, if Respondent chooses to submit exceptions to this order referencing her constitutional right to due process, she may succeed in preserving the issue for appeal.

[35] *Id.* at 3; Order to Show Cause at 1.

[36] Reply to the Government's Motion for Summary Judgment at 4–5.

[37] *Id.* at 4. *See also* 21 U.S.C. 823(f).

[38] Reply to the Government's Motion for Summary Judgment at 4–5.

[39] *See* Declaration of Ashley K. Kagasoff in Support Thereof.

[40] Reply to the Government's Motion for Summary Judgment at 4.

[41] *See Michael G. Dolin, M.D.,* 65 FR 5661 (DEA February 4, 2000); *see also Philip E. Kirk, M.D.,* 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984).

[42] Order to Show Cause at 1.

[43] *NLRB* v. *International Assoc. of Bridge,* 549 F.2d 634, 638 (9th Cir. 1977) (quoting *United States* v. *Consolidated Mines & Smelting Co., Ltd.,* 455 F.2d 432, 453 (9th Cir. 1971)).

[44] *See Michael G. Dolin, M.D.,* 65 FR 5661 (DEA February 4, 2000); *Jesus R. Juarez, M.D.,* 62 FR 14945 (DEA March 28, 1997); *see also Philip E. Kirk, M.D.,* 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984).

[45] 21 U.S.C. 802(21).

[46] *Id.*

[47] 21 U.S.C. 823(f).

[48] Government's Motion for Summary Judgment at 1–3 and cases cited therein.

establishing grounds to deny an application for registration upon sufficient proof establishing the applicant does not possess a state controlled substance registration. That proof is in the record before me, and it warrants the summary revocation of Respondent's DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in her Reply to the Government's Motion for Summary Judgment, including the fact that Respondent is currently appealing the revocation of her state controlled substance registration.[49] These difficulties do not, however, change the fact that without a state controlled substance registration, Respondent is not a ''practitioner'' and cannot be granted a Certificate of Registration.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. In the proceedings now before me, the only material question was answered by Respondent in her Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which she seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition.

[49] Reply to the Government's Motion for Summary Judgment at 2–3.

Accordingly, I **GRANT** the Government's Motion for Summary Disposition.

Upon this finding, I **ORDER** that this case be forwarded to the Administrator for final disposition and I **RECOMMEND** the Administrator **DENY** Respondent's application for a DEA Certificate of Registration.

Dated: October 23, 2014.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015–12023 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–13]

Sharad C. Patel, M.D.; Decision and Order

On March 11, 2015, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (cited as R.D.). Thereafter, on April 1, Respondent filed a pleading entitled as ''Objections to Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge (hereinafter, Resp. Objections). Therein, Respondent objected to the entry of the ALJ's Recommended Decision, on the ground that ''he was never properly, or sufficiently, served with the [Government's] initial motion'' for summary disposition and therefore ''did not respond to the . . . [m]otion . . . because he was unaware of any such motion until the ALJ's Order granting such motion.'' Objections, at 1.

Respondent argues that in his request for hearing, his attorneys provided both a mailing address and email address for receiving the ''notices to be sent pursuant to the proceeding.'' 21 CFR 1316.47(a); Objections at 1. Respondent did not, however, provide a fax number. *Id.* at 2.

Thereafter, Respondent received the ALJ's Order for Briefing on Allegations Concerning Respondent's Lack of State Authority'' by First Class Mail. *Id.* The ALJ's Order specified the date (Mar. 2, 2015) by which the Government was to provide its evidence and arguments (as well as its motion for summary disposition) in support of its contention that Respondent does not possess ''state authority to handle controlled substances,'' as well as the date by which Respondent was to file his response (Mar. 9) to any such motion. *Id.*

On March 2, the Government filed its Motion for Summary Disposition with the Office of Administrative Law Judges. Motion for Summ. Disp., at 1. In the Certificate of Service, the Government represented that it had served the Motion by facsimile, but not by first class mail or email.[1] *Id.* at 4. In its Objections, Respondent asserts that he ''did not respond to the DEA Motion for Summary Disposition because he was unaware of any such motion until the ALJ's Order granting such motion.'' Objections, at 1.

As stated above, on March 11, the ALJ issued his Recommended Decision. Therein, the ALJ noted that the Government had attached a copy of the Emergency Order of Suspension issued by the Kentucky Board of Medical Licensure; the Order, which was issued on November 24, 2014, suspended Respondent's Kentucky medical license ''effectively immediately upon its receipt.'' Mot. For Supp. Disp., Attachment 1, at 18.

In his Recommended Decision, the ALJ noted that Respondent had not filed a response to the Government's motion. R.D. at 2. However, the ALJ also noted that in his hearing request, Respondent had ''admit[ted] that his license is temporary [sic] suspended'' but that ''he expects to prevail before the medical board at an upcoming hearing on May 18, 2015.'' *Id.* at 3. As explained in his decision, the ALJ found that there was no dispute that Respondent ''is not authorized to handle controlled substances in the State in which he maintains his registration'' and is therefore not a practitioner within the meaning of the Controlled Substances Act. *Id.* The ALJ thus recommended that Respondent's registration be revoked and that any pending application be denied.

Thereafter, the ALJ forwarded the record to me, noting in his letter that Respondent's objections were not timely filed. Letter from ALJ to Administrator (Apr. 7, 2015), at 2. The ALJ also provided a copy of a Transmission Verification Report showing that the Recommended Decision was successfully faxed to Respondent's

[1] Respondent's contention regarding the inadequacy of service is not without merit. Of note, Respondent did not consent to the service of pleadings by facsimile and the ALJ's Order for Briefing on Allegation Concerning Respondent's Lack of State Authority did not authorize service of pleadings in this manner. Moreover, while the use of electronic means has the advantage of faster service—at least where the transmission is successful—a hard copy should still be sent by mail, courier, or third party commercial carrier unless the serving party contacts the other party and affirmatively determines that the entire document was received.

counsel on March 11. Thus, Respondent's Objections (which I have treated as his Exceptions) were not received until day twenty-one, one day after they were due.[2] *See* 21 CFR 1316.66(a). Having offered no explanation for why his Objections were late, I agree with the ALJ's finding that Respondent's Objections were out of time.

In any event, in his Objections, Respondent does not dispute that he remains without authority to handle controlled substances in State of Kentucky. Objections, at 3. Rather, he seeks a delay in responding to the Government's Motion until July 1, 2015 on the ground that the State's ''suspension is temporary [and] was not issued after a full and fair hearing on the issues,'' and that ''[t]he sole support for the Government's Motion . . . is the temporary action taken by the state medical board.'' *Id.* He further contends that he ''is vigorously defending himself from the unwarranted suspension of his Kentucky medical license and believes he will ultimately prevail'' and have his medical license and state controlled substance authority restored. *Id.*

However, the Agency has long held that ''a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.'' *James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012). This holding is derived from the plain meaning of two provisions of the Controlled Substances Act.

The first is section 102(21), which defines the term ''practitioner'' to ''mean[ ] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). The second is section 303(f), which sets forth the criteria for obtaining a practitioner's registration and which explicitly provides that ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . *if the applicant is authorized to dispense* . . . controlled substances under the laws of the State in which he practices.'' *Id.* § 823(f) (emphasis added). Based on these provisions, the Agency has long held that revocation is warranted even where a state order has summarily suspended a practitioner's controlled substances authority and the state agency's order remains subject to challenge in either administrative or judicial proceedings. *See Gary Alfred Shearer,* 78 FR 19009 (2013); *see also Newcare Home Health Services,* 72 FR 42126, 42127 n.2 (2007) (collecting cases and holding that ''ALJ properly rejected . . . request for stay'' and that ''[i]t is not DEA's policy to stay proceedings under section 304 while registrant litigate in other forums'').

According to the allegations of the Show Cause Order, Respondent's registration was not due to expire until March 31, 2015. Thus, at the time the ALJ issued his decision, Respondent still held a DEA registration. However, at the time the case was forwarded to my Office, the record contained no evidence as to whether Respondent had filed a timely renewal (or even an untimely renewal) application and whether his registration remained in effect.[3]

In his request for hearing, Respondent contended that ''he is prohibited from applying for his DEA certificate until the Kentucky medical board acts upon his suspension.'' R.D. at 3. The ALJ rejected Respondent's contention, stating that under 21 CFR 1301.36(i), ''the existing registration of an applicant for reregistration will be automatically extended until the Administrator issues her order if the applicant applies for reregistration.'' *Id.*

According to the registration records of the Agency—of which I have taken official notice[4]—Respondent filed a renewal application on March 23, eight days before the expiration date of his registration. However, contrary to the ALJ's explanation of 21 CFR 1301.36(i), where a registrant-applicant has been issued an order to show cause, the regulation actually provides:

> [i]n the event an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration *at least 45 days before the date* on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order.

21 CFR 1301.36(i) (emphasis added).

To be sure, the regulation also provides that a registration may be extended ''under the circumstances contemplated in this section even through the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.'' 21 CFR 1301.36(i). However, based on the Kentucky Board's Emergency Suspension order and the extensive findings (which include allegations related to his prescribing of controlled substances) made therein, I find that the extension of Respondent's registration would be ''inconsistent with the public health and safety.'' *See Paul H. Volkman,* 73 FR 30630, 30641 (2008) (declining to extend registration of practitioner subject to order to show cause who did not file his renewal application until nineteen days before expiration of the registration but finding that the application remained pending before the Agency).

Accordingly, I hold that Respondent's registration has expired but that his application remains pending before the Agency. However, because Respondent is not currently authorized to dispense controlled substances under the laws of the State of Kentucky, the State in which he seeks registration, he is not entitled to be registered. *See* 21 U.S.C. 823(f) & 802(21).

I therefore adopt the ALJ's finding that Respondent is not currently authorized to dispense controlled substances in Kentucky, the State in which he seeks registration, and is therefore not a practitioner within the meaning of the CSA. I further adopt the ALJ's order granting the Government's Motion for Summary Disposition. However, I adopt the ALJ's Recommendation only with respect to the denial of Respondent's pending application to renew his registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Sharad C. Patel, M.D., for a DEA Certificate of Registration as a practitioner, be, and it

[2] It is further noted that Respondent did not mail his Objections until March 31, 2015. Objections, at 4. DEA's regulation provides that ''[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk.'' 21 CFR 1316.45. This case does not raise any issue of delay being attributable to the physical address of the Office of Administrative Law Judges being different from the mailing address of that Office.

[3] Even in summary disposition proceedings which are based on a lack of state authority, the ALJ is obligated to make a finding establishing that the Agency has jurisdiction. Moreover, where it is unclear whether a respondent may have allowed his registration to expire during the course of the proceeding, the ALJ is obligated to determine whether the respondent has filed a renewal application before forwarding the record to the Administrator.

[4] *See* 21 CFR 1316.59(e). Respondent may refute my finding by filing a properly supported motion for reconsideration no later than fifteen (15) calendar days from the date of issuance of this Decision and Order.

hereby is, denied. This Order is effectively immediately.

Dated: May 1, 2015.

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq., for the Government.
Marc S. Murphy, Esq., and Michael Denbow, Esq., for the Respondent.

Order Granting the Government's Motion for Summary Disposition and Findings of Fact, Conclusions of Law, and Recommended Decision of the Administrative Law Judge

Administrative Law Judge Christopher B. McNeil. On January 29, 2015, the Deputy Assistant Administrator of the Drug Enforcement Administration issued an Order to Show Cause as to why the DEA should not revoke DEA Certificate of Registration Number FP2719245 issued to Sharad C. Patel, M.D., the Respondent in this matter. The Order seeks to revoke Respondent's registration pursuant to 21 U.S.C. 824(a)(3) and 823(f), and to deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. 823(f). As grounds for denial, the Government alleges that Respondent is ''without authority to handle controlled substances in Kentucky, the state in which [Respondent is] registered with the DEA.''

On February 20, 2015, the DEA's Office of Administrative Law Judges received Respondent's written request for a hearing, which is dated February 19, 2015. Respondent states that his medical license is ''temporarily suspended'' by the state's medical board and that he plans to challenge the suspension in an upcoming state administrative hearing scheduled for May 18, 2015.

On February 23, 2015 this Office issued an Order for Briefing on Allegations Concerning Respondent's Lack of State Authority. In the Order, I mandated that the Government provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances and if appropriate file a motion for summary disposition no later than 2:00 p.m. Eastern Standard Time (EST) on March 2, 2015. On March 2, 2015, the Government timely submitted a brief in support of the allegation regarding state authority and filed a Motion for Summary Disposition. According to the Government's brief, the Board of Medical Licensure of the Commonwealth of Kentucky issued an Emergency Order of Suspension suspending Respondent's license to practice medicine, effective November 24, 2014. The Government attached the emergency order pertaining to Respondent to the Motion for Summary Disposition. Based on this suspension, the Government moved for a summary disposition of these proceedings.

In my Order for Briefing on Allegations Concerning Respondent's Lack of State Authority, I also provided Respondent the opportunity to respond to the Government's allegations with a brief due not later than 2:00 p.m. EST on March 9, 2015. As of today, no brief was received and therefore the Government's Motion for Summary Disposition will stand unopposed. In Respondent's Request for Hearing, Respondent admits that his license is temporary suspended. Respondent further states that he expects to prevail before the medical board at an upcoming hearing on May 18, 2015. Finally he notes that his DEA Certificate of Registration will expire by its own terms on March 31, 2015, and alleges that he is prohibited from applying for his DEA certificate until the Kentucky medical board acts upon his suspension.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's DEA Certificate of Registration must be revoked because Respondent does not have a medical license issued by the state in which he practices — a fact which Respondent does not deny. Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which he maintains his DEA registration.[1] Pursuant to 21 U.S.C. 823(f), only a ''practitioner'' may receive a DEA registration. Under 21 U.S.C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to maintain a practitioner's registration if that practitioner is not authorized to dispense controlled substances.[2] As noted by the Government in its Motion for Summary Disposition, Respondent's concern regarding the impending expiration of his DEA registration is unfounded. Under 21 CFR 1301.36(i), incorrectly cited by the Government as 21 CFR 1306.36(i), the existing registration of an applicant for reregistration will be automatically extended until the Administrator issues her order if the applicant applies for reregistration.[3]

As detailed above, only a ''practitioner'' may receive a DEA registration. Therefore, I will recommend the revocation of Respondent's DEA registration.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which he seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: March 11, 2015.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015–12025 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

[1] *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also House of Medicine,* 79 FR 4959, 4961 (DEA Jan. 30, 2014); *Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA Nov. 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA Aug. 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA Apr. 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA Apr. 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA Nov. 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[2] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA Nov. 24, 1992), and cases cited therein. In *Chaplan,* DEA Administrator Robert C. Bonner adopts the ALJ's opinion that ''the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances.'' *Id.*

[3] *See also Ronald J. Riegel,* D.V.M., 63 FR 67132–01, 67132 (DEA Dec. 4, 1998).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–34]

Annicol Marrocco, M.D.; Decision and Order

On May 17, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Annicol Marrocco, M.D., (hereinafter, Respondent), of Mahwah, New Jersey. ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration BM8059102, which authorized her to dispense controlled substances in schedules II through V, at the registered address of Olean General Hospital, 515 Main Street, Olean, New York 14760, on the ground that her ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that between January 2008 and August 2009, Respondent issued approximately twenty-one prescriptions to S.C. for oxycodone, a schedule II controlled substance, ''outside the usual course of professional practice and for other than a legitimate medical purpose.'' *Id.* (citing 21 U.S.C. 841(a) and 21 CFR 1306.04(a)). The Show Cause Order further alleged that Respondent failed to maintain medical records supporting the prescriptions, in violation of Florida law; that she was in a personal relationship with S.C.; and that she ''did not examine S.C. except to

listen to his heart and lungs.'' *Id.* at 1–2, 4–5 (citing Fla. Admin Rule 64B8–9.003 and 64B8–9.013).

Next, the Show Cause Order alleged that Respondent had failed to both date and include S.C.'s address on multiple prescriptions, in violation of 21 CFR 1306.05(a). *Id.* at 2. The Show Cause Order then alleged that Respondent had violated DEA regulations that, while allowing a practitioner to issue multiple prescriptions for a schedule II controlled substance, limit the quantity of the prescriptions to a 90-day supply, require that a prescription include the earliest date on which it can be filled, and require that each prescription be issued for a legitimate medical purpose. *Id.* at 2–4 (citing 21 CFR 1306.12(b)(1)).

Next, the Show Cause Order alleged that Respondent ''violated Federal law on at least forty-nine occasions'' by issuing controlled substance prescriptions while practicing as a contract emergency room physician at the Northern Navajo Medical Center in Shiprock, New Mexico, while being registered in New York. *Id.* at 5. The Government further alleged that ''[i]ssuing controlled substance prescriptions in one state under a DEA registration issued for another state is a violation of 21 U.S.C. 822(e) . . . which require[s] separate registrations for separate locations.'' *Id.* (also citing 21 CFR 1301.12(a) & (b)(3)). The Government also alleged that Respondent knowingly and willfully violated these provisions, alleging that ''DEA personnel informed you and your attorney that to move your DEA registration to New Mexico you must first be properly licensed to practice medicine in New Mexico'' and that she ''ha[s] never held a New Mexico medical license.'' *Id.* Finally, the Show Cause Order alleged that Respondent ''no longer maintain[s] a medical practice at [her] registered address'' and that she violated DEA regulations by ''[f]ail[ing] to keep [her] registered address current with the'' Agency. *Id.* (citing 21 CFR 1301.51).

Respondent timely requested a hearing on the allegations; the matter was then placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ). ALJ Ex. 2. Following pre-hearing procedures, the ALJ conducted a hearing on August 21 and September 11, 2013, at which both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.

On November 12, 2013, the ALJ issued his Recommended Decision. Therein, the ALJ found that the Government had established a *prima facie* case that Respondent's continued registration would be inconsistent with the public interest and that she had failed to rebut the Government's showing. R.D. at 75. The ALJ thus recommended that Respondent's registration be revoked. *Id.*

With respect to factor one—the recommendation of the state licensing authority—the ALJ found that ''Respondent has a history of substantial and material disciplinary action taken by the medical licensing boards of three states'' and that the boards of Florida and New York have ''permanently limit[ed] [her] authority to prescribe controlled substances.'' *Id.* at 72. The ALJ thus concluded that ''maintaining Respondent's unrestricted DEA registration would be inconsistent with the public interest.'' *Id.*

With respect to factor two—Respondent's experience in dispensing controlled substances—the ALJ found ''that despite eighteen years of experience as an emergency medicine physician, Respondent lacked the experience necessary to identify and appropriately respond to drug-seeking behavior.'' *Id.* The ALJ also found that Respondent ''lacked the experience necessary to appreciate the need to contact the DEA when questions arose regarding the need for in-state certification after she relocated her principal place of business or professional practice from New York to New Mexico.'' *Id.* The ALJ thus found that factor two supports a finding that Respondent's continued registration is ''inconsistent with the public interest.'' *Id.*

As for factor four—compliance with applicable laws related to controlled substances—the ALJ found that Respondent violated 21 CFR 1306.04(a) by issuing multiple prescriptions for schedule II controlled substances, including OxyContin and oxycodone to S.C., while in a personal relationship with him, and that she acted outside the usual course of professional practice in issuing the prescriptions and lacked a legitimate medical purpose. R.D. 69–70. The ALJ further found that: (1) Respondent issued the prescriptions ''without maintaining medical records or justifying the prescriptions in violation of 21 CFR 1306.04(a)''; (2) Respondent issued OxyContin prescriptions, which were undated, in violation of 21 CFR 1306.05(a); (3) Respondent issued OxyContin prescriptions, which ''lacked the patient's address, in violation of 21 CFR 1306.05(a)''; (4) Respondent issued multiple prescriptions for schedule II controlled substances which lacked ''the earlier date on which'' the prescription could be filled, in violation of 1306.12(b)(1); and (5) Respondent violated the State of Florida's ''Standards for the Use of Controlled Substances for the Treatment of Pain,'' as well as the State's regulation regarding the adequacy of medical records. *Id.* at 73.

The ALJ further concluded that ''[i]ssuing controlled substance prescriptions in one state under a DEA registration issued for practice in another state is a violation of 21 U.S.C. 822(e) and 21 CFR 1301.12(a) and (b)(3).'' *Id.* at 74. While noting that an Agency regulation exempts an official of various federal agencies and the armed forces from these requirements, the ALJ found that because Respondent was a contract-physician she was not exempt under the regulation. *Id.* Based on his finding that ''[b]etween December 28, 2012 and June 8, 2013, Respondent issued prescriptions for controlled substances from her principal place of business or professional practice in Shiprock, New Mexico,'' while ''using the DEA registration that was issued to her for her practice in New York,'' the ALJ concluded that Respondent violated these provisions. *Id.* The ALJ thus found that factor four supports a finding that Respondent's continued registration ''would be inconsistent with the public interest.'' *Id.*

The ALJ further found that factor five—such other conduct which may threaten public health and safety—supports the conclusion that Respondent's continued registration ''would be inconsistent with the public interest.'' *Id.* at 74–75. As support for his conclusion, the ALJ found that Respondent lacked ''candor with the'' Agency, that she ''willful[ly] fail[ed] to determine her obligations when relocating from New York to New Mexico,'' and that she ''refus[ed] to cooperate with the [Agency's] inquiry regarding liability issues in her renewal application.'' *Id.* at 75.

Finally, the ALJ found that Respondent ''failed to affirmatively acknowledge specific acts of improper prescribing,'' as well as that she had ''failed to establish by credible and substantial evidence effective steps taken in remediation as would warrant a sanction other than revocation.'' *Id.* The ALJ thus found that ''the Government has established cause to revoke Respondent's . . . registration.'' *Id.*

Both parties filed exceptions to the ALJ's Recommended Decision. Having

considered the record in its entirety, including the parties' exceptions, I conclude that the Government has established that granting Respondent's application would be inconsistent with the public interest and that Respondent has failed to rebut the Government's *prima facie* case. Accordingly, I will adopt the ALJ's recommendation that I deny any pending application for a new registration. I make the following factual findings.

Findings

Respondent's Licensure Status, the State Board Actions, and Registration Status

Respondent is a board-certified physician in emergency medicine. *See* RX A, at 2. Respondent completed her residency in emergency medicine in 1998 and since then has worked at hospitals in New Jersey, Pennsylvania, New York, Florida, and New Mexico. *Id.* at 1–2. While Respondent holds an active license in New York, Florida, and Pennsylvania, she has been disciplined by the medical boards of each of these States, based on her prescribing of controlled substances to S.C., with whom she had a personal relationship while she was practicing in Florida. *See* GX 9, 11, 12, 13.

In the Settlement Agreement she entered into with the Florida Board, ''Respondent neither admit[ted] nor denie[d] the allegations of fact contained in the [Board's] Administrative Complaint.'' GX 8, at 2. However, she did ''admit[] that the facts alleged in the Administrative Complaint, if proven,[1] would constitute violations of Chapter 458, Florida Statutes, as alleged in the Administrative Complaint.'' *Id.*

More specifically, the State alleged that ''Respondent failed to meet the prevailing standard of care in regard to Patient S.C. in one or more of the following ways.'' GX 7, at 9. The State alleged that Respondent ''fail[ed] to adequately assess and/or diagnose Patient S.C. with chronic pain,'' ''fail[ed] to appropriately treat . . . S.C.,'' ''fail[ed] to use alternative treatment methods,'' ''prescrib[ed] S.C. an inappropriate and/or excessive quantity of [R]oxicodone, oxycodone, and/or OxyContin,'' ''fail[ed] to obtain laboratory results and/or diagnostic scans to collaborate [sic] or monitor S.C.'s condition,'' and ''fail[ed] to properly monitor and/or follow up on . . . S.C.'s condition.'' *Id.* at 9–10 (citing Fla. Stat. § 458.331(1)(t)).

The State further alleged that ''Respondent prescribed [R]oxycodone, oxycodone, and/or OxyContin to Patient S.C., in an inappropriate manner and/or in excessive quantities, which is outside the course of Respondent's professional practice.'' *Id.* at 11–12. The State thus alleged that Respondent violated Florida law ''by prescribing controlled substances other than in the course of her professional practice.'' *Id.* at 12 (citing Fla. Stat. § 458.331(1)(q)). Finally, the State alleged that Respondent violated Florida law by ''fail[ing] to maintain complete medical records that justify the course of treatment [that she] provided to . . . S.C.'' *Id.* at 10; *see also id.* at 11 (citing Fla. Stat. § 458.331(1)(m)).

Pursuant to the Settlement Agreement she entered into with Florida, Respondent received a letter of concern, was fined $5,000, and was required to reimburse the Florida Department of Health's costs of investigating and prosecuting the matter in an amount between $5,587.55 and $6,587.55. GX 8, at 2–3. Respondent was also required to perform 25 hours of community service, as well as to attend ten (10) hours of Continuing Medical Education (CME) in ''Appropriate Prescribing Practices'' and two (2) hours of CME in ''Proper Medical Record Keeping.'' *Id.* at 4–5. Finally, the Board prohibited Respondent from ''prescrib[ing] controlled substances to persons with whom [she] is in a personal, familial or non-familial, relationship.'' GX 8, at 2–5.[2]

As of the hearing, Respondent was working as a contract physician at the Northern Navajo Medical Center, a facility of the Indian Health Service (IHS), which is located in Shiprock, New Mexico; Respondent has worked at this hospital since August 2012. RX A, at 1; Tr. 163. Respondent is not licensed to practice medicine by the State of New Mexico. RX A, at 2.

Respondent also held DEA Certificate Registration BM8059102, pursuant to which she was authorized to dispense controlled substances in schedules II through V, at the registered location of Olean General Hospital, 515 Main St., Olean, New York 14760. GX 20, at 1. This registration had an expiration date of January 31, 2015. *Id.*

On December 31, 2014, Respondent applied for a renewal of this registration and sought to change her registered location to the Northern Navajo Medical Center, P.O. Box 160, Highway 491 North, Shiprock, New Mexico. *See* Government's Notice of Respondent's Filing of Renew Application and Change of Address Request, at 6–8. Thereafter, on January 23, 2015, Respondent submitted a letter seeking to change her registered location to Doctors Express Urgent Care, 1444 W. Passyunk Ave, Philadelphia, PA. *Id.* at 8.

However, at the time Respondent submitted her renewal application, the Agency had issued the Order to Show Cause. A DEA regulation applicable to an applicant who has been served with an Order to Show Cause provides:

> In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

21 CFR 1301.36(i).

Respondent did not file her renewal application more than 45 days before her registration was due to expire and thus her registration was not automatically extended pending the issuance of this Decision and Final Order. Based on my review of the record in this matter, I further conclude that the extension of her registration would be ''inconsistent with the public health and safety.'' *Id.* Accordingly, I hold that her registration expired on January 31, 2015. *See Ralph J. Chambers,* 79 FR 4962 (2014) (citing *Paul H. Volkman,* 73 FR 30630, 30641 (2008)). However, I conclude that her application remains pending before the Agency. *See id.*

The Allegations That Respondent Unlawfully Prescribed Controlled Substances to S.C.

Between February 2007 and August 2009, Respondent worked as an ER physician at the Physicians Regional Medical Center in Naples, Florida. RX A, at 1. According to Respondent, in August 2007, she met S.C., a budding reality TV star, when he came to the ER

[1] These allegations largely track what the Government alleged and I find proved in this matter. *See* GX 7, at 1–7.

[2] Based on the Florida Board's action, New York State Board for Professional Medical Conduct imposed a ''Censure and Reprimand,'' prohibited her from prescribing to persons with whom she is in a relationship, placed her on probation for three years, and fined her $1500. GX 11. Also, based on the actions of the Florida and New York Boards, the Pennsylvania State Board of Medicine imposed a $5000 civil penalty on her. GX 13.

with a broken hand and she treated him by splinting his hand and prescribing Percocet to him.[3] Tr. 207–08. A week or two later, Respondent was told by an x-ray technician that S.C. worked for Ticket Master and that he was hosting a fund-raising event at a local coffee shop. *Id.* at 211. Respondent went to the coffee shop to see if she could get tickets from S.C for an upcoming football game. *Id.* Thereafter, Respondent and S.C. entered into a personal relationship. *Id.*

Respondent did not prescribe any controlled substances to S.C. until January 18, 2008, when she wrote him a prescription for 90 tablets of oxycodone 30mg. GX 1, at 1. Respondent did not recall exactly where she wrote the prescription (this having occurred at either her home or S.C.'s) but acknowledged that it was not at either of the hospitals (both of which were located in Fort Myers, Florida) which were listed on the prescription form she used. Tr. 213. When asked whether she performed a physical exam on this occasion, Respondent testified:

> I conducted a physical exam. I don't know if it was on that specific date, but prior to me issuing this prescription, I had gotten to know him very well, and I learned more about his chronic pain syndrome, and he was a smoker. So, I did, I had listened to his heart and lungs many times before.[4]

Id. When then asked by the Government if subsequent to the August 2007 ER visit, she ''had met with him in a clinical capacity prior to'' issuing the January 18 prescription, Respondent answered:

> I don't understand what you mean, clinical capacity. We developed a friendship, and we . . . were involved in a relationship, at that time. So, you know, I had gotten to know him personally. I knew his family, and you know, we had discussed a lot of his medical conditions, I had discussed with him and his family.

Id.

When then asked where she had conducted her physical examinations of S.C., Respondent stated ''[e]ither by my home or his home.'' *Id.* 215. When asked how she had assessed his pain level, Respondent testified: ''Just by asking him and just seeing how his overall well-being was.'' *Id.* at 215–16. Respondent then asserted that S.C. had told her that ''he was in excruciating pain. He couldn't function without being on his pain medicine.'' *Id.* at 216. Respondent admitted, however, that she did not create ''any formal records'' for the prescriptions. *Id.* Nor did she create a written treatment plan for S.C. *Id.* at 218. She further admitted that she did not order any additional tests, because she was ''work[ing] outside [the] emergency department'' and that ''that was already conducted by his pain management specialist.'' *Id.* at 232–33.

When then asked what was the medical purpose of the prescription, Respondent testified that S.C. ''was in a pain management clinic, up until about November or December of 2007, and he was transitioning. He said he lost his medical insurance. He was trying to find a new treating physician for his chronic pain.'' *Id.* at 216. According to Respondent, S.C. told her that he had back fractures and neck injuries from doing acting stunts and motorcycle racing. *Id.* at 246.

Respondent further explained that S.C. was ''starting to do a lot of traveling at that time'' as he was auditioning for various ''acting jobs,'' and that he asked her if she could help him out until he could get insurance and ''see another provider.'' *Id.* at 216–17; 234. According to Respondent, she looked at the labels of the prescriptions S.C. had received from the pain management specialist who had previously treated him and ''then copied the prescription off the bottles.'' *Id.* at 217. Respondent further denied having made a diagnosis of chronic pain, stating that ''that was established already'' by S.C.'s ''prior physician[].'' *Id.* at 229.

While Respondent admitted that she ''was not familiar with treating chronic pain,'' she did not contact the pain management doctor who had previously treated S.C., explaining that S.C. had told her that ''he was no longer involved with his care, and he did not wish to . . . see that physician any longer.'' *Id.* at 218–19. Respondent explained that she relied on what S.C. and his family had told her, as well as some of his medical records, although she did not look through all of his records. *Id.*

When then asked how she knew that his prior physician would have continued S.C. on controlled substances, Respondent answered that ''[w]hen you're on controlled substances you just don't stop . . . you have to go through either a weaning process or—that's why it requires a specialist to . . . continue treating once you're up to a certain number of high dose pain medication.'' *Id.* at 234–35. She also claimed that his family told her that S.C. did not have a history of substance abuse. *Id.* at 232. Respondent acknowledged that it ''was [her] error'' to accept S.C.'s word instead of contacting his prior physician. *Id.* at 219. She further maintained that she trusted S.C., that ''his family backed up his story,'' and that she had ''no reason to believe at the time'' that she ''was being deceived.'' *Id.* at 220. She also stated that she was in ''a very good friendship'' with S.C. and that over time, she ''lost the physician/patient relationship'' and ''was not objective.'' *Id.*

On or about February 7, 2008, Respondent wrote S.C. three undated prescriptions for OxyContin 80mg.[5] *See* GX 1, at 3, 5, and 7. The prescriptions, which authorized the dispensing of 100 dosage units q12h, 200 dosage units q8h, and 100 dosage units q8h, all lacked S.C.'s address. *See id.* Moreover, none of the prescriptions listed ''the earliest date on which'' it could be filled as required by 21 CFR 1306.12(b)(1)(ii). *See id.* Based on Respondent's dosing

[3] Over the Government's objection, the ALJ allowed Respondent to testify by telephone from her lawyer's office, rather than in person or by appearing at a DEA facility which has Video-Teleconferencing (VTC) capability. Gov. Exceptions, at 2–6. The Government took exception to this ruling.

While the Government makes no claim that Respondent's counsels acted improperly at any time during her testimony, it is manifest that where a witness is allowed to testify by telephone, notes could be passed to the witness during the testimony without the ALJ or Government Counsel ever being aware of this. So too, the use of telephone testimony raises a greater risk that during breaks in the proceeding, the witness could discuss her testimony with others.

I find the Government's exception to be well taken. This is not to say that every witness must testify either in person or by VTC. However, a respondent will invariably be a highly important, if not the most important witness in a proceeding, and thus, under no circumstance is it proper to allow a respondent to testify by telephone. As for other witnesses, with the exception of a witness who testifies only as to the authentication or foundation of proposed exhibits, the taking of testimony by telephone is disfavored and may be used only upon a showing that exceptional circumstances exist and that the failure to obtain a witness's testimony will result in a denial of due process.

[4] At several other points in her testimony, Respondent described the physical exam as listening to S.C.'s heart and lungs, and made no reference to any other tests she did. For example, when asked ''How often did you perform a physical examination of S.C. in the course of issuing prescriptions to him?,'' she answered:

> I can't say for certain, but I did listen—like I said, I mean, he was a smoker, so I did listen to his . . . heart and lungs, which is one of the main exams on a physical, on a regular basis, because I usually had my stethoscope with me, and you know, whenever I saw him, I just did a general, you know—was able to generally assess his overall health and well-being, just from interacting with him and speaking to his family.

Tr. 244–45. Notably, only after Respondent was asked by the Government if she specifically examined S.C.'s back and neck did she assert that she palpated him ''along the spine and surrounding areas.'' *Id.* at 263.

[5] The prescriptions were written on the prescription forms of the Physicians Regional Medical Center and were sequentially numbered from 007424 through 007426. GX 1, at 3–7. While the prescriptions were undated, the evidence shows that prescription number 007425 for 200 OxyContin 80mg. was filled on February 7, 2008. *Id.* at 4.

instructions, the prescriptions provided S.C. with 149 days' supply of the drug.

The evidence further shows that S.C. filled the prescription for 200 tablets at a cost of $2,328.00. *Id.* at 4. Yet Respondent repeatedly claimed that she ''was trying to offer a short-term, fix for his situation'' because ''[h]e was short on money,'' Tr. 236, even though he was working at a local radio station. *Id.* at 238–39. Respondent further claimed that S.C. had told her that an office visit with a pain management specialist cost ''about $400 or $500'' not counting the cost of any prescriptions, and that she trusted what he told her. *Id.* at 239. She also claimed that she was unfamiliar with the cost of various drugs. *Id.* at 237.

Regarding the OxyContin 80mg prescriptions, Respondent stated that she had ''probably not'' physically examined S.C. ''because [she] had done it in the past.'' Tr. 231. Respondent then claimed that she had assessed S.C.'s pain level by ''his appearance and how he would tell me he was feeling.'' *Id.* Respondent did not create a record for the prescriptions. *Id.* at 231–32.

Notwithstanding the quantity of drugs provided by these prescriptions, on or about March 10, 2008,[6] Respondent issued S.C. three more prescriptions, each of which was for 450 oxycodone 30mg, with a dosing instruction to take up to 15 tablets per day ''as needed for pain.'' GX 1, at 9, 11, and 13. As before, the prescriptions were not dated, did not include S.C.'s address, and lacked the earliest date on which they could be filled.[7] *Id.* The evidence further shows that S.C. filled each of the prescriptions on March 10, 2008, and paid $280.74 for each one. *Id.* at 10, 12, and 14.

Here again, Respondent could not state ''for certain'' that she performed a physical exam on S.C. when she issued these prescriptions. Tr. 244. However, Respondent testified that she issued the prescriptions at S.C.'s home because ''this was when he was getting ready to go to Los Angeles for his acting job.'' *Id.* at 245. She also testified that she assessed S.C.'s pain level by ''[j]ust interacting with him, asking how he was feeling,'' and by S.C. letting her know whether he ''was having a good day or a bad day.'' *Id.* at 245–46.

As for why she did not date the prescriptions and include S.C.'s address, Respondent testified that:

> I know I was very distracted when I would write the prescriptions, because it was either at his home or my home, and he had a three-year-old child. It was usually—it was usually at his home.
>
> He had a three-year-old, or a four-year-old, at the time. There were two dogs, a monkey in the house. There was a loud . . . his father was hard of hearing, so . . . the TV was on very loud, and it was a very distracting environment. I don't . . . you know, I cannot explain exactly why the date wasn't on them, because I know that the date needs to be on them. So, I can just . . . go back in my mind and know that it was very distracting.

Tr. 222. Later in her testimony, Respondent explained that S.C. had two German Shepherds, and that there was also a mutt (which he apparently did not own) that was allowed to come into the house. *Id.* at 340. And then there was the monkey, which according to Respondent, was ''three or four feet'' tall and ''dangerous,'' but was nonetheless allowed to run free in the house. *Id.* at 340–41.

As for why she had written the three oxycodone 30mg prescriptions which were filled on March 10, Respondent offered the following testimony:

> I'm just trying to recall, because also, on multiple times, I was told the prescriptions were either lost or destroyed by the animals in the house, by the monkey . . . the monkey was . . . he would take the pill bottle, open it, and throw it in the pool, or you know, various different times . . . I was told that they were lost or stolen or left behind at the different hotels he was staying at.
>
> I just can't—you know, it's unclear, which set of prescriptions it may have occurred with, but it happened on numerous occasions, which is why there is [sic] a number of prescriptions.

Id. at 240–41. Respondent further maintained that S.C.'s stories regarding the monkey were believable because he ''would try to rip up my clothes and my shoes and he would take anything and just try to shred it.'' *Id.* at 341.

As a further reason for why she wrote the multiple prescriptions, Respondent explained that there were occasions in which S.C. would call and tell her that the pharmacy was either ''out of stock for a particular brand name or particular dosage.'' *Id.* at 241; *see also id.* at 245 (''this was around the time where he told me the prescriptions were being destroyed or lost or left at one pharmacy or another, because they weren't in stock'').

At this point, S.C. apparently left the area and went off to pursue his acting career. Tr. 227. As for why she had issued the multiple OxyContin prescriptions, Respondent testified that S.C. had told her that he was going to be in Los Angeles for ''three to six months'' to film a show for MTV and ''he wanted to make sure he didn't run out of pain medication while he was there.'' *Id.* She also testified that she was unaware that she could write ''do not fill until a certain date'' on the prescriptions. *Id.*

Following his appearance on the MTV show and his return to Florida (sometime around October 2008), S.C. was ''getting a lot of opportunities to travel, to do commercials, to do auditions,'' and contracts. *Id.* at 249. According to Respondent, S.C. asked her if she could continue to help him out ''because he was doing a lot of travelling'' and it was hard for him to find ''a physician in a different state.'' *Id.* Respondent agreed to do so and resumed prescribing to him. In her testimony, Respondent did not explain why given S.C.'s success, he could not afford health insurance and find a pain management specialist.

On January 20, 2009, Respondent resumed prescribing to S.C., issuing him a prescription for 40 Roxicodone 30mg, with a dosing instruction of TID or one tablet, three times a day. GX 1, at 15. Between February 3 and March 6, 2009, Respondent issued S.C. the following prescriptions, all of which had a dosing instruction of TID, or one tablet three times a day:

Date	Drug and quantity
2/3/09	90 Roxicodone 30mg.
2/3/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/9/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/10/09	90 Roxicodone 30mg.
2/20/09	90 Roxicodone 30mg.
2/20/09	90 Roxicodone 30mg.
3/6/09	90 Roxicodone 30mg.
3/6/09	280 Roxicodone 15mg.

See GX 1, at 17–35.

Based on Respondent's dosing instruction of TID, a single oxycodone 30mg prescription would have provided S.C. with a thirty-day supply; thus, a single prescription issued on February 3rd, should have lasted him through March 5th.[8] However, the prescriptions Respondent wrote S.C. between February 3 and March 6 authorized the dispensing of 990 tablets of oxycodone 30mg, an eleven-month supply; the prescription for 280 oxycodone 15mg

[6] Here again, the prescriptions were written on the forms of the Physicians Regional Medical Center and were numbered 009325, 009326, and 009329. GX 1, at 9, 11, and 13.

[7] If the drugs were actually taken at fifteen tablets per day, the prescriptions would have provided an additional 90 days' supply.

[8] It is acknowledged that the pharmacy which filled one of the February 3, 2009 prescriptions dispensed only 54 tablets on that date. GX 1, at 17–18. However, even if S.C. was unable to obtain the remaining 46 tablets from the pharmacy within 72 hours as required by DEA's regulation, *see* 21 CFR 1306.13(a), Respondent did not explain why it was necessary to write S.C. a second prescription on that date for a full 90 tablets.

provided S.C. with more than another 1.5 month's supply of the drug.

As for why Respondent issued multiple prescriptions on February 3, 2009, Respondent testified that ''that they were not in stock at the particular pharmacy that he initially went to,'' so S.C. ''called me or told me that he had left the prescription [and] needed a new one, so he could bring it to whatever other pharmacy he was using.'' Tr. 251. However, the evidence shows only that the pharmacy partially filled the prescription in the amount of 54 tablets. GX 1, at 17. Respondent then asserted that she ''never realized that [the prescriptions] were being filled'' and that she ''thought they were either being destroyed'' or ''not being filled at all.'' *Id.* at 251–52. However, Respondent never called any of the pharmacies S.C. used and ''never got word from the pharmacist that they were being filled.'' *Id.* at 252; *see also id.* at 241 (''I was never phoned by any of these pharmacists, telling me that these prescriptions were being filled. I had no idea, because I did not have any records of the number of prescriptions I wrote.'').

Respondent then testified that she did not find S.C.'s claim suspicious because in the ER, ''there were multiple times where patients would'' complain that a pharmacy would not have a particular narcotic or dosage. *Id.* at 252. When asked why the pharmacies would not have just returned the prescriptions to S.C. if the drug was out of stock, Respondent testified that she thought ''that is how they operated down there'' and added that she ''was new to the State.'' *Id.* at 253. However, Respondent has been licensed in Florida since August 2004 and had worked there since at least December 2004.[9] RX A, at 1–2. Respondent could not recall whether she had ever had another patient ask for a replacement prescription claiming that a pharmacist had said a drug was out of stock and yet kept the prescription. *Id.* at 254–55.

Regarding the February 3, 2009 prescriptions, Respondent again could not recall if she had done a physical examination. *Id.* at 255. While Respondent claimed that she had assessed S.C.'s pain level in the same manner as before, she admitted that she did not create a medical record or a written treatment plan. *Id.* at 255–56. Nor could she specifically recall if, on this occasion, she had discussed the risks and benefits of using controlled substances. *Id.* at 256.

As for why she issued three prescriptions on February 9, 2009 instead of a single prescription for 270 tablets, Respondent answered that ''[t]he particular pharmacy . . . didn't have that quantity in stock'' so she split the prescriptions. *Id.* at 260–61. Again, Respondent could not recall if she had conducted a physical exam on S.C. on this date, *id.* at 262, and acknowledged that she did not create a medical record for these prescriptions or a written treatment plan. *Id.* at 264. She claimed, however, that she had assessed his pain level in the same manner as before, and that she had discussed the risks and benefits of using controlled substances on this occasion. *Id.* at 265, 273. Respondent further testified that she used the same approach in assessing S.C.'s need for oxycodone for all of the prescriptions (other than the one she wrote during his ER visit). *Id.* at 274.

Moreover, when asked why she had issued these three prescriptions given that she had issued two similar prescriptions only six days earlier, Respondent testified that she believed that S.C. had begun having seizures and was becoming forgetful. *Id.* at 266. Continuing, Respondent testified that: ''I believe he was—he may have been having seizures, which I found out in May, when I went over [to] his house . . . and he was acting confused . . . and he was in a post-seizure state . . . and I . . . told [his] mom that he was having seizures.'' *Id.* at 266–67. However, Respondent then testified that ''this was actually in—it was around May.'' *Id.* at 267.[10] Still later in her testimony, Respondent explained that ''it was my understanding that he was being truthful and they were truly lost or misplaced or destroyed or left at the pharmacist and never filled. *Id.* at 274.

The evidence shows that the two February 3 prescriptions were filled on February 3 and 5, and that three February 9 prescriptions were filled on February 9, 11, and 16. GX 1, at 18, 19, 21, 23, and 25. So too, the evidence shows that the three prescriptions Respondent wrote on February 10, were filled on February 13, 14, and 17; the two prescriptions she wrote on February 20, were filled on February 21 and 25; and the two prescriptions she wrote on March 6, were filled on March 6 and 9. *See id.* at 26–35.

On questioning by her counsel, Respondent testified that she did not become aware that S.C. had been arrested for doctor-shopping ''until after the case was already over.'' Tr. 348–49. On further questioning by her counsel, and inconsistent with her earlier testimony that the last prescription she wrote for S.C. was in August 2009, *id.* at 267, Respondent denied having written S.C. any more prescriptions ''after the last emergency room visit.'' *Id.* at 349. Yet the evidence shows that S.C.'s last ER visit was on July 3, 2009, *see* GX 15, and the evidence further shows that on July 31, 2009, Respondent issued S.C. a prescription for 30 Roxicodone 15mg. GX 1, at 36.

The evidence further showed that Respondent and S.C. drove to a Publix pharmacy where the prescription was filled. Tr. 97–98. Respondent remained in the car while S.C. went in to the store to fill the prescription. *Id.* at 98. According to the pharmacist, ''S.C. was very chatty and used a lot of small talk'' about being on a reality TV show ''as if he was trying to distract'' her. *Id.* at 97, 105. After the pharmacist handed the filled prescription to S.C., he ''eagerly took the prescription . . . and quickly headed to the back of the store.'' *Id.* at 97. Finding S.C.'s behavior suspicious, the pharmacist called the hospital ER to verify the prescription and was told that Respondent was under investigation and was asked to fax the prescription to the ER and to call the sheriff. *Id.* at 101. The pharmacist then asked an assistant store manager to go into the bathroom and check on S.C. GX 6.

While the pharmacist was still on the phone, S.C. reappeared at the pharmacy counter and asked if there was a problem with the prescription. Tr. 98. The pharmacist told S.C. that she ''need[ed] to clarify the prescription and'' asked him if she could have it back; S.C. complied. *Id.* The pharmacist then counted the tablets and found that two were missing. *Id.* S.C. then told the pharmacist that ''if there are any questions regarding this prescription the doctor is my girlfriend and she is out in the car.'' *Id.*

The pharmacist then proceeded to the parking lot and found Respondent in a car; the pharmacist asked Respondent for her driver's license, and after determining that it was Respondent, asked if she had written the prescription. *Id.* Respondent ''said 'yes.'" *Id.* The pharmacist then returned to the pharmacy and found that ''S.C. was still there''; S.C. ''was very anxious and ask[ed] if he was going to be arrested.'' *Id.* The pharmacist went back inside the pharmacy, called the ER again and verified that Respondent was still employed there. Id. at 98–99. After being told that she was, the pharmacist gave the prescription back to S.C. and called the sheriff. *Id.* at 99.

[9] Prior to working in Naples, Respondent worked at a hospital in Fort Myers. RX A, at 1–2.

[10] The evidence shows that S.C. was hospitalized for seizures on two occasions, May 28, 2009, and July 3, 2009. *See* GX 15 & 16.

Respondent testified that she still believes that the prescriptions she issued S.C. were within the usual course of professional practice and for a legitimate medical purpose. *Id.* at 277. However, Respondent then stated that ''[i]n hindsight . . . my judgment was impaired because of the relationship I had with the individual,'' the prescriptions ''were not within . . . the standards of my medical practice.'' *Id.* Yet Respondent later asserted that she ''was definitely manipulated and taken advantage of. I was victimized.'' *Id.* at 350.

Respondent also testified that at the time she wrote the prescriptions she believed they were ''medically necessary'' because there was a ''prior diagnosis of chronic pain.'' *Id.* And when asked whether, ''[s]itting here today, knowing what you do today, do you still believe that they were medically necessary at the time?'' Respondent answered: ''[y]es.'' *Id.*

Respondent did acknowledge that she violated Florida's regulations by failing to ''keep proper documentation of each visit.'' *Id.* at 351. She then maintained that through the continuing medical education course she was required to take under the Florida Board's Order, ''I realize that will never happen again.'' *Id.*[11]

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied ''if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.'' 21 U.S.C. 823(f). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors[,] and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).[12]

In this matter, I have considered all of the factors and conclude that the Government's evidence with respect to factors two (Respondent's experience in dispensing controlled substances), four (Respondent's compliance with applicable laws related to controlled substances), and five (such other conduct) establishes that she ''*has committed such acts* as would render [her] registration under section 823 of this title inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). While I do not adopt the ALJ findings that Respondent violated federal law by issuing prescriptions while working as a contract physician at the Northern Navajo Medical Center without being registered in New Mexico, I find that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions to S.C. Notwithstanding her claim that her conduct in prescribing to S.C. is an aberration, I find it to be egregious. And based on her insistence that even now, she still believes these prescriptions were legitimate, I conclude that Respondent has failed to produce sufficient evidence to demonstrate why she should be entrusted with a registration.[13]

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except

[11] During its examination of Respondent, the Government asked her if her attorney had spoken ''with a DEA representative about whether [she] needed to obtain a DEA registration in New Mexico.'' Tr. 199. Respondent's counsel objected, asserting that this was a privileged communication and the ALJ sustained the objection. *Id.; see also* R.D. at 39 (''I sustained [Respondent's] objection to the question, finding that the response was likely to call for the disclosure of information protected by the attorney client privilege. I continue to believe the sought-after response would likely have called for [Respondent] to disclose what Mr. Leider [her attorney] did or did not tell her in the course of his representation of her.'').

Notably, in his Recommended Decision, the ALJ did not cite a single case to support his ruling and I conclude that his ruling was erroneous. ''The privilege 'protects only those disclosures necessary to obtain informed legal advice which might not have been made absent the privilege.' '' *In re Walsh,* 623 F.2d 489,494 (7th Cir. 1980) (quoting *Fisher* v. *United States,* 425 U.S. 391, 403 (1976)). Moreover, '''when an attorney conveys to his client facts acquired from other persons or sources, those facts are not privileged.' '' *See In re Sealed Case,* 737 F.2d 94, 100 (D.C. Cir. 1984)) (quoting *Brinton* v. *Department of State,* 636 F.2d 600, 604 (D.C. Cir. 1980) (footnote omitted)). Because the question did not ask Respondent to disclose what facts she had communicated to her lawyer or the legal advice she received from her lawyer, the ALJ erred in barring the testimony. *See United States* v. *DeFazio,* 899 F.2d 626, 635 (7th Cir. 1990) (holding that where attorney ''testified only to what [an] IRS agent said to him, and that he later relayed those statements to [defendant,] [t]he content of this testimony is unprivileged because it did not reveal, either directly or implicitly, legal advice given [defendant] or any client confidences'').

[12] ''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

[13] I acknowledge that Respondent remains licensed in various States, including Pennsylvania, the State where she seeks registration and therefore meets the CSA's prerequisite for holding a practitioner's registration in that State. *See* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'').

However, the possession of state authority '''is not dispositive of the public interest inquiry.''' *George Mathew,* 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew* v. *DEA,* No. 10–73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Accordingly, this factor is not dispositive either for, or against, the granting of Respondent's applications. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As for factor three, there is no evidence that Respondent has been convicted of an offense ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. *Carlos Gonzalez, M.D.,* 76 FR 63118, 63141 (2011).

Fundamental to the CSA's scheme is the Agency's longstanding regulation, which states that ''[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)); *United States* v. *Alerre,* 430 F.3d 681, 691 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006) (stating that the prescription requirement likewise stands as a proscription against doctors acting not ''as a healer[,] but as a seller of wares'').

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied,* 567 F.3d 215, 223–24 (6th Cir. 2009); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR at 30642.

In Florida, a physician is barred from ''prescribing, dispensing, administering, mixing, or otherwise preparing . . . any controlled substance, other than in the course of the physician's professional practice.'' Fla. Stat. § 458.331(q). The statute further explains that ''prescribing, dispensing . . . or otherwise preparing . . . controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice.'' *Id.; see also* Fla. Stat. § 893.05(1) (''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]'').

As found above, while Respondent neither admitted nor denied the factual allegations of the Administrative Complaint which was filed against her by the Florida Board, she did admit that if those facts were proven, they would establish violations of the Florida Statutes as alleged in the Complaint, including not only that she failed to meet the prevailing standard of care, but also that she prescribed controlled substances other than in the course of her professional practice. *See* GX 8, at 2 (citing Fla. Stat. Chap. 458). In this proceeding, the material facts set forth in the Board's complaint have been proven.

Moreover, under the Florida Board of Medicine's then-existing Standards for the Use of Controlled Substances for the Treatment of Pain:

> A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatment for pain, underlying or coexisting disease or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Fla. Admin R. 64B8–9.013(3)(a).[14]

The State's Standards also required a physician ''to keep accurate and complete records to include, but not be limited to: 1. [t]he medical history and physical examination, including history of drug abuse or dependence, as appropriate; 2. [d]iagnostic, therapeutic, and laboratory results; 3. [e]valuations and consultations; 4. [t]reatment objectives; 5. [d]iscussion of risks and benefits; 6.[t]reatments; 7. [m]edications (including date, type, dosage, and quantity prescribed); 8. [i]nstructions and agreements; and 9. [p]eriodic reviews.'' *Id.* at 64B8–9.013(f).

While Respondent asserted that she did a physical examination and that she knew ''about [S.C.'s] chronic pain syndrome'' from talking to both him and his parents, Tr. 214, the fact remains that she failed to document and maintain any medical records to support the prescriptions. Indeed, she specifically denied having diagnosed S.C. as having chronic pain, asserting that the diagnosis ''was established already'' by S.C.'s ''prior physician,'' *id.* at 229, and that she wrote the prescriptions by ''cop[ying] the prescription off the bottles'' S.C. showed her. *Id.* at 217. Yet, notwithstanding that those prescriptions were legally required to contain the name of the prescribing physician, *see* 21 CFR 1306.14(a), and no claim is made that they did not, Respondent never called S.C.'s prior physician.[15]

When then asked how she knew if Respondent's prior physician would have continued S.C. on narcotic controlled substances, Respondent replied that ''[w]hen you're on controlled substances you just don't stop . . . you have to go through either a weaning process—that's why it requires a specialist to . . . continue treating once you're up to a certain number of high dose pain medication.'' Tr. 234–35. Unexplained by Respondent is why she wrote S.C. prescriptions totaling 400 dosage units of OxyContin 80mg, given her testimony that a patient who is on a ''high dose [of] pain medication,'' ''requires a specialist,'' *id.,* which she is not, as well as her admission that she ''was not familiar with treating chronic pain.'' *Id.* at 218.

Moreover, Respondent repeatedly provided S.C. with prescriptions which enabled him to obtain schedule II controlled substances including OxyContin 80mg and oxycodone 30mg, drugs which are among the most highly abused and diverted controlled substances, in quantities which greatly exceeded both her own dosing instructions and DEA regulations. As found above, on or about February 7, 2008, Respondent issued S.C. prescriptions for 400 dosage units of OxyContin 80mg. Putting aside that Respondent wrote two different dosing instructions on the three prescriptions

[14] This version of the Standards was promulgated in 1999, amended in both 2002 and 2003, and remained in effect until a new version of the Standards was promulgated in 2010.

[15] Respondent also testified that she looked at S.C.'s medical records. Thus, she clearly had available to her information as to Respondent's prior physician. While Respondent testified that S.C. was no longer seeing this physician because ''he lost his medical insurance,'' *id.* at 216, as well as that ''he did not wish to . . . see that physician any longer,'' *id.* at 219, because she never called the physician, she had no idea if S.C. had told her the truth or if his prior physician had discharged him.

(one prescription calling for one tablet every 12 hours, the other two calling for one tablet every eight hours), these dosing instructions provided S.C. with more than a 149-day supply of the drug.[16] However, under DEA regulations, Respondent could lawfully prescribe a maximum of a 90-day supply. *See* 21 CFR 1306.12(b)(1).

Notwithstanding that she had written the three OxyContin prescriptions only one month earlier and that if Respondent took the drugs in accordance with her dosing instructions, he would have had at least a four-month supply of the drug remaining, on or about March 10, 2008, Respondent wrote S.C. three more prescriptions. Each of these prescriptions authorized the dispensing of 450 dosage units of oxycodone 30mg, and, with a dosing instruction of up to 15 tablets or 450 milligrams per day, provided S.C. with an additional thirty-day supply. By comparison, the OxyContin prescriptions provided a daily dose of 160 or 240mg per day.

Assuming S.C. took the full fifteen tablets per day, the three March 10, 2008 prescriptions provided S.C. with an additional 90-day supply of oxycodone. Thus, based on her own dosing instructions, the February and March 2008 prescriptions provided S.C. with nearly an eight-month supply of oxycodone.

As for why she issued these six prescriptions, Respondent offered multiple explanations. First, regarding the OxyContin prescriptions, Respondent testified that S.C. had told her he was going to be in Los Angeles for three to six months filming a show for MTV and did not want to run out of medication. Tr. 227. Second, she asserted that S.C. told her that the monkey ''would take the pill bottle, open it, and throw it in the pool.'' *Id.* at 240–41. Third, she claimed that S.C required additional prescriptions because the pharmacy was either out of stock of the particular brand or dosage, or that he left the prescription at the pharmacy. *Id.* at 241 & 245.

[16] This calculation was based on Respondent's actual dosing instructions for each prescription. These three prescriptions would have provided a 200-day supply of the drug had I calculated this figure using a dosing instruction of one tablet every twelve hours for all three prescriptions, which is consistent with the manufacturer's prescribing instructions. *See Physician's Desk Reference* 2707 (61st ed. 2007) (''It is most appropriate to increase the q12h dose, not the dosing frequency. There is no clinical information on dosing intervals shorter than q12h.''); *see also id.* (''The intent of the titration period is to establish a patient-specific q12h dose that will maintain adequate analgesia with acceptable side effects for as long as pain relief is necessary.'').

None of these explanations provides a persuasive justification that mitigates her misconduct. As for the first one, surely the Los Angeles area has an ample supply of pain management specialists who could have treated S.C. were he to run out of medication. Moreover, even if S.C. was a legitimate patient, given her testimony that patients on high doses of narcotics require a specialist to continue their treatment, Respondent's decision to provide S.C. with an eight-month supply of oxycodone when she had no ability to supervise his medication use—not that that ever appeared to be a concern to her—reflects a stunning disregard for her obligations as a prescriber of controlled substances. *See Gonzales,* 546 U.S. at 274 (''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse'').

As for the explanation that S.C. told her that he needed additional prescriptions because the pharmacies were out of either the branded medication (such as OxyContin) or the particular dosage strength, or that he left the prescription at the pharmacy, Respondent never called any of the pharmacies to verify S.C.'s claims. Tr. 241 & 252. Moreover, even if the pharmacies S.C. used were out of OxyContin, Respondent offered no explanation as to why, in a one-month period, she increased S.C.'s daily dose of oxycodone from either 160 or 240mgs per day (depending upon which prescription she wrote) to 450mgs per day.

Then there is Respondent's testimony that she believed S.C. when he told her that his pet monkey was opening his pill bottles and throwing the drugs in the pool. While Respondent initially offered this far-fetched story to explain why she had written the three undated oxycodone 30mg prescriptions, all of which were filled on the same date (March 10, 2008) and bore serial numbers suggesting they were all written in close temporal proximity, she offered no testimony to the effect that she had asked to see the pill bottles to determine if the prescriptions had actually been filled. Moreover, Respondent eventually backtracked on this testimony, explaining that it was ''unclear[] which set of prescriptions it may have occurred with.'' Tr. 241. Accordingly, I find this testimony incredible.

Respondent further violated DEA regulations because she failed to date the three March 2008 prescriptions and include S.C.'s address on them. *See* 21 CFR 1306.05(a) (''All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient . . . .''). As for why she did not date the prescriptions and include S.C.'s address on them, Respondent offered the ludicrous explanation that because of a young child, the dogs, the monkey, and S.C.'s hard-of-hearing father (who required that the volume on the TV be ''very loud''), ''it was a very distracting environment.'' Tr. 222. Yet somehow Respondent was able to include on the prescriptions the drug name, the dosage strength, the quantity, a dosing instruction, as well as her DEA number, printed name and signature. In short, I do not find her testimony credible as to why the prescriptions were undated.

While Respondent apparently ceased her prescribing to S.C. while he was in Los Angeles, she resumed prescribing to him in January 2009, notwithstanding that with his opportunities and the ''contracts he was getting,'' S.C. presumably could have afforded to see a pain management specialist. Tr. 249. As found above, between February 3 and March 6, 2009, Respondent issued S.C. eleven prescriptions for 90 Roxicodone (oxycodone) 30mg. Moreover, on several dates, Respondent issued S.C. two or more prescriptions.

Based on her dosing instruction of one tablet, three times per day, the prescriptions authorized the dispensing of 990 tablets of oxycodone 30mg, or an eleven-month supply of the drug. Moreover, on March 6, Respondent issued S.C. a prescription for 280 Roxicodone 15 mg (also with a dosing instruction of one tablet, three times per day). Thus, between February 3 and March 6, 2009, Respondent's prescriptions provided S.C. with more than a one-year supply of oxycodone if he actually took the drugs as directed.

As for why she issued S.C. the two February 3 prescriptions, Respondent testified that S.C. had called her and told her that the pharmacy he initially went to was out of stock and that he left the prescription there. Once again, Respondent merely accepted S.C.'s story, which was only partially true, and did not call the pharmacy.

While Respondent maintained that she did not find this suspicious because some of her ER patients had complained that a pharmacy would not have a particular drug, she could not recall if she had ever had another patient claim that he/she needed a new prescription because the pharmacist had kept it. When then asked why the pharmacist would not have simply returned the prescription to S.C., Respondent

asserted that was ''how they operated down there'' and that she ''was new to the State,'' even though she had worked in Florida for more than four years at that point. Yet the evidence shows that every single prescription she issued to S.C. in this period was filled, *see* GX 1, at 17–35, and while the first February 3 prescription was only partially filled (with the pharmacy dispensing 54 tablets), even if the pharmacy could not fill the remaining portion of the prescription within 72 hours, *see* 21 CFR 1306.13(a), there was no need for Respondent to issue him a second prescription for a full 90 tablets.

As for why she then issued S.C. three more prescriptions just six days later (on Feb. 9), Respondent initially claimed that S.C. had begun having seizures and was becoming forgetful, but then acknowledged that this did not happen until three months later. Other than in her earlier ludicrous testimony that the monkey was throwing S.C.'s drugs in the pool or that Respondent was leaving the drugs in his hotel room, or the drugs had been stolen—none of which was documented in a medical record because she maintained none on S.C.—Respondent failed to address why she issued S.C. three more prescriptions the next day. So too, Respondent failed to address why she wrote the multiple prescriptions on February 20 and March 6.

In her testimony, Respondent maintained ''that over time'' she ''lost the physician/patient relationship.'' Tr. 220. To the contrary, the evidence suggests that the only time she prescribed to S.C. pursuant to a valid doctor-patient relationship was in August 2007, when she treated him for his broken hand in the ER. Her testimony as to whether she performed physical examinations of S.C. was exceedingly vague and changed, both as to the dates she performed these exams and the scope of the exams. Indeed, she explicitly denied having even made a diagnosis, *id.* at 229, claiming that S.C.'s prior physician had done that, and yet she proceeded to provide him with prescriptions for more than 1750 tablets of two of the most highly abused prescription narcotics (400 OxyContin 80mg and 1350 oxycodone 30mg) without even calling S.C.'s prior physician. She also offered no explanation for the inconsistency between the dosing instructions on the various OxyContin prescriptions or for increasing S.C.'s daily dose of oxycodone from 240mgs (per the OxyContin prescriptions) to 450mgs per day (per the oxycodone 30 prescriptions) only one month later. Moreover, she provided the first set of prescriptions with full knowledge that S.C. was going off to California for several months and that she would have no ability to monitor him. And she failed to create any medical records and a written treatment plan.

As for the 2009 prescriptions, notwithstanding that she had not ''treated'' S.C. in nearly ten months, she could not recall if she had done a physical exam. Moreover, within a one-month period, she provided him with more than a one-year supply of oxycodone based on her own dosing instructions. As for her testimony that she believed the various excuses S.C. offered for why he needed additional prescriptions, and did so even when the excuse was patently absurd, the ALJ did not find this credible. Nor do I. And here again, she failed to create any medical records and a written treatment plan.

I therefore conclude that with the exception of the Percocet prescription she wrote when she treated S.C. in the ER, Respondent repeatedly acted outside of the usual course of professional practice and lacked a legitimate medical purpose when she prescribed oxycodone (including OxyContin) to him. *See* 21 CFR 1306.04(a). While Respondent contends ''that her actions were not for personal gain,'' Resp. Post-Hrng. Br. at 36, to sustain a violation, the Government was not required to prove that she provided the prescriptions in exchange for either money or to obtain S.C.'s affection. In sum, I conclude that Respondent knowingly diverted controlled substances when she prescribed to S.C.

I also conclude that Respondent violated Agency regulations requiring that she: (1) Date the prescriptions as of the date of their issuance, 21 CFR 1306.05(a); (2) include S.C.'s address on the prescriptions, *see id.* ; (3) where issuing multiple prescriptions for schedule II drugs, not prescribe more than a 90-day supply, 21 CFR 1306.12(b)(1); and (4) where issuing multiple prescriptions, ''provide[] written instructions on each prescription . . . indicating the earliest date on which a pharmacy may fill each prescription. *Id.* 1306.12(b)(ii). She also violated Florida law and regulations by failing to create medical records.

Respondent nonetheless argues that she ''has had a long career in emergency medicine and has had no instances of malpractice or disciplinary action prior to the instant case.'' Resp. Exceptions, at 11. She further contends that ''[t]he events surrounding her relationship with S.C. and her treatment of his purported medical conditions represent an aberrant set of circumstances that are unlikely to ever be repeated.'' *Id.*

It is acknowledged that except for the matters at issue here, Respondent has practiced medicine as an ER physician for approximately sixteen years and dispensed controlled substances without incident. It also acknowledged that two of her co-workers wrote letters attesting to her ability as a clinician. *See* RX P & R.

I nonetheless reject her contention that her misconduct is an aberration. As the evidence shows, Respondent engaged in two separate bouts of unlawful prescribing. Indeed, while her prescribings to S.C. in the February–March 2008 time period were egregious (providing him with 1750 tablets of highly abused schedule II narcotics), in January 2009, she resumed prescribing to him, providing him with more than another 1,000 pills of this highly abused narcotic in a one-month period. Moreover, notwithstanding her admitted lack of familiarity with treating chronic pain, and that while S.C. was in LA, she had months to reflect on her prescribing practices with respect to him as well as to familiarize herself with Florida's standards for using controlled substances to treat pain, Respondent resumed prescribing to S.C. a highly abused narcotic in unlawful quantities, *see* 21 CFR 1306.12(b)(1), that also greatly exceeded what was medically necessary according to her own dosing instructions.

I therefore find that the Government's evidence with respect to factors two and four establishes that Respondent has committed such acts as to render her ''registration inconsistent with the public interest.'' [17] I further find that

[17] While I have considered the allegation that Respondent violated the CSA by issuing prescriptions while working at the Northern Navajo Medical Center without being licensed by New Mexico and registered with DEA in that State, I decline to rule on the allegation because several material issues have not been adequately addressed. While the Government elicited testimony from a registration program specialist to the effect that in order for Respondent to obtain a registration in New Mexico, she was required to obtain a New Mexico medical license, it is unclear whether New Mexico has authority to require a federal contract physician to be licensed in the State if she works solely at an IHS facility. The limited case law suggests to the contrary. *See Taylor* v. *United States,* 821 F.2d 1428, 1431 (9th Cir. 1987) (noting that under the Supremacy Clause, a State ''lacks power to require licensing of federal health care providers and physicians'' and that ''[t]he United States has . . . essentially deemed [an] Army [h]ospital and its staff fit to provide health care services''); *United States* v. *Composite State Bd. of Medical Examiners,* 656 F.2d 131, 135 n.4 (5th Cir. 1981) (citing *Sperry* v. *Florida ex rel. Florida Bar,* 373 U.S. 379 (1963)). *Cf.* 25 U.S.C. 1621t (''Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State in which the tribal health

Respondent's misconduct was egregious and makes out a *prima facie* case for denying her application.

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

The ALJ also found that Respondent engaged in actionable misconduct under this factor. More specifically, the ALJ found, *inter alia,* that: (1) Respondent lacked candor in her testimony regarding her prescribings to S.C.; and (2) she failed to cooperate with DEA Investigators who were investigating her 2012 renewal application. R.D. at 63–66. Of these, I conclude that only the first finding is supported by substantial evidence.

As for the second contention, the evidence showed that during the course of investigating her renewal application, Agency Investigators went to a hospital at which Respondent was then working and asked to speak to her about the ''yes'' answer she had provided to one of the liability questions on the application. Tr. 388. Respondent declined to answer any questions without an attorney being present. *Id.* While the Investigators then explained ''this was not a criminal investigation'' and that it ''was purely regulatory in scope'' as it involved the Florida Board matter, Respondent again refused ''to discuss the matter.'' *Id.* at 390. The DI then testified that he was never able to complete his interview of Respondent. *Id.* at 391; 398.

Based on this evidence, the ALJ found that Respondent ''flatly refused to answer [the DI's] questions to resolve the liability issues she noted on her renewal application in the absence of an attorney, and made no attempt to arrange a subsequent meeting with [the DI], with or without counsel.'' R.D. at 65–66. The ALJ thus reasoned that ''Respondent's failure to cooperate . . . suggests a substantial and willful disregard for her duty to comply with DEA directives as a regulated entity'' and ''[t]his conduct threatens public health and safety.'' *Id.* at 66.

I find the ALJ's reasoning unpersuasive. Respondent was entitled to consult with her attorney before answering the DI's questions and had no obligation to agree to an interview without her attorney being present. Moreover, the DI offered no testimony to the effect that he made any further attempt to interview her, let alone that she rebuffed a further interview request or that she agreed to an interview and then failed to follow through. Accordingly, I reject the ALJ's finding and conclusion as unsupported by substantial evidence.

However, I agree with the ALJ's legal conclusion that Respondent lacked candor in her testimony. More specifically, as ultimate factfinder, *see* 5 U.S.C. 557(b), I do not find credible her testimony that she did not know ''exactly why'' she did not include the date and S.C.'s address on the OxyContin 80mg and Oxycodone 30mg prescriptions other than that S.C.'s house was a ''very distracting'' environment. Tr. 222. As found above, notwithstanding her assertion, Respondent was not so distracted that she failed to include on the prescriptions such required information as the name of the drug, its dosage strength, the quantity, and her signature. *Id.*

Nor do I find credible her testimony that she palpated S.C.'s back and neck as part of the physical exams she claimed to have performed. *Id.* at 263. As found above, at several earlier points in her testimony, Respondent described the physical exam she performed as listening to S.C.'s heart and lungs, making no mention of having palpated any part of S.C. *See id.* at 214 & 244–45. Indeed, she asserted that she palpated S.C.'s back and neck only after the Government specifically asked her if she did. *Id.* at 263.

Finally, I do not find credible Respondent's testimony that she wrote the multiple oxycodone 30mg prescriptions because she *actually believed* S.C.'s claim that the monkey had taken the pill bottle, managed to open it, and then threw the medication in the pool. *Id.* at 240–41, 341. Accordingly, I find that substantial evidence supports a finding that Respondent lacked candor when she testified in this proceeding. *See Hoxie* v. *DEA,* 419 F.3d 477, 483 (''Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.''). Thus, I conclude that the record supports a finding that Respondent lacked candor when she testified in this proceeding and that she has committed such other conduct which may threaten public health and safety. 21 U.S.C. 823(f)(5).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that [an applicant] has committed acts inconsistent with the public interest, the [applicant] must '' 'present sufficient mitigating evidence to assure the Administrator that [she] can be entrusted with the responsibility carried by such a registration.' '''' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [her] actions and demonstrate that [she] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

So too, in making the public interest determination, ''this Agency places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74334, 74338 (2007) (quoting *Hoxie,* 419 F.3d at 483 (''Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.''))).

Moreover, while an applicant must accept responsibility and demonstrate that she will not engage in future misconduct in order to establish that her registration is consistent with the public

program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act.''). However, this determination is not within the Agency's authority.

Moreover, the Government does not address whether a physician is nonetheless required to obtain a registration specific to an IHS facility if the State lacks authority to require a physician to obtain a license in that State, or whether a physician who does not possess a license in the State where the facility is located and is not required to possess such a license, can nonetheless obtain a registration for that location.

Because I find that the Government has otherwise proved that Respondent's continued registration is inconsistent with public interest and that she has failed to produce sufficient evidence to rebut this conclusion, I decline to remand the matter or issue a briefing order. On this record, I decline to adopt the ALJ's conclusions of law (# 8, 9, and 10) that Respondent violated federal law because she issued prescriptions while practicing at the Northern Navajo Medical Center without being registered in New Mexico and that she is not exempt from registration in that State. *See* R.D. 74. I also decline to adopt the ALJ's finding that Respondent's ''decision to rely exclusively on representations made to her by her future employers constitutes a willful and reckless disregard for her duty to inquire of the DEA regarding the need for re-registration and in-state licensure,'' R.D. at 64, and that this is actionable misconduct under factor five. *Id.*

interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be revoked' '' or an application should be denied. *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504 (2007)); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36504). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').[18]

In his decision, the ALJ acknowledged that Respondent produced some evidence of remedial measures she has undertaken. R.D. at 68. More specifically, the evidence shows that Respondent completed a four-day course in controlled substance management and a two-day course in medical record keeping. RXs F & I.

However, based on Respondent's testimony, the ALJ also found that ''it is far from clear that the courses have brought about changes in [her] that would support continued DEA registration.'' R.D. at 68. As the ALJ explained, ''[e]ven now, Respondent would attribute her action to being victimized by . . . SC's conduct, while averring that she believed, at the time, that her prescription practice was compliant with DEA regulations.'' *Id.* The ALJ thus concluded that ''Respondent has [not] admitted to the full extent of her . . . misconduct.'' *Id.*

Respondent takes exception to the ALJ's conclusion that she has failed to accept responsibility for her misconduct, contending that this ''is contradicted by the facts in the record.'' Exceptions, at 2. Respondent argues that she ''readily admitted to losing the physician-patient relationship when treating S.C.'' and that she ''also admitted that she violated Florida law and standards of practice when she treated S.C. without creating a medical record, [a] written treatment plan, etc.'' *Id.* at 3–4.

It is acknowledged that at various points in her testimony, Respondent admitted to several professional failings. For example, she admitted that it was her error to accept S.C.'s word rather than call his prior physician. She also testified that she ''lost the physician/patient relationship'' and ''was not objective.'' Still later, she testified that ''[i]n hindsight . . . my judgment was impaired because of the relationship I had with the individual'' and that the prescriptions ''were not within . . . the standards of my medical practice.'' And she also admitted that she violated Florida's regulations by failing to ''keep proper documentation.''

While this testimony would have supported a finding that Respondent has accepted responsibility for her misconduct, at other points, she offered testimony that substantially undermines this conclusion. Notwithstanding her earlier admission that she lost the doctor/patient relationship (not that she ever had one outside of S.C.'s ER visit), she then testified that ''I was definitely manipulated and taken advantage of. I was victimized.'' Tr. 350. Respondent's statement is simply irreconcilable with the obligations imposed on a physician who is entrusted with the authority to prescribe controlled substances.

So too, notwithstanding her testimony that the prescriptions ''were not within . . . the standards of my medical practice'' and her having taken a course in controlled substance management, Respondent testified that she still believes she issued the prescriptions for a legitimate medical purpose. Tr. 277. Still later in her testimony—and after maintaining that she was victimized by S.C.—she again testified that knowing what she knows today, she still believes that the prescriptions were medically necessary. *Id.* at 277–78.

In short, this suggests that Respondent has learned nothing from the various state board proceedings, the course she took in controlled substance management, or this Proceeding. Accordingly, I have no confidence that she will refrain from similar acts were she to become love struck with a drug abuser or diverter in the future. Her equivocal testimony provides substantial evidence to support a finding that she does not accept responsibility for her misconduct.

As explained above, notwithstanding her contention that her prescribing to S.C. is an aberration, I find that her misconduct was egregious. Moreover, as found above, Respondent lacked candor in her testimony. Accordingly, I conclude that denial of her application is necessary to protect the public interest.

Order

Pursuant to the authority vested in me by 21 U.S. C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Annicol Marrocco, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective June 18, 2015.

Dated: May 4, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015–12035 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–09–P

[18] Thus, in *Gaudio,* ''I explained that 'even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.' '' 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504) (citing *Butz* v. *Glover Livestock Commission Co., Inc.,* 411 U.S. 182, 187–88 (1973)); *cf. McCarthy,* 406 F.3d at 189 (''Although general deterrence is not, by itself, sufficient justification for expulsion or suspension, we recognize that it may be considered as part of the overall remedial inquiry.''); *Paz Securities, Inc., et al.* v. *SEC,* 494 F.3d 1059, 1066 (D.C. Cir. 2007) (agreeing with *McCarthy*). In *Gaudio,* I further noted that the ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest, *see* 21 U.S.C. 801, and the broad grant of authority conveyed in the statutory text, which authorizes the [suspension or] revocation of a registration when a registrant 'has committed such acts as would render [his] registration . . . inconsistent with the public interest,' *id.* § 824(a)(4), and [which] specifically directs the Attorney General to consider ['such other conduct which may threaten public health and safety,' *id.* § 823(f)].'' 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504).

Unlike factors two (''[t]he applicant's experience in dispensing'') and three (''[t]he applicant's conviction record''), neither factor four (''Compliance with applicable laws related to controlled substances'') nor factor five (''Such other conduct which may threaten public health and safety'') contain the limiting words of ''[t]he applicant.'' As the Supreme Court has held, ''[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'' *Russello* v. *United States,* 464 U.S. 16, 23 (1983). Thus, the text of factors four and five suggest that these factors are not limited to assessing the specific practitioner's compliance with applicable laws and whether she has engaged in ''such other conduct'' (such as giving false testimony), but rather, authorizes the Agency to also consider the effect of a sanction on inducing compliance with federal law by other practitioners.

DEPARTMENT OF JUSTICE

[OMB Number 1105–0092]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Previously Approved Collection; September 11th Victim Compensation Fund Claimant Eligibility and Compensation Form

AGENCY: September 11th Victim Compensation Fund, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Civil Division, September 11th Victim Compensation Fund, will be 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: Comments are encouraged and will be accepted for 60 days until July 20, 2015.

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 Nell McCarthy, Deputy Special Master, September 11th Victim Compensation Fund, 1100 L Street NW., Washington, DC 20531 (phone: 1–855–885–1555).

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 Fund, 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 of a currently approved collection.

2. *The Title of the Form/Collection:* Eligibility and Compensation Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* N/A. Civil Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

The September 11th Victim Compensation Fund of 2001 provides compensation to any individual (or beneficiary of a deceased individual) who was physically injured or killed as a result of the terrorist-related aircraft crashes of September 11, 2001. The information collected from the Eligibility and Compensation Form will be used to determine whether claimants will be eligible for compensation from the Fund, and if so, the amount of compensation they will be awarded. The Form consists primarily of two main sections: Eligibility and Compensation.

The Eligibility section seeks the information required by the Zadroga Act to determine whether a claimant is eligible for the Fund, including information related to: participation in lawsuits related to September 11, 2001; presence at a 9/11 crash site between September 11, 2001 and May 30, 2002; and physical harm suffered as a result of the air crashes and/or debris removal.

The Compensation section seeks the information required by the Zadroga Act to determine the amount of compensation for which the claimant is eligible. Specifically, the section seeks information regarding the out-of-pocket losses (including medical expenses) incurred by the claimant that are attributable to the 9/11 air crashes or debris removal; the claimant's loss of earnings or replacement services that are attributable to the 9/11 air crashes or debris removal; and any collateral source payments (such as insurance payments) that the claimant received as a result of the terrorist–related aircraft crashes of September 11, 2001 or debris removal efforts.

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 72,000 respondents will complete the form in an average of 10 hours.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 720,000 hours.

If additional information is required contact Jerri Murray, Department Clearance Office, United States Department of Justice, Justice Management Division, Policy and Planning staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 14, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12065 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0008]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Semi-Annual Progress Report for Grantees From the Enhanced Training and Services To End Violence Against and Abuse of Women Later in Life Program (Training Program)

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be 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: Comments are encouraged and will be accepted for 60 days until July 20, 2015.

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 Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) 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;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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:* Revision of a currently approved collection

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from the Enhanced Training and Services to End Violence Against and Abuse of Women Later in Life Program (Training Program)

(4) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0008. U.S. Department of Justice, Office on Violence Against Women

(5) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 18 grantees of the Training Program. Training Program grants may be used for training programs to assist law enforcement officers, prosecutors, and relevant officers of Federal, State, tribal, and local courts in recognizing, addressing, investigating, and prosecuting instances of elder abuse, neglect, and exploitation and violence against individuals with disabilities, including domestic violence and sexual assault, against older or disabled individuals. Grantees fund projects that focus on providing training for criminal justice professionals to enhance their ability to address elder abuse, neglect and exploitation in their communities and enhanced services to address these crimes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 18 respondents (Training Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Training Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 36 hours, that is 18 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 13, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12046 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0012]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) will be 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: Comments are encouraged and will be accepted for 60 days until July 20, 2015.

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 Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) 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;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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:* Revision of a currently approved collection

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Education, Training and Enhanced Services to End Violence Against and Abuse of Women with Disabilities Grant Program (Disability Grant Program)

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0012. U.S. Department of Justice, Office on Violence Against Women

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 18 grantees of the Disability Grant Program. Grantees include states, units of local government, Indian tribal governments or tribal organizations and non-governmental private organizations. The goal of this program is to build the capacity of such jurisdictions to address such violence against individuals with disabilities through the creation of multi-disciplinary teams. Disability Grant Program recipients will provide training, consultation, and information on domestic violence, dating violence, stalking, and sexual assault against individuals with disabilities and enhance direct services to such individuals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will

take the approximately 18 respondents (Disability Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Disability Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 36 hours, that is 18 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 13, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12045 Filed 5–18–15; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–83,312]

Eaton Corporation, Cooper Power Systems, Power Delivery Division, Including On-Site Leased Workers From Adecco Employment, Olean, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 27, 2014, applicable to workers of Eaton Corporation, Cooper Power Systems, Power Delivery Division, Olean, New York. The workers were engaged in activities related to the production of components and protective equipment consisting of surge arresters. The notice was published in the **Federal Register** on February 24, 2014 (79 FR 10187).

At the request of the State of New York, the Department reviewed the certification for workers of the subject firm. Information from the subject firm shows that workers leased from Adecco Employment were employed on-site at Eaton Corporation, Cooper Power Systems, Power Delivery Division, Olean, New York. The Department has determined that these workers were sufficiently under the control of Eaton Corporation, Cooper Power Systems, Power Delivery Division, Olean, New York to be considered leased workers.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by a shift in production abroad of components and protective equipment consisting of surge arresters.

Based on these findings, the Department is amending this certification to include workers leased from Adecco Employment working on-site at the Olean, New York location of the subject firm.

The amended notice applicable to TA–W–83,312 is hereby issued as follows:

All workers from Eaton Corporation, Cooper Power Systems, Power Delivery Division, including on-site leased workers from Adecco Employment, Olean, New York, who became totally or partially separated from employment on or after December 18, 2012, through January 27, 2016, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1074, as amended.

Signed at Washington, DC, this 17th day of April 2015.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015–12051 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–83,309
Southern California Edison, A Subsidiary Of Edison International, It Department, Including On-Site Leased Workers From Infosys, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, Anand Pag, Incremental Sysems Corporation And @Business, Inc., Irwindale, California

TA–W–83,309A
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., Rosemead, California

TA–W–83,309B
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., Irvine, California

TA–W–83,309C
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., Alhambra, California

TA–W–83,309D
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., Rancho Cucamonga, California

TA–W–83,309E
Southern California Edison, A Subsidiary Of Edison International, IT DEPARTMENT, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @ Business, Inc., Fullerton, California

TA–W–83,309F
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, INC., San Clemente, California

TA–W–83,309G
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, Ibm, Ijus Llc, Anand Pag, Incremental Sysems Corporation And @Business, INC., Pomona, California

TA–W–83,309H
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., La Palma, California

TA–W–83,309I
Southern California Edison, A Subsidiary Of Edison International, IT Department, Including On-Site Leased Workers From INFOSYS, IGATE/PATNI, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, ANAND PAG, Incremental Sysems Corporation And @Business, Inc., Westminster, California

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. § 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on May 2, 2014, applicable to workers of Southern California Edison, a subsidiary of Edison International, IT Department, Irwindale, California (TA–W–83,309), Southern California Edison, a subsidiary of Edison International, IT Department, at the locations identified above. The Department's Notice of Determination was published in the **Federal Register** on May 21, 2014 (Volume 79 FR 29214).

At the request of a company official of @Business, Inc., the Department reviewed the certification for workers of the subject firm. The workers were engaged in activities related to the supply of information technology services.

The company reports that workers leased from @Business, Inc. were employed on-site at Southern California Edison, a subsidiary of Edison International, IT Department, Irwindale, California (TA–W–83,309), Rosemead, California (TA–W–83,309A), Irvine, California (TA–W–83,309B), Alhambra, California (TA–W–83,309C), Rancho Cucamonga, California (TA–W–83,309D), Fullerton, California (TA–W–83,309E), San Clemente, California (TA–W–83,309F), Pomona, California (TA–W–83,309G), La Palma, California (TA–W–83,309H), and Westminster, California (TA–W–83,309I). The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include leased workers from @Business, Inc. working on-site at Southern California Edison, a subsidiary of Edison International, IT Department, Irwindale, California (TA–W–83,309), Rosemead, California (TA–W–83,309A), Irvine, California (TA–W–83,309B), Alhambra, California (TA–W–83,309C), Rancho Cucamonga, California (TA–W–83,309D), Fullerton, California (TA–W–83,309E), San Clemente, California (TA–W–83,309F), Pomona, California (TA–W–83,309G), La Palma, California (TA–W–83,309H), and Westminster, California (TA–W–83,309I).

The amended notice applicable to TA–W–83,309 is hereby issued as follows:

''All workers of Southern California Edison, a subsidiary of Edison International, IT Department, including on-site leased workers from Infosys, iGate/Patni, Cognizant, Info Tech, Collabera, Deloitte, IBM, IJUS LLC, Anand Pag, Incremental Systems Corporation, and @Business, Inc., Irwindale, California (TA–W–83,309), Rosemead, California (TA–W–83,309A), Irvine, California (TA–W–83,309B), Alhambra, California (TA–W–83,309C), Rancho Cucamonga, California (TA–W–83,309D), Fullerton, California (TA–W–83,309E), San Clemente, California (TA–W–83,309F), Pomona, California (TA–W–83,309G), La Palma, California (TA–W–83,309H), Westminster, California (TA–W–83,309I), Norwalk, California (TA–W–83,309K), San Dimas, California (TA–W–83,309K), Compton, California (TA–W–83,309L), Rialto, California (TA–W–83,309M), Fontana, California (TA–W–83,309N), Long Beach, California (TA–W–83,309O), Ontario, California (TA–W–83,309P), Thousand Oaks, California (TA–W–83,309Q), Big Creek, California (TA–W–83,309R), Bishop, California (TA–W–83,309S), Hesperia, California (TA–W–83,309T), Bakersfield, California (TA–W–83,309U), Romoland, California (TA–W–83,309V), Cathedral City, California (TA–W–83,309W), Santa Clarita, California (TA–W–83,309X), Tulare, California (TA–W–83,309Y), Ventura, California (TA–W–83,309Z), Victorville, California (TA–W–83,309AA), and Boulder City, Nevada (TA–W–83,309BB), who became totally or partially separated from employment on or after December 18, 2012 through May 2, 2016, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC this 28th day of April, 2015.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015–12050 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–85,664A]

Kelly Services Working On-Site Kraft Foods Group Global, Inc. Woburn, Massachusetts; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. § 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 28, 2015, applicable to workers from Kraft Foods Group Global, Woburn, Massachusetts. The Department's Notice of Determination was published in the **Federal Register** on February 18, 2015 (80 FR 8695).

At the request of a State Workforce Official, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of gelatin and other food ingredients.

The investigation confirmed that workers leased from Kelly Services were employed on-site at Kraft Foods Group Global, Woburn, Massachusetts. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Kelly Services working on-site at Kraft Foods Group Global, Woburn, Massachusetts.

The amended notice applicable to TA–W–85,664 is hereby issued as follows:

All workers of Kraft Foods Group Global, Inc., Woburn, Massachusetts (TA–W–85,664) and Kelly Services, working on-site at Kraft Foods Group Global, Inc., Woburn, Massachusetts (TA–W–85,664A), who became totally or partially separated from employment on or after November 20, 2013 through January 28, 2017, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 15th day of April, 2015.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015–12083 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Revised Determination on Reconsideration

[TA–W–85,429]

San Bernardino Sun, A Subsidiary of California Newspaper Partnership, Magazine Advertisement Unit, San Bernandino, California

[TA–W–85,429A]

Inland Valley Daily Bulletin, A Subsidiary of California Newspaper Partnership, Magazine Advertisement Unit, Ontario, California

By application dated November 3, 2014, the State of California requested administrative reconsideration of the Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative

Trade Adjustment Assistance applicable to workers and former workers of San Bernardino Sun, a subsidiary of California Newspapers Partnership, San Bernardino, California (SBSUN) and Inland Valley Daily Bulletin, a subsidiary of California Newspapers Partnership, Ontario, California (IVDB). SBSUN and IVDB are engaged in the production of newspapers.

On October 6, 2014, the Department issued a determination which identified SBSUN and IVDB as one firm located in Ontario, California, and stated that the subject firm did not shift production of newspapers, or like or directly competitive articles, to a foreign country; did not increase imports of newspapers, or like or directly competitive articles; and is neither a Supplier or Downstream Producer to a firm that employer a worker group eligible to apply for Trade Adjustment Assistance (TAA) under Section 222(a) of the Trade Act of 1974, as amended.

The request for reconsideration included new information which clarifies that SBSUN and IVADB are different entities and supported the petitioner's allegation that magazine advertisement production shifted from California to a foreign country.

During the reconsideration investigation, the Department carefully reviewed new and previously-submitted information from several separated workers, the State of California, the subject firm, and public sources. The Department also reviewed industry trends with regards to like or directly competitive articles.

Consequently, the Department determines that the subject worker group was incorrectly identified to consist of workers and former workers of one firm instead of two affiliated firms—SBSUN and IVDB—and clarifies that the subject worker groups consist of workers within the ''Magazine Advertisement Unit'' of the after-mentioned firms (SBSUN–MAU and IVCB–MAU, respectively). The Department also determines that, with regards to SBSUN–MAU and IVCB–MAU, the group eligibility criteria have been met.

Section 222(a)(1) has been met because a significant number or proportion of the workers in SBSUN–MAU and IVCB–MAU have become totally or partially separated.

Section 222(a)(2)(B) has been met because the employment declines within SBSUN–MAU and IVCB–MAU are related to the shift in production of magazine advertisements to a foreign country followed by likely or actual increased imports of magazine advertisements (or like or directly competitive articles).

In accordance with Section 246 the Trade Act of 1974, as amended (''Act''), 26 U.S.C. 2813, the Department herein presents the results of its investigation regarding certification of eligibility to apply for alternative trade adjustment assistance (ATAA) for older workers.

The group eligibility requirements for workers of a firm under Section 246 (a)(3)(A)(ii) of the Trade Act are satisfied if the following criteria are met:

(I) Whether a significant number of workers in the workers' firm are 50 years of age or older;

(II) Whether the workers in the workers' firm possess skills that are not easily transferable; and

(III) The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

Section 246(a)(3)(A)(ii)(I) has been met because a significant number of workers in the firms are 50 years of age or older. Section 246(a)(3)(A)(ii)(II) has been met because the workers in the workers' firms possess skills that are not easily transferrable. Section 246(a)(3)(A)(ii)(III) has been met because conditions within the workers' industry are adverse.

Conclusion

After careful review of information obtained during the initial and reconsideration investigations, I determine that workers of SBSUN–MAU and IVCB–MAU, who are engaged in employment related to the production of advertisements, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

All workers of San Bernardino Sun, a subsidiary of California Newspapers Partnership, Magazine Advertisement Unit, San Bernardino, California (TA–W–85,429), and Inland Valley Daily Bulletin, a subsidiary of California Newspapers Partnership, Magazine Advertisement Unit, Ontario, California (TA–W–85,429A), who became totally or partially separated from employment on or after July 15, 2013 through two years from the date of this certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 28th day of April 2015.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015–12082 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–83,035; TA–W–83,035A; TA–W–83,035B]

Hewlett Packard Company, HP Enterprise Services, America Sales Operations, Omaha, Nebraska; Hewlett Packard Company, Order Management, America Sales Operations, Omaha, Nebraska; Hewlett Packard Company, Technology & Operations, Sales Operations, Ww Sales Transformation, Quote To Order, Quote And Configuration Including Remote Workers From Arkansas, California, Colorado, Florida, Idaho, Massachusetts And Texas And Including Leased Workers From Modis Omaha, Nebraska; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 12, 2013, applicable to workers of Hewlett Packard Company, HP Enterprise Services, America Sales Operations, Omaha, Nebraska (TA–W–83,035). The workers were engaged in activities related to the supply of Order management services and post sales customer activities.

During the course of a subsequent Trade Adjustment Assistance (TAA) investigation, the Department reviewed the certification (TA–W–83,035) for workers of the subject firm and received additional information regarding the aforementioned certification.

The investigation revealed that that workers of Hewlett Packard Company, Order Management, America Sales Operations, Omaha, Nebraska (TA–W–83,035A) and Hewlett Packard Company, Technology & Operations, Sales Operations, WW Sales Transformation, Quote to Order, Quote and Configuration, including remote workers from Arkansas, California, Colorado, Florida, Idaho, Massachusetts, and Texas, including leased workers from Modis, Omaha, Nebraska (TA–W–83,035B) supplied support services to the subject firm and reported to the subject firm.

Based on these findings, the Department is amending this certification (TA–W–83,035) to include the workers of Hewlett Packard Company, Order Management, America Sales Operations, Omaha, Nebraska

(TA–W–83,035A) and Hewlett Packard Company, Technology & Operations, Sales Operations, WW Sales Transformation, Quote to Order, Quote and Configuration, including remote workers from Arkansas, California, Colorado, Florida, Idaho, Massachusetts, and Texas, and including leased workers from Modis, Omaha, Nebraska (TA–W–83,035B).

The amended notice applicable to TA–W–83,035 is hereby issued as follows:

All workers of Hewlett Packard Company, HP Enterprise Services, America Sales Operations, Omaha, Nebraska (TA–W–83,035); Hewlett Packard Company, Order Management, America Sales Operations, Omaha, Nebraska (TA–W–83,035A); and Hewlett Packard Company, Technology & Operations, Sales Operations, WW Sales Transformation, Quote to Order, Quote and Configuration, including remote workers from Arkansas, California, Colorado, Florida, Idaho, Massachusetts, and Texas, and including leased workers from Modis, Omaha, Nebraska (TA–W–83,035B), who became totally or partially separated from employment on or after August 28, 2012 through September 12, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 23rd day of April, 2015.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2015–12049 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; General Inquiries to State Agency Contacts

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, ''General Inquiries to State Agency Contacts,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S. C. 3501 *et se.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 18, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201502-1220-005* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue, NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

For Further Information: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S. C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the General Inquiries to State Agency Contacts information collection. The BLS awards funds to State Agencies in order to assist them in operating either or both the Labor Market Information and the Occupational Safety and Health Statistics Federal/State Cooperative Statistical Programs. To ensure a timely flow of data and to be able to evaluate and improve the programs, it is necessary to conduct ongoing communications between the BLS and State partners dealing with, for example, deliverables, program enhancements, and administrative issues. The BLS Authorizing Statute authorizes this information collection. *See* 29 U.S.C. 1 & 2.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0168.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 10, 2015 (80 FR 7500).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0168. The OMB is particularly interested in comments that:

- 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 submission of responses.

Agency: DOL–BLS.

Title of Collection: General Inquiries to State Agency Contacts.

OMB Control Number: 1220–0168.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 54.

Total Estimated Number of Responses: 23,890.

Total Estimated Annual Time Burden: 15,927 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: May 12, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–11984 Filed 5–18–15; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL SCIENCE FOUNDATION

Comment Request: National Science Foundation Proposal/Award; Information—NSF Proposal and Award Policies and Procedures Guide

AGENCY: National Science Foundation.

ACTION: Request for comment notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request renewed clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on the NSF Proposal and Award Policies and Procedures Guide (PAPPG). The primary purpose of this revision is to implement NSF's new Public Access Policy, as well as to revise the PAPPG to incorporate a number of other policy-related changes.

The draft NSF PAPPG is now available for your review and consideration on the NSF Web site at *http://www.nsf.gov/bfa/dias/policy/.*

To facilitate review, revised text has been highlighted in yellow throughout the document to identify significant changes. A brief comment explanation of the change also is provided.

NSF is particularly interested in public comment on the policy changes that are identified in the PAPPG. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

In addition to the type of comments identified above, comments also are invited on: (a) Whether the proposed 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 proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; 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.

DATES: Written comments should be received by July 20, 2015 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 1265, Arlington, VA 22230, or by email to *splimpto@nsf.gov.* The draft NSF Proposal and Award Policies and Procedures Guide may be found at: *http://www.nsf.gov/bfa/dias/policy/.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton on (703) 292–7556 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: ''National Science Foundation Proposal/Award Information—NSF Proposal and Award Policies and Procedures Guide''.

OMB Approval Number: 3145–0058.

Expiration Date of Approval: November 30, 2017.

Type of Request: Intent to seek approval to extend with revision an information collection for three years.

Proposed Project: The National Science Foundation Act of 1950 (Pub. L. 81–507) sets forth NSF's mission and purpose:

> To promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense . . . .

The Act authorized and directed NSF to initiate and support:

- Basic scientific research and research fundamental to the engineering process;
- Programs to strengthen scientific and engineering research potential;
- Science and engineering education programs at all levels and in all the various fields of science and engineering;
- Programs that provide a source of information for policy formulation; and
- Other activities to promote these ends.

NSF's core purpose resonates clearly in everything it does: Promoting achievement and progress in science and engineering and enhancing the potential for research and education to contribute to the Nation. While NSF's vision of the future and the mechanisms it uses to carry out its charges have evolved significantly over the last six decades, its ultimate mission remains the same.

Use of the Information: The regular submission of proposals to the Foundation is part of the collection of information and is used to help NSF fulfill this responsibility by initiating and supporting merit-selected research and education projects in all the scientific and engineering disciplines. NSF receives more than 50,000 proposals annually for new projects, and makes approximately 11,000 new awards.

Support is made primarily through grants, contracts, and other agreements awarded to approximately 2,000 colleges, universities, academic consortia, nonprofit institutions, and small businesses. The awards are based mainly on merit evaluations of proposals submitted to the Foundation.

The Foundation has a continuing commitment to monitor the operations of its information collection to identify and address excessive reporting burdens as well as to identify any real or apparent inequities based on gender, race, ethnicity, or disability of the proposed principal investigator(s)/project director(s) or the co-principal investigator(s)/co-project director(s).

Burden on the Public: The Foundation estimates that an average of 120 hours is expended for each proposal submitted. An estimated 50,000 proposals are expected during the course of one year for a total of 6,000,000 public burden hours annually.

Dated: May 14, 2015.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–12086 Filed 5–18–15; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0108]

Information Collection: Disposal of High-Level Radioactive Wastes in Geologic Repositories

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Disposal of High-Level Radioactive Wastes in Geologic Repositories.'' NRC regulations require States and Indian tribes to submit certain information to the NRC if they request consultation with the NRC staff concerning the review of a potential repository site, or wish to participate in a license application review for a potential repository.

DATES: Submit comments by July 20, 2015. 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 Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0108. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail comments to: Tremaine Donnell, Office of Information Services, Mail Stop: T–5 F53, 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: Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258; email: *INFOCOLLECTS.Resource@NRC.GOV.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0108 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 Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0108.
- NRC's Agencywide Documents Access and Management System (ADAMS).

You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then 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 supporting statement is available in ADAMS under Accession No. ML15104A080.

- 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.
- NRC's Clearance Officer: A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

Please include Docket ID NRC–2015–0108 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 in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and 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. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Title 10 of the Code of Federal Regulations (10 CFR) Part 60, ''Disposal of High-Level Radioactive Wastes in Geologic Repositories.''
2. *OMB approval number:* 3150–0127.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* The information need only be submitted one time.
6. *Who will be required or asked to respond:* State or Indian tribes, or their representatives, requesting consultation with the NRC staff regarding review of a potential high-level radioactive waste geologic repository site, or wishing to participate in a license application review for a potential geologic repository (other than a potential geologic repository site at Yucca Mountain, Nevada, which is regulated under 10 CFR part 63).
7. *The estimated number of annual responses:* 1; however, none are expected in the next 3 years.
8. *The estimated number of annual respondents:* 1; however, none are expected in the next 3 years.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 121; however, none are expected in the next 3 years.
10. *Abstract:* Part 60 of 10 CFR requires States and Indian tribes to submit certain information to the NRC if they request consultation with the NRC staff concerning the review of a potential repository site, or wish to participate in a license application review for a potential repository (other than the Yucca Mountain, Nevada site, which is regulated under 10 CFR part 63). Representatives of States or Indian tribes must submit a statement of their authority to act in such a representative capacity. The information submitted by the States and Indian tribes is used by the Director of the Office of Nuclear

Material Safety and Safeguards as a basis for decisions about the commitment of NRC staff resources to the consultation and participation efforts. The NRC anticipates conducting a public rulemaking to revise portions of 10 CFR part 60 in the near future (*i.e.,* within the next 5 years). If, as part of this rulemaking, revisions are made affecting the information collection requirements, the NRC will follow OMB requirements for obtaining approval for any revised information collection requirements. [Note: All of the information collection requirements pertaining to Yucca Mountain were included in 10 CFR Part 63, and were approved by OMB under control number 3150–0199. The Yucca Mountain site is regulated under 10 CFR part 63 (66 FR 55792, November 2, 2001).]

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 13th day of May 2015.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2015–12018 Filed 5–18–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0102]

Information Collection: Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed information collection: Request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed collection of information of Office of Management and Budget (OMB) approval for a proposed collection of information. The information collection is entitled, ''Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients.''

DATES: Submit comments by July 20, 2015. 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 Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0102. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail comments to: Tremaine Donnell, Office of Information Services, Mail Stop: T–5 F53, 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: Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258; email: *INFOCOLLECTS.Resource@NRC.GOV.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0102 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 Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0102. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2015–0102 on this Web site.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then 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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No.: ML15086A164. The supporting statement available in ADAMS under Accession No. ML15086A166.
- 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.
- NRC's Clearance Officer: A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, Tremaine Donnell, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

Please include Docket ID NRC–2015–0102 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 in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and 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. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations other than Conventional Residences Receiving Such Patients.
2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.
3. *Type of submission:* New.
4. *The form number, if applicable: NA.*
5. *How often the collection is required or requested:* One-time.
6. *Who will be required or asked to respond:* Institutions that treat thyroid cancer patients with I–131 and the thyroid cancer patients who have been treated.
7. *The estimated number of annual responses:* 5,175 (175 for treating institutions and 5000 for individuals).
8. *The estimated number of annual respondents:* 5,175.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1,675 (175 hours for treating institution and 1500 hours for individuals).
10. *Abstract:* Although most patients return to their home after receiving diagnostic or therapeutic of Iodine-131, some patients released by the licensee may stay at another location (such as a hotel) for a few days. However, the extent of this practice is unclear. The same uncertainty exists regarding patients returning to nursing homes and other institutional settings. Therefore, one of the main objectives of this study is to obtain reliable statistical data that provides good estimates of the prevalence of these practices. The second objective is to determine, by measurements, the external and internal doses received by members of the general public at hotels, nursing homes, or other institutional settings that receive treated patients immediately after their release.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 13th day of May 2015.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2015–12017 Filed 5–18–15; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

President's Commission on White House Fellowships Advisory Committee: Closed Meeting

AGENCY: President's Commission on White House Fellowships, U.S. Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The President's Commission on White House Fellowships (PCWHF) was established by an Executive Order in 1964. The PCWHF is an advisory committee composed of Special Government Employees appointed by the President. The Advisory Committee meet in June to interview potential candidates for recommendation to become a White House Fellow.

The meeting is closed.

Name of Committee: President's Commission on White House Fellowships Selection Weekend.

Date: June 11–14, 2015.

Time: 7:00 a.m.–9:30 p.m.

Place: St. Regis Hotel, 16th & K Street, Washington, DC 20006.

Agenda: The Commission will Interview 30 National Finalists for selection of new class of White House Fellows.

Location: St. Regis Hotel, 16th and K Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Jennifer Y. Kaplan, 712 Jackson Place NW., Washington, DC 20503, Phone: 202–395–4522.

President's Commission on White House Fellowships.

Jennifer Y. Kaplan,

Director.

[FR Doc. 2015–12085 Filed 5–18–15; 8:45 am]

BILLING CODE 6325–44–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2014–78; Order No. 2482]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning a modification to a Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 20, 2015.

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:

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III. Ordering Paragraphs

I. Introduction

On May 12, 2015, the Postal Service filed notice that it has agreed to a Modification to the existing Global Expedited Package Services 3 negotiated service agreement approved in this docket.[1] In support of its Notice, the Postal Service includes a redacted copy of the Modification and a certification of compliance with 39 U.S.C. 3633(a), as required by 39 CFR 3015.5. Notice, Attachment 1 and 2.

The Postal Service also filed the unredacted Modification and supporting financial information under seal. Notice at 2. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.*

The Modification updates the customer's mailing and contact information, revises the choice of payment method, and replaces Annex 1, which contains new rates. *Id.* at 1; *Id.* Attachment 1. The rates in the

[1] Notice of the United States Postal Service of Filing Modification to Global Expedited Package Services 3 Negotiated Service Agreement, May 12, 2015 (Notice).

Modification are intended to go into effect on June 1, 2015. Notice at 1. The Postal Service asserts that the Modification will not impair the ability of the contract to comply with 39 U.S.C. 3633. *Id.* Attachment 2.

II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than May 20, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints James F. Callow to represent the interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2014–78 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints James F. Callow to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than May 20, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–11990 Filed 5–18–15; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74956; File No. SR–NYSEMKT–2015–38]

Self-Regulatory Organizations; NYSE MKT, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Modifying the NYSE Amex Options Fee Schedule Related to Fees and Credits Associated With the Customer Best Execution Auction

May 13, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 1, 2015, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (''SEC'' or ''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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Amex Options Fee Schedule (''Fee Schedule'') related to fees and credits associated with the Customer Best Execution Auction (''CUBE Auction'' or ''Auction''). The Exchange proposes to implement the fee change effective May 1, 2015. The text of the proposed rule change is available on the Exchange's Web site 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 purpose of this filing is to amend Section I.G. of the Fee Schedule[3] to modify existing CUBE fees and credits and to add a new rebate for CUBE participants who qualify for Tiers 2, 3, 4 or 5 of the Amex Customer Engagement (''ACE'') Program.[4] The Exchange proposes to implement the fee change effective May 1, 2015.

The Exchange proposes to increase the fees associated with RFR Responses participating in the Auction by $0.05—from $0.55 to $0.60 for Non-Customers in Penny Pilot issues; and from $0.90 to $0.95 for Non-Customers in non-Penny Pilot issues. In addition, the Exchange proposes to decrease the Initiating Participant Credit by $0.05 for Penny Pilot issues—from $0.40 to $0.35; and $0.10 for non-Penny Pilot issues—from $0.80 to $0.70. The Exchange also proposes to introduce a rebate for certain Initiating Participants that qualify for the ACE Program. Specifically, as proposed, those ATP Holders who qualify for Tiers 2, 3, 4 or 5 of the ACE Program would receive a $0.12 per contract rebate for up to 5,000 Customer contracts per CUBE Order executed in a CUBE Auction (the ''ACE Initiating Participant Rebate'' or ''Rebate''). The proposed Rebate is payable in addition to any other fees or credits accrued from the CUBE Auction (*e.g.,* in addition to the Initiating Participant Credit for both Penny and non-Penny Pilot issues). Thus, as proposed, the maximum potential CUBE credit for Penny Pilot issues is $0.47 ($0.12 Rebate + $0.35 Initiating Participant Credit) and for non-Penny Pilot issues is $0.82 ($0.12 Rebate + $0.70 Initiating Participant Credit). The ACE Initiating Participant Rebate is available regardless of whether the CUBE Order trades with the Contra Order or RFR Response(s), whereas the current Initiating Participant Credits are payable only for each CUBE Order contract that does not trade with the Contra Order.

The proposed amendments to CUBE Auction pricing are designed to incentivize market participants that have committed a certain amount of volume to the Exchange to provide even more liquidity through CUBE Auctions. This additional volume and liquidity would benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery and price improvement.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[6] in particular, 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 Exchange believes that the proposed changes to CUBE Auction fees are reasonable, equitable and not

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Fee Schedule, Section I.G., *available at, https://www.theice.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf.*

[4] *See id.,* Section I.E.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

unfairly discriminatory. First, the proposal to increase the fees associated with RFR Responses that participate in the CUBE applies equally to all non-Customer ATP Holders that choose to participate in the CUBE, and access to the Exchange is offered on terms that are not unfairly discriminatory. In addition, the proposed RFR Response fees are within the range of fees charged to non-Customers on other exchanges for executions within similar electronic crossing mechanisms. For example, the BOX Options Exchange LLC (''BOX'') charges Professional Customers and Broker Dealers who respond to an auction with Improvement Orders $0.72 per contract in Penny issues and $1.12 per contract in non-Penny issues, while charging BOX Market Makers who respond either $0.55 in Penny issues or $0.95 in non-Penny issues.[7]

The Exchange believes that the proposal to reduce the current Initiating Participant Credits are reasonable, equitable and non-discriminatory because they apply equally to all ATP Holders that choose to participate in the CUBE, and access to the Exchange is offered on terms that are not unfairly discriminatory. Finally, the proposed CUBE Auction credits for Penny and non-Penny issues to be paid to Initiating Participants for each CUBE Order contract that does not trade with the Contra Order are within the range of rebates paid on other exchanges for executions within similar electronic crossing mechanisms. For example, the International Securities Exchange, LLC (''ISE'') pays a Price Improvement Mechanism (''PIM'') Break-up Rebate of $0.35 per contract in Select Symbols (*i.e.,* Penny Pilot issues) and $0.80 per contract in Non-Select Symbols (*i.e.,* non-Penny Pilot issues) for contracts submitted to a PIM that do not trade with their contra order.[8]

Similarly, the proposed changes to CUBE Auction credits are reasonable, equitable and not unfairly discriminatory. Specifically, the ACE Initiating Participant Rebate is based on the amount of business transacted on the Exchange and is designed to attract more volume and liquidity to the Exchange generally, and to CUBE Auctions specifically, which will benefit all market participants (including those that do not participate in the ACE Program) through increased opportunities to trade at potentially improved prices as well as enhancing price discovery. Furthermore, the proposed Rebate is reasonably designed and not unfairly discriminatory because it [sic] available regardless of the parties that trade with the CUBE Order (*i.e.,* whether the CUBE Order trades with the Contra Order or otherwise).

In addition, the proposal to offer an additional incentive to participate in the CUBE Auction to those ATP Holders that have achieved certain monthly volume thresholds is also not new or novel. For example, the MIAX Options Exchange (''MIAX'') offers an additional per contract rebate on certain agency orders executed in its electronic auction mechanism (''PRIME''), which provides for a maximum credit of $0.12 per contract, based on a member achieving certain monthly volume thresholds.[9] In addition, the proposal to cap the Rebate at 5,000 Customer contracts per CUBE Order is likewise consistent with the practice of other exchanges. For example, the Chicago Board of Options Exchange (''CBOE'') caps the number of contracts submitted to its price improvement auction that are eligible for additional volume rebates at 1,000 contracts.[10] The Exchange notes that although the proposed Rebate applies solely to Customer orders, it is nonetheless equitable and not unfairly discriminatory because it would enhance the incentives to ATP Holders to transact Customer orders on the Exchange and an increase in Customer order flow would bring greater volume and liquidity to the Exchange. Increased volume to the Exchange benefits all market participants by providing more trading opportunities and tighter spreads, even to those market participants that do not participate in the ACE Program.

Additionally, the Exchange believes the proposed changes are consistent with the Act because they may attract greater volume and liquidity to the Exchange, which would improve its overall competitiveness and strengthen its market quality for all market participants.

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,[11] 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 purposes of the Act. The Exchange believes the proposed amendments to CUBE Auction pricing are pro-competitive as the fees are to incentivize increases in volume and liquidity to the Exchange, which would benefit all of Exchange participants through increased opportunities to trade as well as enhancing price discovery. The Exchange also believes that the proposed ACE Initiating Participant Rebate would enhance the competiveness of the Exchange relative to other exchanges that offer similar rebates tied to volume incentives.[12]

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. 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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[13] of the Act and subparagraph (f)(2) of Rule 19b–4[14]

[7] *See* BOX fee schedule, *available at, http://boxexchange.com/assets/BOX_Fee_Schedule.pdf.* The BOX fee schedule has several parts that must be taken collectively to arrive at the all-in cost of responding to an auction. For example, a Broker Dealer who responds to an auction with an Improvement Order will pay $0.72 per contract in Penny issues. The $0.72 fee represents the Improvement Order fee of $0.37 from Section I of the fee schedule, plus the $0.35 fee to add liquidity in Penny issues quoted with an MPV of $0.01 from Section II of the schedule.

[8] *See* ISE fee schedule, *available at, http://www.ise.com/assets/documents/OptionsExchange/legal/fee/ISE_fee_schedule.pdf.*

[9] *See* MIAX fee schedule, Priority Customer Rebate Program, *available at, http://www.miaxoptions.com/content/fees* (providing a $0.10 per contract rebate for all Priority Customer orders executed in the PRIME Auction and providing that any Member or applicable affiliate that qualifies for MIAX's Priority Customer Rebate Program volume tiers 3, 4, or 5 will be credited an additional $0.02 per contract for each Priority Customer order executed in the PRIME Auction as a PRIME Agency Order over a threshold of 1,500,000 contracts in a month, subject to certain enumerated exceptions).

[10] *See* CBOE fee schedule, Volume Incentive Program (''VIP''), *available at, http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf* (providing that VIP credits on orders executed electronically in Automated Improvement Mechanism will be capped at 1,000 contracts per order for simple executions and 1,000 contracts per leg for complex executions).

[11] 15 U.S.C. 78f(b)(8).

[12] *See supra* n. 9, 10.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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) [15] 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–NYSEMKT–2015–38 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–NYSEMKT–2015–38. 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 Web site (*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 Web site 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 filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2015–38, and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12063 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74948; File No. SR–EDGA–2015–18]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related To Fees for Use of EDGA Exchange, Inc.

May 13, 2015.

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 April 30, 2015, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. 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 filed a proposal to amend its fees and rebates applicable to Members [5] of the Exchange pursuant to EDGA Rule 15.1(a) and (c) (''Fee Schedule'') to: (i) Decrease the rebate for orders yielding Flag BY, which routes to the BATS Y-Exchange, Inc. (''BYX'') and removes liquidity using routing strategies Destination Specific (''DIRC''), ROUC, ROUE, ROBB, or ROCO; [6] (ii) amend the criteria for the MidPoint Discretionary Order Add Volume Tier; and (iii) make an immaterial, non-substantive change. Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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 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 parts 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: (i) Decrease the rebate for orders yielding Flag BY, which routes to BYX and removes liquidity using routing strategies DIRC, ROUC, ROUE, ROBB, or ROCO; (ii) amend the criteria for the MidPoint Discretionary Order Add Volume Tier; and (iii) make an immaterial, non-substantive change.

Flag BY

In securities priced at or above $1.00, the Exchange currently provides a rebate of $0.00160 per share for Members' orders that yield Flag BY, which routes to BYX and removes

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer, or any person associated with a registered broker or dealer [sic], that has been admitted to membership in the Exchange. A Member will have the status of a ''member'' of the Exchange as that term is defined in Section 3(a)(3) of the Act.'' *See* Exchange Rule 1.5(n).

[6] The DIRC, ROUC, ROUE, ROBB, or ROCO routing strategies are set forth in Exchange Rule 11.11(g).

liquidity using routing strategies DIRC, ROUC, ROUE, ROBB, or ROCO. The Exchange proposes to amend its Fee Schedule to decrease the rebate for orders that yield Flag BY to $0.00150 per share in securities priced at or above $1.00.[7] The proposed change represents a pass through of the rate BATS Trading, Inc. (''BATS Trading''), the Exchange's affiliated routing broker-dealer, is provided for routing orders to BYX that remove liquidity. The proposed change is in response to BYX's May 2015 fee change where BYX decreased its rebate from $0.00160 per share to $0.00150 per share for orders in securities priced at or above $1.00.[8] When BATS Trading routes to and removes liquidity from BYX, it will now receive a standard rebate of $0.00150 per share. BATS Trading will pass through the rebate provided by BYX to the Exchange and the Exchange, in turn, will pass through this rate to its Members.

MidPoint Discretionary Order Add Volume Tier

The Exchange proposes to amend the criteria for the MidPoint Discretionary Order Add Volume Tier. Under the tier, a Member qualifies for a reduced fee of $0.0003 per share where that Member: (i) Adds an ADV of at least 0.25% of the TCV including non-displayed orders that add liquidity; and (ii) adds or removes an ADV of at least 1,500,000 shares yielding fee codes DM or DT. Fee code DM is applied to Non-Displayed orders that add liquidity using MidPoint Discretionary orders [9] and fee code DT is applied to Non-Displayed orders that remove liquidity using MidPoint Discretionary Orders. Orders that yield fee code DM or fee code DT that do not meet to the criteria of the MidPoint Discretionary Order Add Volume Tier are charged a fee of $0.00050 per share. The Exchange now proposes to decrease the ADV requirement to require that a Member add or remove an ADV of at least 500,000 shares yielding fee codes DM or DT. Easing the criteria of the MidPoint Discretionary Order Add Volume Tier is intended to further incentive Members to submit an increased number of MidPoint Discretionary orders to the Exchange, thereby increasing the liquidity on the Exchange at the midpoint of the National Best Bid or Offer (''NBBO'').

Non-Substantive Changes

The Exchange also proposes to make an immaterial, non-substantive change to its Fee Schedule by removing '', Inc.'' from the reference to the Exchange in the heading of the Fee Schedule. This non-substantive change is intended to make the reference to the Exchange in the heading of the Fee Schedule consistent with the manner in which its affiliated exchanges [10] are referenced in their respective fee schedules.

Implementation Date

The Exchange proposes to implement these amendments to its Fee Schedule on May 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[11] in general, and furthers the objectives of Section 6(b)(4),[12] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent [sic] market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

Flag BY

The Exchange believes that its proposal to decrease the rebate for orders that yield Flag BY represents an equitable allocation of reasonable dues, fees, and other charges among Members and other persons using its facilities. Prior to the BYX's May 2015 fee change, BYX provided BATS Trading a rebate of $0.00160 per share to remove liquidity in securities priced at or above $1.00, which BATS Trading passed through to the Exchange and the Exchange provided its Members. When BATS Trading routes to BYX, it will now be provided a rebate of $0.00150 per share. The Exchange does not levy additional fees or offer additional rebates for orders that it routes to BYX through BATS Trading. Therefore, the Exchange believes that the proposed change to Flag BY is equitable and reasonable because it accounts for the pricing changes on BYX, which enables the Exchange to provide its Members the applicable pass-through rebate. Lastly, the Exchange notes that routing through BATS Trading is voluntary and believes that the proposed change is non-discriminatory because it applies uniformly to all Members.

MidPoint Discretionary Order Add Volume Tier

The Exchange believes amending the criteria for the MidPoint Discretionary Order Add Volume Tier represents an equitable allocation of reasonable dues, fees, and other charges among Members and other persons using its facilities because it is designed to further incentivize Members to increase their use of MidPoint Discretionary orders on EDGA. MidPoint Discretionary Orders increase displayed liquidity on the Exchange while also enhancing execution opportunities at the mid-point of the NBBO. Promotion of displayed liquidity at the NBBO enhances market quality for all Members. Members utilizing MidPoint Discretionary orders provide liquidity at the midpoint of the NBBO increasing the potential for an order to receive price improvement, and easing the tier's criteria so that Members may be eligible for a decreased fee is a reasonable means by which to encourage the use of such orders. In addition, the Exchange believes that by encouraging the use of MidPoint Discretionary orders by easing the tier's criteria, Members seeking price improvement would be more motivated to direct their orders to EDGA because they would have a heightened expectation of the availability of liquidity at the midpoint of the NBBO. The Exchange also believes that the proposed addition of the MidPoint Discretionary Order Add Volume Tier is non-discriminatory because it will be available to all Members.

Non-Substantive Changes

The Exchange believes that the non-substantive change to its Fee Schedule is reasonable because it is not designed to amend any fee, nor alter the manner in which it assesses fees or calculates rebates. This non-substantive change to

[7] The Exchange does not propose to amend its fee for orders that yield Flag BY in securities priced below $1.00.

[8] *See* BYX Exchange Fee Schedule Changes Effective May 1, 2015 *available at http://cdn.batstrading.com/resources/fee_schedule/2015/BATS-BYX-Exchange-BZX-Exchange-EDGA-Exchange-and-EDGX-Exchange-Fee-Schedule-Changes-Effective-May-1–2015.pdf.*

[9] *See* Exchange Rule 11.8(e) for a description of MidPoint Discretionary orders.

[10] The Exchange's affiliated exchanges are BATS Exchange, Inc., BATS Y-Exchange, Inc., and EDGX Exchange, Inc. (''EDGX''). The Exchange understands that EDGX also intends to file a proposed rule change with the Commission making a similar change to how EDGX is referenced in the heading of its fee schedule.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

the Fee Schedule is intended to make the reference to the Exchange in the heading of the Fee Schedule consistent with the manner in which its affiliated exchanges are referenced in their respective fee schedules, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendments to its Fee Schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

Fee Code BY

The Exchange believes that its proposal to pass through the amended rebate for orders that yield Flags BY would increase intermarket competition because it offers customers an alternative means to route to BYX for the same rebate that they would be provided if they entered orders on that trading center directly. The Exchange believes that its proposal would not burden intramarket competition because the proposed rebate would apply uniformly to all Members.

MidPoint Discretionary Order Add Volume Tier

The Exchange believes that its proposal to ease the criteria for the MidPoint Discretionary Order Add Volume Tier would increase intermarket competition because it would further incentivize Members to send an increased amount MidPoint Discretionary orders to the Exchange in order to qualify for the tier's decreased fee. The Exchange believes that its proposal would neither increase nor decrease intramarket competition because the MidPoint Discretionary Order Add Volume Tier would apply uniformly to all Members and the ability of some Members to meet the tier would only benefit other Members by contributing to increased liquidity at the midpoint of the NBBO and better market quality at the Exchange.

Non-Substantive Changes

The Exchange believes that the non-substantive change to the Fee Schedule will not affect intermarket nor intramarket competition because the change is not designed to amend any fee or alter the manner in which the Exchange assesses fees or calculates rebates.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and paragraph (f) of Rule 19b–4 thereunder.[14] At any time within 60 days of the filing of the 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.

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–EDGA–2015–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2015–18. 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 Web site (*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 Web site 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2015–18 and should be submitted on or before June 9,2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

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[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74951; File No. SR–NYSEARCA–2015–38]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Adopting New Equity Trading Rules Relating to Trading Sessions, Order Ranking and Display, and Order Execution To Reflect the Implementation of Pillar, the Exchange's New Trading Technology Platform

May 13, 2015.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 15 CFR 240.19b–4.

notice is hereby given that, on April 30, 2015, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 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 adopt new equity trading rules relating to Trading Sessions, Order Ranking and Display, and Order Execution to reflect the implementation of Pillar, the Exchange's new trading technology platform. The text of the proposed rule change is available on the Exchange's Web site 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 29, 2015, the Exchange announced the implementation of Pillar, which is an integrated trading technology platform designed to use a single specification for connecting to the equities and options markets operated by NYSE Arca and its affiliates, New York Stock Exchange LLC (''NYSE'') and NYSE MKT LLC (''NYSE MKT''). NYSE Arca Equities will be the first trading system to migrate to Pillar.[4] NYSE Arca Equities trading on Pillar would be an all-electronic price-time priority equities trading platform.

The Exchange will be submitting proposed rule changes to correspond to the anticipated migration to Pillar, which would be done in phases. During the first phase, ETP Holders would continue to connect to existing NYSE Arca gateways to access the Pillar trading platform. In the second phase, the Exchange will introduce new customer gateways and connectivity as well as additional order type processing. To implement the first phase of Pillar migration, the Exchange will be submitting more than one rule filing. The Exchange will later submit rule filings to implement the second phase of Pillar migration.

During the first phase of Pillar implementation, the Exchange would roll out the new technology platform over a period of time based on a range of symbols. Because orders entered in symbols not yet migrated to Pillar would continue to operate under current rules, the Exchange will keep its current rules, pending complete migration of symbols to Pillar and retirement of the current trading system, and add new rules that would be applicable to symbols that trade on the Pillar trading platform. As proposed, the new rules governing trading on Pillar would have the same numbering as current rules, but with the modifier ''P'' appended to the rule number. For example, Rule 7.34, governing Trading Sessions, would remain unchanged and continue to apply to any trading in symbols on the current trading platform. Proposed Rule 7.34P would govern Trading Sessions for trading in symbols migrated to the Pillar platform. Once all symbols have migrated to the Pillar platform, the Exchange will file a rule proposal to delete rules that are no longer operative.

In this filing, the Exchange proposes to adopt new Pillar rules relating to Trading Sessions (NYSE Arca Equities Rule 7.34 (''Rule 7.34'')), Order Ranking and Display (NYSE Arca Equities Rule 7.36 (''Rule 7.36'')), and Order Execution (NYSE Arca Equities Rule 7.37 (''Rule 7.37'')). As proposed, the new rules would be NYSE Arca Equities Rules 7.34P (Trading Sessions) (''Rule 7.34P''), 7.36P (Order Ranking and Display) (''Rule 7.36P''), and 7.37P (Order Execution) (''Rule 7.37P''). These three rules would set forth the foundation of the Exchange's equity trading model in Pillar, including the hours of operation, how orders would be ranked and displayed, and how orders would be executed.

As discussed in greater detail below, the Exchange is not proposing that the core functionality of rules applicable to trading on Pillar would be different from rules applicable to trading on the current NYSE Arca equities trading system. However, with Pillar, the Exchange would introduce new terminology. Further, because the Exchange would operate both its current trading system for some symbols and the Pillar trading platform for other symbols, until rollout of Pillar across all symbols is complete, the Exchange is proposing to add all new rule text for proposed Rules 7.34P, 7.36P, and 7.37P. Because these rules and related proposed terminology changes would be the foundation for all other rule changes that will be proposed in connection with Pillar, the Exchange believes that filing for these rule changes before other rule changes will provide the public notice of how Pillar would operate generally.

Proposed Use of ''P'' Modifier

To reflect how the ''P'' modifier would operate, the Exchange proposes to add rule text immediately following the reference to ''Rule 7 Equities Trading,'' and before ''Section 1. General Provisions'' that would provide that rules with a ''P'' modifier would be operative for symbols that are trading on the Pillar trading platform. As further proposed, if a symbol is trading on the Pillar trading platform, a rule with the same number as a rule with a ''P'' modifier would no longer be operative for that symbol and the Exchange would announce by Trader Update when symbols are trading on the Pillar trading platform.

Similarly, the Exchange proposes to add rule text following the title ''Rule 1 Definitions'' that provides that definitions with a paragraph designation that includes a ''P'' modifier would be operative for symbols trading on the Pillar trading platform. A definition with the same paragraph designation as a definition with a ''P'' modifier would not be operative for symbols trading on Pillar. Finally, to provide clarity that definitions that do not have a version with a ''P'' modifier would apply across all symbols, regardless of the trading platform, the Exchange proposes to state explicitly that definitions that do not have a companion version with a ''P'' modifier would continue to be operative for all symbols.

The Exchange believes that adding these explanations regarding the ''P'' modifier in Exchange rules would provide transparency regarding which rules and definitions would be operative depending on the trading platform on which a symbol is trading.

[4] *See* Trader Update dated January 29, 2015, available here: *http://www1.nyse.com/pdfs/Pillar_Trader_Update_Jan_2015.pdf.*

Trading Sessions

Rule 7.34 governs trading sessions. As set forth in Rule 7.34(a), the Exchange has three trading sessions:

(1) the Opening Session, which begins at 1:00:00 a.m. Pacific Time and concludes at the commencement of the Core Trading Session. The Opening Auction and Market Order Auction occur during the Opening Session;

(2) the Core Trading Session, which begins at 6:30:00 a.m. Pacific Time or at the conclusion of the Market Order Auction, whichever comes later, and concludes at 1:00:00 p.m. Pacific Time; and

(3) the Late Trading Session, which begins following the conclusion of the Core Trading Session and concludes at 5:00:00 p.m. Pacific Time.

Proposed Rule 7.34P(a)(1)–(3) would similarly provide for three trading sessions, but with several proposed differences from Rule 7.34(a):

• First, the Exchange proposes non-substantive differences in the names of the trading sessions on the Pillar trading platform. Specifically, for Pillar, the Exchange proposes to call its three trading sessions the ''Early Trading Session,'' the ''Core Trading Session,'' and the ''Late Trading Session.'' The Exchange believes that the use of the term ''Early Trading Session,'' rather than the ''Opening Session,'' better describes when the session occurs, which is before the Core Trading Session, and therefore would be clearer to market participants. In addition, the Exchange proposes the auction that opens the ''Early Trading Session'' would be called the ''Early Open Auction,'' instead of the ''Opening Auction'' and that the auction that opens the ''Core Trading Session'' would be called the ''Core Open Auction'' instead of the ''Market Order Auction.'' The Exchange believes that the auctions that open the respective sessions should be named to reflect both the name of the session and that it is an opening auction for the respective session.

• Second, the Exchange proposes that all time references for the trading sessions would be to Eastern Time, and would not include references to seconds.[5] The Exchange's current rules for trading sessions use references to Pacific Time. In today's national trading environment, the Exchange believes that use of Eastern Time would reduce investor confusion by conforming references to time to how all other exchanges denote time in their rules. The Exchange similarly believes that references to seconds in proposed Rule 7.34P are unnecessary, as none of the other Exchange rules for the beginning and end of trading sessions use seconds.

• Third, the Exchange proposes that Rule 7.34P(a)(1) regarding Early Trading Sessions would be more detailed than Rule 7.34 by adding text that is currently in Rule 7.35(a)(1), without any substantive differences.[6] Specifically, the Exchange proposes to include in Rule 7.34P(a)(1) that the Corporation [7] would begin accepting orders 30 minutes before the Early Trading Session begins. Because this rule text concerns when orders may be entered, the Exchange believes that it should be included in the rule governing trading sessions for Pillar. Proposed Rule 7.34P(a)(1) would further provide that the Early Open Auction would begin the Early Trading Session.

• Fourth, the Exchange proposes to provide that the Core Open Auction would occur during the Core Trading Session. Rule 7.34(a) currently provides that the Market Order Auction occurs during the Opening Session. Because this auction is intended to open trading for the Core Trading Session,[8] the Exchange believes it should be considered part of the Core Trading Session, rather than the Early Trading Session. The Exchange therefore proposes to specify in proposed Rule 7.34P(a)(2) that the Core Open Auction would begin the Core Trading Session. The Exchange further proposes to specify that the Core Trading Session would end at the conclusion of Core Trading Hours or the Core Closing Auction, whichever comes later. The proposed cross reference to Core Trading Hours, which is defined in Rule 1.1(j), takes into consideration that the Core Trading Session may end earlier than 4:00 p.m. when the Exchange has an early scheduled close, *e.g.,* the day before Christmas.

• Fifth, the Exchange proposes not to include in proposed Rule 7.34P the text currently in Rule 7.34 relating to extended Core Trading Session hours. Rules 7.34(a)(3)(A) and (B) provide that the Core Trading Session for specified securities concludes at 1:15:00 p.m. Pacific Time unless otherwise determined by the Corporation and that the Exchange would maintain on its Web site which securities for which the Core Trading Session would extend to 1:15:00 p.m. Because the Exchange does not have any securities for which the Core Trading Session extends to 1:15:00 p.m. Pacific Time, nor does it plan to provide for such an extended Core Trading Session for any securities, the Exchange proposes not to include this provision in proposed Rule 7.34P.

• Finally, the Exchange proposes that text currently found in Rules 7.34(a)(4), 7.34(a)(5), and 7.34(b) not be included in proposed Rule 7.34P. Rules 7.34(a)(4) and (5) currently describe how the Exchange handles trading halts in specified securities that occur during different trading sessions. The Exchange believes that rule text relating to halts should be centralized in a single rule and will be proposing in a separate rule filing to add the text of current Rule 7.34(a)(4) and (5) to proposed Rule 7.18P. Rule 7.34(b) sets forth Market Maker obligations to enter Q Orders for securities in which they are registered. The Exchange believes that this topic is not related to trading sessions directly and that this rule text should be included with the definition of Q Orders and therefore will be proposing in a separate rule filing to add the text of current Rule 7.34(b) to proposed Rule 7.31P.[9] Because Rule 7.34(a)(4) defines the term ''Derivative Securities Product'' and because that definition would not be included in proposed Rule 7.34P, the Exchange proposes to add a new definition to Rule 1.1 to define the terms Derivative Securities Product and UTP Derivative Securities Product. As proposed, the term ''Derivative Securities Product'' would mean a security that meets the definition of ''derivative securities product'' in Rule 19b–4(e) under the Securities Exchange Act of 1934 [10] and a ''UTP Derivatives Securities Product'' would mean a Derivative Securities Product that trades on the Exchange pursuant to unlisted trading privileges.

The Exchange proposes to include the text of Rule 7.34(c) in proposed Rule 7.34P(b) with non-substantive differences and to provide more detail. Rule 7.34(c) provides that any Day Order entered into the NYSE Arca Marketplace [11] may remain in effect for

[5] The Exchange also proposes to change the time in the definition of Core Trading Hours, which is defined in Rule 1.1(j), from Pacific to Eastern Time references.

[6] In a separate rule filing, the Exchange will propose Rule 7.35P, which would govern auctions in Pillar.

[7] The term ''Corporation'' is defined in Rule 1.1(k) as NYSE Arca Equities, Inc., as described in the NYSE Arca Equities, Inc.'s Certification of Incorporation and Bylaws.

[8] Rule 7.35 currently specifies that the Market Order Auction occurs at 9:30 a.m., which is the same time that the Core Trading Session begins for securities that do not have an auction.

[9] The Exchange will be submitting a separate rule filing to propose Rule 7.31P, which would govern orders and modifiers in Pilar.

[10] 17 CFR 240.19b–4(e)

[11] The term ''NYSE Arca Marketplace'' is defined in Rule 1.1(e) as the electronic securities communication and trading facility designated by

Continued

one or more consecutive trading sessions on a particular day and that for each Day Order entered, the User [12] must designate for which trading session(s) the order will remain in effect. Proposed Rule 7.34P(b) would instead provide that any order entered into the NYSE Arca Marketplace must include a designation for which trading session(s) the order would remain in effect.

Proposed new Rule 7.34P(b) would also provide that an order would be eligible to participate only in the designated trading session(s) and may remain in effect for one or more consecutive trading sessions on a particular day. The Exchange further proposes to add that unless otherwise specified, an order designated for a later trading session would be accepted but not eligible to trade until the designated trading session begins. For example, if an order is entered at 8:00 a.m. Eastern Time and is designated for the Core Trading Session only, it would be accepted but would not participate in the Early Trading Session. As discussed in more detail below, proposed Rule 7.34P(c) would specify orders that may not be entered either during or in advance of a designated trading session. In addition, the Exchange proposes to add that an order designated solely for a trading session that has already ended would be rejected. For example, an order entered at 10:00 a.m. Eastern Time that is designated only for the Early Trading Session would be rejected. The Exchange believes that the proposed changes would provide transparency in Exchange rules of when orders may be entered and when orders would be rejected.

The Exchange also proposes to add in Rule 7.34P(b)(2) and (3) that an order with a day time-in-force instruction entered before or during the Early Trading Session would be deemed designated for the Early Trading Session and the Core Trading Session and that an order with a day time-in-force instruction entered during the Core Trading session would be deemed designated for the Core Trading Session. The Exchange believes that the proposed rule text provides transparency regarding which sessions during which an order may be eligible to participate.

The Exchange proposes to describe the processes currently set forth in Rule 7.34(d) in proposed Rule 7.34P(c). Rule 7.34(d) describes which orders are permitted in each session. The Exchange proposes to revise how this topic is described in proposed Rule 7.34P(c) to provide generally that orders are eligible to participate in a session, unless otherwise provided in the rule. Accordingly, rule text in Rule 7.34(d) that specifies order types that are eligible to participate in a particular session would not be included in new Rule 7.34P because the proposed new text would make it unnecessary to specify the order types eligible to participate in a particular session. Those order types that would not be eligible to participate in each of the Exchange's three trading sessions are described below.

With respect to the Early Trading Session, the Exchange proposes in new Rule 7.34P(c)(1) to provide that, unless otherwise specified in proposed paragraphs (c)(1)(A)—(E) of the new rule, orders and modifiers defined in Rule 7.31P that have been designated for the Early Trading Session would be eligible to participate in the Early Trading Session. The Exchange believes that the proposed rule text makes clear that unless specified in paragraphs (c)(1)(A)–(E) of new Rule 7.34P, all orders and modifiers in Rule 7.31P, if designated for the Early Trading Session, would be eligible to participate in the Early Trading Session.

Unlike under current rules, the Exchange proposes that Tracking Orders would be eligible to participate in the Early Trading Session on the Pillar trading platform. Because the Exchange routes orders during the Early Trading Session and because Tracking Orders are intended to be passive liquidity on the Exchange to interact with an order before it is routed, the Exchange believes that Tracking Orders should be available in the Early Trading Session. Accordingly, rule text from Rule 7.34(d)(1)(C) would not be included in new Rule 7.34P(c)(1).

The Exchange proposes that the following orders and modifiers in Rule 7.31P would not be eligible to participate in the Early Trading Session:

- Proposed Rule 7.34P(c)(1)(A) would provide that Market Orders, Q Orders, and Pegged Orders would not be eligible to participate in the Early Trading Session, which is current functionality. The Exchange further proposes to specify that any Market Orders, Q Orders, and Pegged Orders that include a designation for the Early Trading Session would be rejected. Such orders would be rejected if they also include a designation for another trading session; the designation for the Early Trading Session whether alone or with another designation would result in a rejection of the order. The Exchange further proposes to add that Market Pegged Orders entered before or during the Early Trading Session would be rejected regardless of the session designated for the order.[13] For example, a Market Order, Q Order, or Primary Pegged Order designated for the Core Trading Session only that is entered at 8:00 a.m. Eastern Time would be accepted, but a Market Pegged Order designated for the Core Trading Session only entered at the same time would be rejected.
- Proposed Rule 7.34P(c)(1)(B) would specify that Limit Orders designated IOC and Cross Orders would not be eligible to participate in the Early Open Auction and would be rejected if entered before the Early Open Auction concludes. The reference to Limit Orders designated IOC includes any order with an IOC instruction, including MPL Orders. Limit Orders designated IOC and Cross Orders are not currently eligible to participate in auctions, accordingly, this proposed rule change does not represent new functionality. However, the Exchange believes that the proposed change promotes transparency in Exchange rules regarding when an order would be accepted or rejected.
- Proposed Rule 7.34P(c)(1)(C) would specify that Limit Orders designated IOC and Cross Orders entered before or during the Early Trading Session and designated for the Core Trading Session only would be rejected if entered before the Core Open Auction concludes. The Exchange believes that this proposed rule would provide transparency because orders designated IOC must be eligible for an immediate execution and are not eligible for auctions, and an IOC order designated with a later trading session is by its terms inconsistent.
- Proposed Rule 7.34P(c)(1)(D) would provide that for securities that are not eligible for an auction on the Exchange, Market Orders designated for Core Trading Session and Auction-Only Orders would be routed directly to the primary listing market on arrival. This proposed treatment of Market Orders and Auction-Only Orders in securities that are not eligible for an auction on the Exchange would be different from current functionality.[14] Currently,

the Board of Directors through which orders of Users are consolidated for execution and/or display.

[12] The term ''User'' is defined in Rule 1.1(yy) as any ETP Holder or Sponsored Participant who is authorized to obtain access to the NYSE Arca Marketplace pursuant to Rule 7.29.

[13] As set forth in proposed Rule 7.34P(b), orders that are entered during the Early Trading Session and designated for a later session only would be accepted and become eligible to trade once the designated trading session begins.

[14] Proposed Rule 7.34P(c)(1)(D) would also represent a change to current Exchange functionality regarding MOC Orders and LOC Orders. Currently, the Exchange does not accept such orders before 9:30 a.m. Eastern Time. On the Pillar trading platform, the Exchange would accept such orders during the Early Trading Session, and

Market Orders or Auction-Only Orders are routed to the primary listing market on arrival only if they include a ''Primary Only'' order designation. The Exchange proposes that on the Pillar trading platform, during the Early Trading Session, a Market Order or Auction-Only Order in a security that is not eligible for an auction on the Exchange would be routed to the primary listing market regardless of whether it includes a Primary Only designation. The Exchange believes that this proposed functionality would be consistent with the expectations of a User with respect to such orders, which would not be eligible for an execution on the Exchange. The Exchange proposes to further provide that any order routed directly to the primary listing market on arrival, which includes the above-described orders and Primary Only Orders, would be cancelled if that market is not accepting orders.

• Proposed Rule 7.34P(c)(1)(E) would provide that MOO Orders, MOC Orders, LOC Orders, and Primary Only Orders designated for the Early Trading Session would be rejected. This represents current functionality. LOO Orders may be designated for the Early Trading System in order to participate in a reopening auction following a trading halt. LOO Orders in securities not eligible for an auction on the Exchange that are designated for an Early Trading Session would be routed to the primary listing market, consistent with proposed Rule 7.34P(c)(1)(D) . The Exchange proposes to include this text in proposed Rule 7.34P in order to provide transparency of when an order would be rejected.

With respect to the Core Trading Session, the Exchange proposes in new Rule 7.34P(c)(2) to provide that, unless otherwise specified in proposed paragraphs (c)(2)(A)–(B) of the new rule, orders and modifiers defined in Rule 7.31P and 7.44P that have been designated for the Core Trading Session would be eligible to participate in the Core Trading Session.[15] The Exchange believes that the proposed rule text makes clear that, unless specified in paragraphs (c)(2)(A)–(B) of new Rule 7.34P, all orders and modifiers in Rule 7.31P and 7.44P, if designated for the Core Trading Session, would be eligible to participate in the Core Trading Session. The proposed exceptions to the general rule would be:

• Proposed Rule 7.34P(c)(2)(A) would provide that Market Orders in securities that are not eligible for the Core Open Auction would be routed to the primary listing market until the first opening print of any size on the primary listing market or 10:00 a.m. Eastern Time, whichever is earlier. This proposed rule text is based on current Rule 7.35(c), which states that for all exchange-listed securities for which the Exchange does not conduct a Market Order Auction, ''the Corporation will route all Market Orders to the primary market until the first opening print on the primary market.'' This current rule makes clear that the Exchange refrains from processing Market Orders until the primary listing market has printed a transaction, and not just opened for trading based on an opening quote. Because this rule relates to how orders are treated during a trading session, the Exchange believes that it is more appropriately included in proposed Rule 7.34P(c) than in a rule governing auctions.

In moving the rule text, the Exchange is proposing two substantive differences. First, to specify that the first opening print may include an odd-lot transaction, the Exchange proposes to provide in Rule 7.34P(c)(2)(A) that Market Orders in securities that are not eligible for the Core Open Auction would be routed to the primary listing market until the first print of any size on the primary listing market. The Exchange believes it is appropriate to include an odd-lot transaction print because such a transaction indicates that trading has begun on the primary listing market. Second, the Exchange proposes to provide for an outside time frame for when the Exchange would stop routing Market Orders to the primary listing market and begin processing those orders on the Exchange. As proposed, the Exchange would continue routing Market Orders to the primary listing market until the first print of any size on such market or 10:00 a.m. Eastern Time, whichever is earlier. The Exchange believes that if the primary listing market has not opened for trading by 10:00 a.m. Eastern Time and has not halted the security, the Exchange should begin processing Market Orders in all securities. The proposed time of 10:00 a.m. Eastern Time is based on NYSE Rule 123D and NYSE MKT Rule 123D—Equities, which provide for delayed opening procedures for NYSE- and NYSE MKT-listed securities. Specifically, under those rules, a security is considered in a delayed opening if it is not open by 10:00 a.m. Eastern Time.

• Proposed Rule 7.34P(c)(2)(B) would provide that Auction-Only Orders in securities that are not eligible for an auction on the Exchange would be accepted and routed directly to the primary listing market. This proposed rule text is a continuation of the treatment of such orders as described in proposed Rule 7.34P(c)(1)(D) in that during the Core Trading Session, the Exchange would continue to accept and route such orders directly to the primary listing market. This proposal represents a change from current practice, as Rule 7.31(t) currently provides that the Exchange does not route Auction-Only orders to other exchanges. Instead, the Exchange currently rejects Auction-Only Orders in securities that are not eligible for an auction on the Exchange, unless they include a Primary Only Order designation. In Pillar, the Exchange would accept such orders and route them to the primary listing market.[16]

With respect to the Late Trading Session, the Exchange proposes in new Rule 7.34P(c)(3) to provide that unless otherwise specified in proposed paragraphs (c)(3)(A)–(C) of the new rule, orders and modifiers defined in Rule 7.31P that have been designated for the Late Trading Session would be eligible to participate in the Late Trading Session. The Exchange believes that this proposed rule text makes clear that unless specified in paragraphs (c)(3)(A)–(C) of new Rule 7.34P, all orders and modifiers in Rule 7.31P, if designated for the Late Trading Session, would be eligible to participate in the Late Trading Session.

Unlike under current rules, the Exchange proposes that Tracking Orders would be eligible to participate in the Late Trading Session, as they would be in the Early Trading Session, on the Pillar trading platform. Because the Exchange routes orders during the Late Trading Session and because Tracking Orders are intended to be passive liquidity on the Exchange to interact with an order before it is routed, the Exchange believes that Tracking Orders should be available in the Late Trading Sessions. Accordingly, rule text from current Rule 7.34(d)(3)(C) would not be included in new Rule 7.34P(c)(3).

The Exchange proposes that the following orders and modifiers in Rule 7.31P would not be eligible to participate in the Late Trading Session:

if for a security that is not eligible for an auction on the Exchange, route such orders to the primary listing market if such market is accepting orders.

[15] The Exchange notes that orders and modifiers described in Rule 7.44 governing the Retail Liquidity Program (''RLP'') are eligible to participate in the Core Trading Session only. The Exchange will submit a separate rule filing to adopt Rule 7.44P to govern RLP in Pillar.

[16] Because the treatment of Auction-Only Orders in securities that are not eligible for any auction on the Exchange would be covered in proposed Rule 7.34P, the Exchange would propose that new Rule 7.31P not include this same topic.

• Proposed Rule 7.34P(c)(3)(A) would provide that Market Orders, Q Orders, and Pegged Orders would not be eligible to participate in the Late Trading Session, which is current functionality. The rule would further provide that Market Orders, Q Orders, and Pegged Orders that include a designation for the Late Trading Session would be rejected. For example, if a Market Order, Q Order, or Pegged Order were entered during the Core Trading Session and designated for both the Core and Late Trading Session, because it includes a designation for the Late Trading Session, such order would be rejected. The Exchange believes that this proposed rule text provides transparency in Exchange rules of when an order would be accepted or rejected.

• Proposed Rule 7.34P(c)(3)(B) would provide that orders that route directly to the primary listing market on arrival would be cancelled if that market is not accepting orders, which is current functionality.

• Proposed Rule 7.34P(c)(3)(C) would provide that MOO Orders, MOC Orders, LOC Orders, and Primary Only Orders designated for the Late Trading Session would be rejected. This represents current functionality. LOO Orders may be designated for the Late Trading System in order to participate in a reopening auction following a trading halt. LOO Orders in securities not eligible for an auction on the Exchange that are designated for an Early Trading Session would be routed to the primary listing market. The Exchange proposes to include this text in proposed Rule 7.34P in order to provide transparency of when an order would be rejected.

Proposed Rule 7.34P(d) regarding customer disclosures is based on Rule 7.34(e) with non-substantive differences to conform terminology with the proposed changes to new Rule 7.34P, including use of the term ''Early Trading Session'' instead of ''Opening Session,'' ''Core Open Auction'' instead of ''Market Order Auction,'' and ''Limit Order'' instead of ''Limited Price Order.''

Finally, proposed Rule 7.34P(e) is based on Rule 7.34(f) without any substantive differences and would provide that trades on the NYSE Arca Marketplace executed and reported outside of the Core Trading Session would be designated as .T trades.

Order Ranking and Display

Rule 7.36 governs order ranking and display for the current Arca trading system. The rule provides that the NYSE Arca Marketplace shall display to Users and other market participants all non-marketable limit orders in the Display Order Process. The rule further provides that the NYSE Arca Marketplace will also disseminate current consolidated quotation/last sale information, and such other market information as may be available from time to time pursuant to agreement between the Corporation and other market centers.

Rule 7.36(a) sets forth that orders of Users are ranked and maintained in the Display Order Process and/or the Working Order Process of the NYSE Arca Book [17] according to price-time priority, such that within each price level, orders are organized by the time of entry in the manner described in the rule.

Rule 7.36(a)(1) describes the Display Order Process and Rule 7.36(a)(2) describes the Working Order Process. Rule 7.36(a)(3) sets forth that if an order has been modified in size, the order retains priority if the modification involves a decrease in the size of the order, but if the modification increases the size of the order or changes the price, the order will be treated as a new order and receive a new time priority. Rule 7.36(b) provides that, except as provided in Rule 7.7, all orders displayed in the Display Order Process are displayed on an anonymous basis. Finally, Rule 7.36(c) provides that the best-ranked displayed orders to buy (sell) in the NYSE Arca Book and the aggregate size of such orders are collected and made available to quotation vendors for dissemination pursuant to Rule 11Ac1–1 under the Exchange Act. The rule further provides that if non-marketable odd-lot sized orders can be aggregated to equal at least a round lot, such odd-lot sized orders will be displayed as the best ranked displayed orders to sell (buy) at the least aggressive price at which such odd-lot sized orders can be aggregated to equal at least a round lot.

Proposed Rule 7.36P would describe for the Pillar trading platform order ranking and display of orders, without any substantive differences from Rule 7.36. As discussed in detail below, the Exchange believes that the proposed new rule text provides transparency with respect to how the Exchange's price-time priority model would operate through the use of new terminology applicable to all orders on the Pillar trading platform.

Rule 7.36P(a) would set forth definitions for purposes of all of Rule 7 Equities Trading on the Pillar trading platform, including Rule 7.37P (Order Execution and Routing), described below. The Exchange believes that these proposed definitions would provide transparency regarding how the Exchange operates, and would serve as the foundation for amendments to orders and modifiers that will be in proposed Rule 7.31P.

• Proposed Rule 7.36P(a)(1) would define the term ''display price'' to mean the price at which a Limit Order is displayed, which may be different from the limit price or working price of the order. For example, Rule 7.31 provides for order types that may be displayed at prices that are different from the limit price, such as a PNP Blind Order.[18] The Exchange proposes to define the term ''display price'' in Pillar to explain these existing concepts uniformly in Exchange rules applicable to trading on the Pillar trading platform.

• Proposed Rule 7.36P(a)(2) would define the term ''limit price'' to mean the highest (lowest) specified price at which a Limit Order to buy (sell) is eligible to trade. The limit price is designated by the User. As noted in the proposed definitions of display price and working price, the limit price designated by the User may differ from the price at which the order would be displayed or eligible to trade.

• Proposed Rule 7.36P(a)(3) would define the term ''working price'' to mean the price at which an order is eligible to trade at any given time, which may be different from the limit price or display price of an order. The new term ''working price'' identifies for all orders the price at which an order is eligible to trade at any given time. Some exchanges refer to this concept as the price at which an order is ''ranked.'' [19] The Exchange believes that the term ''working price'' would provide clarity regarding the price at which an order may be executed at any given time. Specifically, the Exchange believes that use of the term ''working'' denotes that this is a price that is subject to change, depending on circumstances. The Exchange will be using this term in connection with orders and modifiers when it files a separate rule filing to adopt Rule 7.31P.

• Proposed Rule 7.36P(a)(4) would define the term ''working time'' to mean the effective time sequence assigned to

[17] The term ''NYSE Arca Book'' is defined in Rule 1.1(a) as the NYSE Arca Marketplace's electronic file of orders, which contain all of the User's orders in each of the Display Order, Working Order, and Tracking Order Processes.

[18] *See* Rule 7.31(e)(4). The Exchange notes that in connection with Pillar, the Exchange will be renaming the PNP Blind Order as an ''Arca Only Order,'' which will be proposed in a separate rule filing to adopt new Rule 7.31P. *See* Trader Update dated March 2, 2015, available here: *https://www.nyse.com/publicdocs/nyse/markets/nyse/Pillar_Trader_Update_Mar_2015.pdf.*

[19] *See, e.g.,* BATS Exchange, Inc. Rule 11.9(g)(1)(A) (referring to where an order is ''ranked'' as the price of an order).

an order for purposes of determining its priority ranking. The Exchange proposes to use the term ''working time'' in its rules for trading on the Pillar trading platform instead of terms such as ''time sequence'' or ''time priority,'' which are used in rules governing trading on the Exchange's current system. The Exchange believes that use of the term ''working'' denotes that this is a time assigned to an order for purpose of ranking and is subject to change, depending on circumstances.

Proposed Rule 7.36P(b) would govern the display of non-marketable Limit Orders on the Pillar trading system and is intended to be comparable to the preamble to Rule 7.36, without any substantive differences. As proposed, the Exchange would display all non-marketable Limit Orders, unless the order or modifier instruction specifies that all or a portion of the order is not to be displayed.

The Exchange proposes to define in proposed Rule 7.36P(b)(1) what it means for an order to be displayed for ranking purposes. As proposed, an order would be considered displayed for ranking purposes if the price, side, and size of the order are disseminated via a market data feed, which includes a proprietary market data feed of the Exchange. As further proposed, odd-lot sized Limit Orders and the displayed portion of Reserve Orders would be considered displayed for ranking purposes. This proposed rule text is intended to provide transparency in Exchange rules regarding which orders are considered displayed for ranking purposes, and therefore eligible to be considered Priority 2—Display Orders (described below). Specifically, odd-lot sized orders are displayed on the Exchange's proprietary data feed and would be displayed on the public feed if aggregated to equal a round lot or more would thus be considered ''displayed'' orders for purposes of priority ranking.

Proposed Rule 7.36P(b)(2) would be comparable to Rule 7.36(b) without any substantive differences and would provide that except as otherwise permitted by Rule 7.7,[20] all non-marketable displayed Limit Orders would be displayed on an anonymous basis. The Exchange proposes not to include reference to the Display Order Process in Rule 7.36P(b)(2) because, as discussed above, the Exchange is not proposing to use that terminology in Pillar.

[20] Rule 7.7 provides that bids and offers disseminated by the Exchange will not include an ETP Holder's identify unless the ETP Holder affirmatively elects to disclosed its identify.

Finally, proposed Rule 7.36P(b)(3) would be comparable to Rule 7.36(c) regarding dissemination, without any substantive differences. The Exchange proposes to use the term ''will'' in Proposed Rule 7.36P(b)(3) instead of ''shall.'' In addition, the Exchange would not include in proposed Rule 7.36P rule text from the second sentence of the preamble to Rule 7.36. The Exchange is a participant in the CQ Plan and CTA Plan for Tape A- and B-listed securities and a participant in the Nasdaq UTP Plan for Tape C-listed securities. The respective governing documents of those plans set forth the Exchange's obligations regarding dissemination of quotes and last-sale information and thus, the Exchange does not believe it is necessary to duplicate a subset of those requirements in its rules. Finally, the Exchange proposes to cite to the governing federal rule by referencing Rule 602 of Regulation NMS [21] instead of Rule 11Ac1–1 under the Exchange Act, which was superseded by Regulation NMS.

Proposed Rule 7.36P(c) would describe the Exchange's general process for ranking orders and would be comparable to the text immediately following Rule 7.36(a), without any substantive differences. As proposed, Rule 7.36P(c) would provide that all non-marketable orders would be ranked and maintained in the NYSE Arca Book according to price-time priority in the following manner: (1) Price; (2) priority category; (3) time; and (4) ranking restrictions applicable to an order or modifier condition. Accordingly, orders would be first ranked by price. Next, at each price level, orders would be assigned a priority category. Orders in each priority category would be required to be exhausted before moving to the next priority category. Within each priority category, orders would be ranked by time. These general requirements for order ranking are applicable to all orders, unless an order or modifier has a specified exception to this ranking methodology, as described in more detail below. The Exchange is proposing this ranking description instead of using the concepts of a Display Order Process, Working Order Process, and Tracking Order Process in Rule 7.36. However, substantively there would be no difference in how the Exchange ranks orders on the Pillar trading platform from how it ranks orders in in the current trading system. For example, a non-displayed order would always be ranked after a displayed order at the same price, even if the non-displayed order has an earlier working time.

[21] 17 CFR 242.602.

To provide transparency regarding the Exchange's ranking process, the Exchange proposes to set forth in Rule 7.36P additional detail regarding each step. Proposed Rule 7.36P(d) would describe how orders are ranked based on price. Specifically, as proposed, all orders would be ranked based on the working price of an order. Orders to buy would be ranked from highest working price to lowest working price and orders to sell would be ranked from lowest working price to highest working price. The rule would further provide that if the working price of an order changes, the price priority of an order would change. This price priority is current functionality, but the new rule would use the proposed term ''working price.'' The Exchange believes the proposed rule text provides transparency regarding the price-ranking process at the Exchange.

Proposed Rule 7.36P(e) would describe the proposed priority categories for ranking purposes. As proposed, at each price point, all orders would be assigned a priority category. If at a price point there are no orders in a priority category, the next category would have first priority. The proposed rules applicable to the Pillar trading platform would not use the terms ''Display Order Process,'' ''Working Order Process'' and ''Tracking Order Process'' for describing priority categories. The Exchange does not believe that Rule 7.36P, which sets forth the general rule regarding ranking, should provide specifics for one or more order types and therefore the Exchange will address separately in new Rule 7.31P governing orders and modifiers which priority category correlates to order types and modifiers. Accordingly, details regarding which proposed priority categories would be assigned to the display and reserve portions of Reserve Orders, which is in Rule 7.36, will be addressed in new Rule 7.31P and therefore not be included in proposed Rule 7.36P, except as described below.

The proposed priority categories would be:

- Proposed Rule 7.36P(e)(1) would specify ''Priority 1—Market Orders,'' which provides that unexecuted Market Orders would have priority over all other same-side orders with the same working price. This proposed priority is the same as current Exchange priority rules under which resting Market Orders have priority over other orders at

the same price.[22] Circumstances when an unexecuted Market Order would be eligible to execute against an incoming contra-side order include when a Market Order has exhausted all interest at the NBBO and is waiting for an NBBO update before executing again, pursuant to Rule 7.31(a), or when a Market Order is held unexecuted because it has reached a trading collar, pursuant to Rule 7.31(a)(3)(A). In such circumstances, the unexecuted Market Order(s) would have priority over all other resting orders at that price.

• Proposed Rule 7.36P(e)(2) would specify ''Priority 2—Display Orders.'' This proposed priority category would replace the ''Display Order Process.'' As proposed, non-marketable Limit Orders with a displayed working price would have second priority. For an order that has a display price that differs from the working price of the order, if the working price is not displayed, the order would not be ranked Priority 2 at the working price.

• Proposed Rule 7.36P(e)(3) would specify ''Priority 3—Non-Display Orders.'' This priority category would be used in Pillar rules, rather than the ''Working Order Process.'' As proposed, non-marketable Limit Orders for which the working price is not displayed, including the reserve interest of Reserve Orders, would have third priority.

• Proposed Rule 7.36P(e)(4) would specify ''Priority 4—Tracking Orders.'' This priority category would replace the ''Tracking Order Process,'' as discussed in further detail below in connection with proposed Rule 7.37P. As proposed, Tracking Orders would have fourth priority.

Proposed Rule 7.36P(f) would set forth that within each priority category, orders would be ranked based on time priority.

• Proposed Rule 7.36P(f)(1) would provide that an order is assigned a working time based on its original entry time, which is the time an order is first placed on the NYSE Arca Book. This proposed process of assigning a working time to orders is current functionality and is substantively the same as current references to the ''time of original order entry'' found in several places in Rule 7.36. To provide transparency in Exchange rules, the Exchange further proposes to include in proposed Rule 7.36P(f) how the working time would be determined for orders that are routed. As proposed:

○ Proposed Rule 7.36P(f)(1)(A) would specify that an order that is fully routed to an Away Market[23] on arrival would not be assigned a working time unless and until any unexecuted portion of the order returns to the NYSE Arca Book. The Exchange notes that this is the current process for assigning a working time to an order and proposes to include it in Exchange rules to provide transparency regarding what is considered the working time of an order that was fully routed on arrival.

○ Proposed Rule 7.36P(f)(1)(B) would specify that for an order that is partially routed to an Away Market on arrival, the portion that is not routed would be assigned a working time. If any unexecuted portion of the order returns to the NYSE Arca Book and joins any remaining resting portion of the original order, the returned portion of the order would be assigned the same working time as the resting portion of the order. If the resting portion of the original order has already executed and any unexecuted portion of the order returns to the NYSE Arca Book, the returned portion of the order would be assigned a new working time. This process for assigning a working time to partially routed orders is the same as currently used by the Exchange. The Exchange proposes to include this detail in Exchange rules to provide transparency regarding what is considered the working time of an order.

• Proposed Rule 7.36P(f)(2) would provide that an order would be assigned a new working time any time the working price of an order changes. This proposed rule text would be based on the rule text in Rule 7.36(a)(3), without any substantive differences. A change to the working price could be because of a User's instruction or because the order or modifier has a price that can change based on a reference price, such as an MPL Order, which is priced based on the PBBO.

• Proposed Rule 7.36P(f)(3) would provide that an order would be assigned a new working time if the size of the order increases and that an order would retain its working time if the size of the order is decreased. This proposed rule text would be based on rule text in the first and second sentences of Rule 7.36(a)(3), without any substantive differences.

• Proposed Rule 7.36P(f)(4) would provide that an order retains its working time if the order marking is changed from: (A) Sell to sell short; (B) sell to sell short exempt; (C) sell short to sell; (D) sell short to sell short exempt; (E) sell short exempt to sell; and (F) sell short exempt to sell short. This rule text would use for the Pillar trading platform rules the same rule text as in Rule 7.16(f)(viii), without any substantive differences. The Exchange proposes to include the text from Rule 7.16(f)(viii) regarding order priority when changing order marking to Rule 7.36P to consolidate ranking in a single rule.

Proposed Rule 7.36P(g) would specify that the Exchange would enforce ranking restrictions applicable to specified order or modifier instructions. These order and modifier instructions would be identified in proposed new Rules 7.31P and 7.44P, which the Exchange will submit in a rule filing prior to implementing the Pillar trading platform.

In addition, the Exchange proposes a definition in Rule 1.1(aP) of NYSE Arca Book that would be applicable to the Pillar rules. The proposed definition would differ from the current definition of NYSE Arca Book in Rule 1.1(a) in that it would not include references to the terms ''Display Order Process,'' ''Working Order Process,'' and ''Tracking Order Process,'' which as discussed above, are terms that will not be used in Pillar. As proposed, new Rule 1.1(aP) would provide that the term ''NYSE Arca Book'' refers to the NYSE Arca Marketplace's electronic file of orders, which contains all orders entered on the NYSE Arca Marketplace.

Order Execution and Routing

Current Rule 7.37, titled ''Order Execution,'' governs order execution and routing at the Exchange. The preamble to the rule provides that like-priced orders, bids and offers shall be matched for execution following steps 1 through 4 of the rule, provided, however, for an execution to occur in any Order Process, the price must be equal to or better than (1) the PBBO, in the case of a Limit Order or Q Order or (2) the NBBO in the case of an Inside Limit Order, a Pegged Limit Order, or a Market order. If such an order is not executable within those parameters, the rule provides that it may be routed to away markets as provided in Rule 7.37(d).

The rule then sets forth steps 1 through 4. Step 1 is the Display Order Process, which provides that incoming orders are first matched for execution against other orders in the Display Order process. The rule provides further specificity regarding how certain orders are ranked. The rule also sets forth that the size of an incoming Reserve Order

[22] This priority is currently specified in Rule 7.16(f)(viii).

[23] The Exchange proposes Rule 1.1(ffP), which would define the term ''Away Market.'' The proposed definition is based on the existing definition of ''NOW Recipient,'' which is a term that the Exchange would not be using in Pillar. For Pillar, the proposed definition of ''Away Market'' would reference the term ''alternative trading system'' instead of ECN.

includes both the displayed and reserve size and the size of the portion of the Reserve Order resident in the Display Order Process is equal to its displayed size. If an incoming marketable order is not executed in its entirety, the remaining part of the order is routed to the ''Working Order'' process. The rule further provides that an incoming order that is not marketable enters the Working Order Process to execute against any Discretionary Orders at or better than the NBBO.

Step 2 is the Working Order Process, which provides that incoming marketable orders are matched against orders in the Working Order process by the order of ranking of the orders in the Working Order Process. The rule sets forth how specified orders, such as Discretionary Orders, interact within the Working Order Process. The rule further provides that if the incoming marketable order has not been executed in its entirety, the remaining portion of the order shall be routed to the Tracking Order Process.

Step 3 is the Tracking Order Process, which is currently available during Core Trading Hours only. In the Tracking Order Process, if an order that is eligible to route to an away market has not been executed in its entirety under Steps 1 through 2, the NYSE Arca Marketplace shall match and execute any remaining part of such order in the Tracking Order Process in time/price priority.

Step 4 sets forth the Exchange's process for routing away and specifies certain orders that are not eligible to be routed. For orders that are eligible to be routed, the rule specifies that if the order is designated as a Market, Inside Limit, or Pegged Order, the Exchange shall utilize all available quotes in the routing determination, or if the order is designated as a Limit Order, the Exchange shall utilize available Protected Quotations in the routing determination. The rule sets forth additional detail that orders will be routed as Intermarket Sweep Orders (''ISO'') and any remaining portion of the order will be ranked and displayed in the NYSE Arca Book pursuant to Rule 7.36.

The rule further provides that an order that is routed away shall remain outside the NYSE Arca Marketplace for a prescribed period of time and may be executed in whole or in part subject to the applicable trading rules of the relevant market center or market participant and that when an order remains outside the NYSE Arca Marketplace, it will have no time standing relative to other orders received from Users at the same price that may be executed against the NYSE Arca Book. The rule also provides that when an order is outside the NYSE Arca Marketplace, it will not have time standing in the NYSE Arca Book. Finally, with respect to routing, the rule provides that for an order that is eligible to route away, Users may instruct NYSE Arca to bypass any market centers that are not posting Protected Quotations within the meaning of Regulation NMS.

Rule 7.37(e), (f), and (g) set forth how the Exchange operates consistent with Regulation NMS for locking and crossing quotations and specified exceptions to Regulation NMS, including the self-help exception; ISO Exception; single price openings, reopenings, and closing transactions; benchmark trades; stopped orders; and the contingent order exemption.

Commentary .01 to Rule 7.37 sets forth the Exchange's use of data feeds for the handling, execution, and routing of orders, as well as for regulatory compliance.

The Exchange proposes Rule 7.37P to describe the order execution and routing rules for the Pillar trading platform. Proposed Rule 7.37P would not be substantively different from Rule 7.37. The Exchange proposes that the title for new Rule 7.37P would be ''Order Execution and Routing.'' The title of Rule 7.37 is ''Order Execution.'' The Exchange believes that because Rule 7.37P, like Rule 7.37, would include the Exchange's routing procedures, referencing to ''Routing'' in the rule's title would provide additional transparency in Exchange rules regarding what topics would be covered in new Rule 7.37P.

Proposed Rule 7.37P(a) and its subsections would set forth the Exchange's order execution process and would cover the same subject as the preamble to Rule 7.37, without any substantive differences. As proposed, an incoming marketable order would be matched for execution against contra-side orders in the NYSE Arca Book according to the price-time priority ranking of the resting orders, subject to specified parameters. Proposed Rule 7.37P(a)(1) would provide that orders that are routed to an Away Market on arrival would not be assigned a working time or be matched for execution on the NYSE Arca Book. This provision would apply to orders that the Exchange routes based on the time an order is entered, *e.g.,* a Market Order in a security that is not eligible for an auction on the Exchange that is entered during the Early Trading Session, or an order with an instruction to route directly to the primary market on arrival, *e.g.,* a Primary Only Order. The Exchange believes that the proposed rule provides transparency that an order that is intended to route on arrival would not be subject to order execution at the Exchange.

Proposed Rule 7.37P(a)(2) would provide that, unless an order qualifies for an exception to the Order Protection Rule in Rule 611 of Regulation NMS,[24] orders will not trade at prices that would trade through a protected quotation.[25] Proposed Rule 7.37P(a)(3) would provide that Limit Orders would be executed at prices equal to or better than the PBBO and proposed Rule 7.37P(a)(4) would provide that Market Orders and Inside Limit Orders would be executed at prices equal to or better than the NBBO. The proposed rule for the Pillar trading platform is based on existing requirements as set forth in the preamble to Rule 7.37 and is consistent with the order processing of Market Orders, Limit Orders, and Inside Limit Orders as set forth in Rule 7.31.

As discussed above, the Exchange proposes to eliminate the terminology associated with the Display Order Process, Working Order Process, and Tracking Order Process. Therefore, similar to proposed Rule 7.36P, the Exchange would not include these terms in new Rule 7.37P. Moreover, the Exchange does not believe that it is necessary to restate in new Rule 7.37P the Exchange's ranking process, which would be set forth in proposed Rule 7.36P. In addition, consistent with the Exchange's proposed approach to new Rule 7.34P and 7.37P, the Exchange proposes to eliminate, where feasible, reference to specific order types and instead state the Exchange's general order execution methodology. Any exceptions to such general requirements would be set forth in connection with specific order or modifier definitions in proposed Rule 7.31P. Accordingly, the Exchange will not include in new Rule 7.37P the process currently referred to as ''Step 3'' and instead, details regarding how Tracking Orders would operate would be included in proposed Rule 7.36P(e)(3), as discussed above regarding ranking priority assigned to Tracking Orders, and new Rule 7.31P.

Proposed Rule 7.37P(b) would set forth the Exchange's order routing process and is intended to cover the same subject as Rule 7.37(d), which is

[24] 17 CFR 242.611.

[25] The term ''trade through'' is defined in Rule 1.1(fff) as the purchase or sale of an NMS stock during regular trading hours, either as principal or agent, at a price that is lower than a Protected Bid or higher than a Protected Offer. The term ''protected quotation'' is defined in Rule 1.1(eee) as a quotation that is a Protected Bid or a Protected Offer, and those terms are defined in the rule as well.

currently referred to as ''Step 4'' in order processing, without any substantive differences. Proposed Rule 7.37P(b) would provide that unless an order has an instruction not to route, after being matched for execution with any contra-side orders in the NYSE Arca Book pursuant to proposed Rule 7.37P(a), marketable orders would be routed to Away Markets.

The proposed rule would then set forth additional details regarding routing:

• Proposed Rule 7.37P(b)(1) would provide that an order that cannot meet the pricing parameters of proposed Rule 7.37P(a) may be routed to Away Market(s) before being matched for execution against contra-side orders in the NYSE Arca Book. The Exchange believes that this proposed rule text provides transparency that an order may be routed before being matched for execution, for example, to prevent locking or crossing or trading through a protected quotation.

• Proposed Rule 7.37P(b)(2) would provide that if an order with an instruction not to route would trade through or lock or cross a protected quotation and is not eligible for an exception to either Rule 610 or 611 of Regulation NMS,[26] it would cancel, re-price, or be held undisplayed on the NYSE Arca Book, as provided for in Rules 7.31P and 7.44P.

• Proposed Rule 7.37P(b)(3) would provide that orders eligible to route would be routed to all available Away Markets unless the order includes an instruction to bypass market centers that are not displaying protected quotations. This rule text covers the subject matter of current Rule 7.37(d)(2)(A), 7.37(d)(2)(B), and 7.37(d)(4), with no substantive differences. As with current functionality, proposed Rule 7.37P(b)(1) specifies that all Away Markets, as defined in proposed Rule 1.1(ffP), would be considered as part of the routing determination unless the User has opted out of routing to Away Markets that do not display protected quotations.

• Proposed Rule 7.37P(b)(4) would provide that Limit Orders that are routed to Away Market(s) may be routed to more than one price level, up (down) to the limit price of an order to buy (sell). This represents current routing functionality and means that a Limit Order may be routed to more than just the top of book bid or offer of an Away Market, provided that the order would not be routed to prices that are outside of the limit price of the order and consistent with Rule 611 of Regulation NMS,[27] as provided for in proposed Rule 7.37P(a)(2). The Exchange believes that including this level of detail in the rule provides transparency regarding the potential for an order to be routed to more than one price level on an Away Market. The Exchange believes that routing to depth of Away Markets provides a greater opportunity for an order to be executed in full.

• Proposed Rule 7.37P(b)(5) would provide that, except for orders routed to the primary listing market on arrival pursuant to Rule 7.34P or designated to route to the primary listing market pursuant to Rule 7.31P, orders routed to Away Markets would be sent as IOC ISOs. This routing is based on current Rule 7.37(d)(2)(B)(i) with no substantive differences.

• Proposed Rule 7.37P(b)(6) would provide that after any order or portion thereof that has been routed would not be eligible to trade on the NYSE Arca Book, unless all or a portion of the order returns unexecuted. This routing methodology is current functionality and covers that same subject as current Rule 7.37(d)(2)(C) and (D), with no substantive differences. In contrast to Rule 7.37(d)(2)(C) and (D), however, the Exchange proposes that Rule 7.37P(b)(6) would focus on the fact that once routed, an order would not be eligible to trade on the Exchange, rather than stating the obvious that it would be subject to the routing destination's trading rules once routed. In addition, because, as discussed above, the working time assigned to orders that are routed is being proposed to be address in new Rule 7.36P(f)(1)(A) and (B), the Exchange believes it would be duplicative to restate this information in new Rule 7.37P.

• Proposed Rule 7.37P(b)(7) would set forth how the Exchange would process requests to cancel orders that have been routed. Rule 7.37(d)(2)(E) currently provides that requests from Users to cancel their orders while the order is routed away to another market center or market participant and remains outside the NYSE Arca Marketplace shall be processed, subject to the applicable trading rules of the relevant market center or market participant.

The Exchange proposes to specify in new Rule 7.37P(b)(7)(A) that requests to cancel orders that are eligible to be matched for execution against orders in the NYSE Arca Book would not be processed unless and until all or a portion of the order returns unexecuted. New Rule 7.37P(b)(7)(B) would specify that for orders routed to the primary listing market on arrival pursuant to Rule 7.34P or designated to route to the primary listing market pursuant to Rule 7.31P, requests to cancel would be routed to the primary listing market, which is current functionality.

New Rule 7.37P(b)(7)(C) would provide, as currently set forth in Rule 7.31(x) regarding Primary Only Orders, for MOC Orders or LOC Orders in NYSE- or NYSE MKT-listed securities, requests to cancel or reduce in size that are electronically entered after the times specified in NYSE Rules 123C(3)(b) and NYSE MKT Rule 123C(3)(b)—Equities and Supplementary Material .40 to those rules would be rejected.[28] The Exchange proposes to include this text in proposed Rule 7.37P(b)(7) because it concerns how the Exchange would process requests to cancel orders with instructions to route on arrival. By including this rule text in proposed Rule 7.37P, the proposed processing of electronically entered requests to cancel MOC or LOC Orders in NYSE- or NYSE MKT-listed securities would also apply to such orders that do not include a Primary Only Order designation, but which, pursuant to Rule 7.34P, would be routed to the primary listing market on arrival. The Exchange believes that the proposed changes would provide transparency regarding how requests to cancel orders that have been routed would be processed in Pillar, which would not be substantively different from how the Exchange's current trading system operates.

• Proposed Rule 7.37P(b)(8) would provide that an order marked ''short'' when a short sale price test restriction is in effect would not be routed. Instead of routing, the Exchange would reprice or cancel the order consistent with Rule 7.16, which will be proposed as Rule 7.16P in a separate rule filing for Pillar.

The Exchange believes the specific routing methodologies for an order type or modifier should be included with how the order type is defined, which will be in Rule 7.31P. Accordingly, the Exchange does not believe it needs to specify in new Rule 7.37P whether an order is eligible to route, and if so, whether there are any specific routing

[26] 17 CFR 242.610 and 17 CFR 242.611.

[27] 17 CFR 242.611.

[28] NYSE Rule 123C(3)(b) and NYSE MKT Rule 123C(3)(b)—Equities provide that between 3:45 p.m. and 3:58 p.m., MOC and LOC Orders may be cancelled or reduced in size only to correct a legitimate error, and NYSE Rule 123C(3)(c) and NYSE MKT Rule 123C(3)(c) provide that MOC and LOC Orders may not be cancelled or reduced in size at all after 3:58 p.m. Supplementary Material .40 to those rules provides, among other things, that the times specified in those rules will be adjusted based on the early scheduled closing time and references to 4:00 p.m. mean the early scheduled close, 3:45 p.m. means 15 minutes before the early scheduled close, and 3:58 p.m. means two minutes before the early scheduled close.

instructions applicable to the order and therefore will not be carrying over such specifics that are included in Rule 7.37.

The remaining proposed rule text of Rule 7.37P is based on Rule 7.37, with limited non-substantive differences:

• Proposed Rule 7.37P(c) would provide that after executing with eligible contra-side interest on the NYSE Arca Book and/or returning unexecuted after routing to Away Market(s), any unexecuted non-marketable portion of an order would be ranked consistent with new Rule 7.36P. This rule represents current functionality and is based on Rule 7.37(d)(3) without any substantive differences.

• Proposed Rule 7.37P(d) would set forth the Exchange's use of data feeds, and includes the rule text that is currently set forth in Commentary .01 to Rule 7.37, without any substantive differences. Proposed Rule 7.37P(d)(1) would not include the clause ''away market quotes disseminated by'' as unnecessary language, with the proposed rule text using the proposed defined term ''Away Markets'' as follows, ''[t]he Exchange receives data feeds directly from broker dealers for purposes of routing interest to Away Markets that are not displaying protected quotations.''

• Proposed Rule 7.37P(e) would set forth the same rule text from Rule 7.37(e) regarding locking or crossing quotations in NMS stocks with a non-substantive difference to update a cross-reference in the rule to rule numbering in Rule 7.37P. The Exchange proposes an additional non-substantive difference to specify in Rule 7.37P(e)(3) that the prohibition against Locking and Crossing Quotations in paragraph Rule 7.37P(e)(2) would not apply in the circumstances specified in Rules 7.37P(e)(3)(A)–(C). Proposed Rules 7.37P(e)(3)(A)–(C) is rule text that is identical to Rule 7.37(e)(3)(A)–(C).

• Proposed Rule 7.37P(f) would set forth the exceptions to the Order Protection Rule [29] and would enumerate the self-help exception in Rule 7.37P(f)(1), which is based on Rule 7.37(f) regarding Self-Help Exceptions, with two proposed modifications. The Exchange would not include the second sentence of Rule 7.37(f)(1), which provides that the Exchange will disregard another Trading Center's bid and offer if the other Trading Center has repeatedly failed to respond within one second to an incoming IOC order after adjusting for order transmission time, in new Rule 7.37P(f)(1). The self-help exception set forth in Rule 611(b)(1) of Regulation NMS [30] and related Securities and Exchange Commission staff guidance regarding this exception [31] does not require trading centers to use the self-help exception if a destination trading trading center fails to respond within one second to an incoming IOC order, but state that such a failure would justify use of the exception. Rather, a trading center is free to adopt reasonable policies and procedures consistent with the flexible purposes of the self-help exception. Because the Exchange does not use the method described in the second sentence of current Rule 7.37(f)(1) to determine whether to declare self-help, the Exchange proposes not to include it in new Rule 7.37P(f)(1). Second, Rule 7.37(f)(1)(B) provides that the Exchange follows ''published NYSE Arca policies and procedures for electing the self-help exception.'' Because the Exchange publishes those policies and procedures internally only, to reduce investor confusion, the Exchange proposes to modify the text in proposed Rule 7.37P(f)(1)(B) to provide instead that the Exchange would follow ''established NYSE Arca policies and procedures for electing the self-help exception.''

Proposed Rules 7.37P(f)(2)–(4) are based on the rule text from Rule 7.37(g) regarding Additional Exceptions to the Order Protection Rule, with non-substantive differences to reflect different rule numbering and update the rule text to reflect current operations. First, the Exchange proposes not to include the first and third sentences of Rule 7.37(g)(1) in proposed Rule 7.37P(f)(2)(A) relating to the Intermarket Sweep Order Exception because when executing or displaying ISOs that it receives from ETP Holders, it is the responsibility of the entering broker dealer and not the Exchange to simultaneously route ISOs. Therefore, the current rule text does not represent how the Exchange operates, nor does it reflect the requirements of Regulation NMS. The Exchange proposes additional non-substantive differences to the rule text relating to this exception to update references, for example, to refer to NYSE Arca's best bid or best offer rather than its own protected quotation and remove reference to the ''NYSE Arca System.''

Second, the Exchange proposes not to include the second sentence of Rule 7.37(g)(3) relating to how the Exchange would conduct a single-price reopening in proposed Rule 7.37P(f)(3). To reduce investor confusion and promote transparency in its rules, the Exchange believes that its rule governing auctions should set forth how the Exchange conducts a single-price auction to reopen a stock following a trading halt. Third, the Exchange proposes not to include current Rule 7.37(g)(5) text regarding Stopped Orders because the Exchange does not currently, and will not in Pillar, support Stopped Orders on the Exchange. Finally, the Exchange proposes not to include current Rule 7.37(g)(6) text regarding transactions other than ''regular-way'' contracts because in Pillar, the Exchange would not execute any orders on terms other than standardized terms and conditions, *i.e.,* ''regular way'' contracts.

Proposed Rule 7.37P(f)(5) regarding the Contingent Order Exemption from the Order Protection Rule is based on rule text from Rule 7.37(h) regarding Exemptions with different rule numbering and one substantive difference. Rule 7.37(g)(2) specifies the requirements to meet the qualified contingent trade exemption to Rule 611(a) of Regulation NMS [32] and are based on the requirements specified in the Commission's Order granting an exemption for qualified contingent trades.[33] Rule 7.37(f)(2)(G) currently specifies the original requirement that the exempted transaction must be part of a contingent trade that involves at least 10,000 shares or has a market value of at least $200,000. The Commission later modified the exemption for qualified contingent trades to remove that size condition.[34] The Exchange therefore proposes not to include in its proposed Rule 7.37P(f)(2)(D) the size requirement.

* * * * *

As discussed above, because of the technology changes associated with the migration to the Pillar trading platform, the Exchange will announce by Trader Update when rules with a ''P'' modifier will become operative and for which symbols. The Exchange believes that keeping existing rules on the book

[29] 17 CFR 242.611(b).

[30] 17 CFR 611(b)(1).

[31] *See* Question 4.07, ''Responses to Frequently Asked Questions Concerning Rule 611 and Rule 610 of Regulation NMS,'' available at *https://www.sec.gov/divisions/marketreg/nmsfaq610-11.htm* (''Beyond this basic parameter of repeated failure to turn around an IOC order within one second, trading centers are free to adopt reasonable policies and procedures that are consistent with the flexible purposes of the self-help exception.'').

[32] 17 CFR 242.611(a).

[33] *See* Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006) (Order Granting an Exemption for Qualified Contingent Trades from Rule 611(a) of Regulation NMS under the Securities Exchange Act of 1934).

[34] *See* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 9, 2008) (Order Modifying the Exemption for Qualified Contingent Trades from Rule 611(a) of Regulation NMS under the Securities Exchange Act of 1934).

pending the full migration of Pillar will reduce confusion because it will ensure that the rules governing trading on a trading platform will continue to be available pending the full migration.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[35] in general, and furthers the objectives of Section 6(b)(5),[36] 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 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 rules to support Pillar would remove impediments to and perfect the mechanism of a free and open market because the proposed rule set would promote transparency in Exchange rules by using consistent terminology governing equities trading, thereby ensuring that members, regulators, and the public can more easily navigate the Exchange's rulebook and better understand how equity trading is conducted on the Exchange. Adding new rules with the modifier ''P'' to denote those rules that would be operative for the Pillar trading platform would remove impediments to and perfect the mechanism of a free and open market by providing transparency of which rules govern trading once a symbol has been migrated to the Pillar platform.

The Exchange believes that the proposed restructuring in new Rules 7.34P, 7.36P, and 7.37P would remove impediments to and perfect the mechanism of a free and open market by assuring consistency of terms used in the Exchange's rulebook. The proposed revisions to the Exchange's equity trading rules to reflect terminology associated with Pillar would remove impediments to and perfect a free and open market because the proposed changes are designed to simplify the structure of the Exchanges rules and permit the use of consistent terminology throughout numerous rules, without changing the underlying functionality. For example, the Exchange believes the proposed definitions set forth in Rule 7.36P, *i.e.,* display price, limit price, working price, and working time, promote transparency in Exchange rules and make them easier to understand because these proposed definitions will serve as the foundation for additional rule changes to support Pillar.

The Exchange further believes that moving specified rule text that relates to specific order types that is set forth in Rules 7.34, 7.36 and 7.37 to proposed Rule 7.31P (which will be the subject of a separate filing), and therefore not include such detail in proposed Rules 7.34P, 7.36P and 7.37P, would make Exchange rules easier to navigate because information regarding how a specific order type would operate would be in a single location in the Exchange's rule book.

With respect to proposed Rule 7.34P, the Exchange believes that the proposed changes to functionality would remove impediments to and perfect the mechanism of a fair and orderly market. First, the Exchange believes that because an auction that opens a trading session should occur within that trading session, it would remove impediments to and perfect the mechanism of a fair and orderly market for the Core Open Auction to occur during the Core Trading Session instead of the Early Trading Session. Second, the Exchange believes that the proposed change to route to the primary listing market Market Orders and Auction-Only Orders in symbols that are not eligible for an execution on the Exchange would remove impediments to and perfect the mechanism of a free and open market by ensuring that such orders reach a destination where they may be eligible to obtain an execution or participate in an auction. This is current functionality, but it is only available for orders that have been designated as ''Primary Only.'' Expanding this functionality to orders that do not include that designation would also protect investors and the public interest by enabling such interest to reach a destination where it is more likely to obtain an execution opportunity or participate in an auction. Finally, the Exchange believes that making Tracking Orders available during the Early and Late Trading Sessions would remove impediments to and perfect the mechanism of a free and open market by providing additional execution opportunities on the Exchange through the availability of additional passive liquidity.

With respect to proposed Rules 7.36P and 7.37P, as discussed above, the Exchange is not proposing any functional changes to how it ranks, displays, executes, or routes orders. The Exchange believes, however, that the proposed rule text promotes transparency through the use of consistent terminology that will serve as the foundation for additional Pillar-related rule proposals. The Exchange also believes that adding more detail regarding current functionality in new Rules 7.34P, 7.36P, and &.37P, as described above, would promote transparency by providing notice of when orders would be accepted, routed, rejected, cancelled, or be assigned a working time by the Exchange.

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 purposes of the Act. The proposed change is not designed to address any competitive issue but rather to adopt new rules to support the Exchange's new Pillar trading platform. As discussed in detail above, with this rule filing, the Exchange is not proposing to change its core functionality regarding its price-time priority model, and in particular, how it would rank, display, execute or route orders in Pillar. Rather, the Exchange believes that the proposed rule change would promote consistent use of terminology to support the Pillar trading platform making the Exchange's rules easier to navigate.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or *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.

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.

[35] 15 U.S.C. 78f(b).

[36] 15 U.S.C. 78f(b)(5).

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–2015–38 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–2015–38. 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 Web site (*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 Web site 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 will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2015–38, and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12028 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74955; File No. SR–ICEEU–2015–007]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Collateral and Haircut Policy

May 13, 2015.

I.Introduction

On March 13, 2015, ICE Clear Europe Limited (''ICE Clear Europe'' or ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] to implement a new collateral and haircut policy (the ''Haircut Policy'') applicable to Permitted Cover posted by Clearing Members to meet the Clearing House's Margin and Guaranty Fund requirements. The proposed rule change was published for comment in the **Federal Register** on March 31, 2015.[3] The Commission did not receive comment letters regarding the proposed change. For the reasons discussed below, the Commission is granting approval of the proposed rule change.

II. Description of the Proposed Rule Change

ICE Clear Europe proposes to implement a Haircut Policy, which would codify and consolidate certain existing practices of the Clearing House with respect to Permitted Cover. The proposed Haircut Policy is designed (i) to set out overall principles with respect to the assets accepted by the Clearing House as Permitted Cover; (ii) to establish a framework for determining absolute and relative limits, as applicable, on the value of the collateral that may be posted by a Clearing Member as Permitted Cover; (iii) to establish a value-at-risk (''VaR'') based methodology for determining haircuts for all Permitted Cover; (iv) to mitigate wrong-way risk from Permitted Cover; (v) to address sources for pricing Permitted Cover; and (vi) to set out certain related monitoring, reviewing and reporting procedures. The Haircut Policy would apply to Permitted Cover provided for all product classes (F&O, CDS and FX).[4] Following implementation, the Clearing House will from time to time adjust the haircuts applicable to Permitted Cover under the methodology set forth in the policy.

The general aims of the proposed Haircut Policy are to ensure that the Clearing House can efficiently liquidate all forms of Permitted Cover, that appropriate prices are used for valuation of Permitted Cover and that appropriate haircuts (including, as applicable, cross-currency haircuts) are used. The proposed Haircut Policy would codify certain general principles considered by the Clearing House in accepting assets as Permitted Cover, including availability of pricing information, the existence of liquid and active markets for buyers and sellers of those assets, the existence of sufficient price history, the ability to liquidate Permitted Cover without causing a market disruption, compliance with legal and regulatory requirements and sufficient operational and technological framework to handle deposit, liquidation and return of such assets as Permitted Cover.

Under the proposed Haircut Policy, cash collateral must be in one of several specified currencies underlying contracts cleared by the Clearing House. Additional general requirements would apply to financial instruments, including prohibitions on acceptance of instruments that have non-''vanilla'' features such as embedded options, instruments issued by a Clearing Member or its affiliate, instruments issued by a CCP or by entities that provide critical services to the Clearing House (other than central banks) and certain credit-based limits. Such limits would require that the issuer is rated at least ''BBB−'' by S&P (or its equivalent), the average yield on the asset over the previous three months is not greater than 8%, and the 5-year CDS spread of the issuer has not exceeded 500 basis points over the previous three months. The proposed Haircut Policy provides that where market conditions warrant, or where the Clearing House's sovereign risk model indicates deteriorating credit below a certain threshold (*i.e.,* ''BBB−'' by S&P), the Clearing House may remove securities from the list of Permitted Cover and/or vary applicable haircuts. ICE Clear Europe will notify Clearing Members and other market participants of such actions by Circular. ICE Clear Europe maintains the current List of Permitted

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–74579 (Mar. 25, 2015), 80 FR 17132 (Mar. 31, 2015) (SR–ICEEU–2015–007).

[4] ICE Clear Europe notes that although the Haircut Policy generally also applies to Permitted Cover posted with respect to Guaranty Fund requirements, certain additional requirements apply to Guaranty Fund contributions under the Rules and Finance Procedures. Those additional requirements are not proposed to be changed in connection with the Haircut Policy.

Cover (along with haircut rates, limits and restrictions) on its Web site at *https://www.theice.com/publicdocs/clear_europe/list-of-permitted-covers.pdf.*

The proposed Haircut Policy contains a methodology for setting absolute limits on the value of non-cash Permitted Cover that can be posted by a Clearing Member.[5] Absolute collateral limits would apply across a group of affiliated Clearing Members and apply across all product categories cleared by that group. The policy also sets out relative (or concentration) limits for Permitted Cover provided by a Clearing Member. ICE Clear Europe publishes on its Web site the current absolute and relative limits on government bonds provided as Permitted Cover. In addition, the policy sets out procedures for monitoring of limits on a daily basis and for remediation of breach of a limit by a Clearing Member. The risk management department will monitor all collateral limits on a daily basis using a collateral breakdown report which flags limit breaches. Breaches will be reviewed internally and the relevant Clearing Member will be contacted. Breaches can be remediated by posting additional collateral, removal of collateral that is in breach of a limit, or both of the above.

The policy also provides for a risk-based reduction in absolute limits for government bonds based on the credit default swap (''CDS'') spread for the relevant issuer in order to mitigate wrong-way risk arising from government bonds accepted as Permitted Cover. Once the spread exceeds a specified level for a particular issuer, the absolute limit for Permitted Collateral of that issuer would be reduced pursuant to a defined formula. If the spread exceeds a second level, the absolute limit will be reduced to 5% of the otherwise applicable original limit. Spread levels are determined using a five-day average to avoid excessive volatility. The specified parameters will be reviewed on a quarterly basis.

Specific wrong-way risk arising in connection with clearing of Western European sovereign CDS is addressed through a requirement that U.S. dollar denominated collateral be provided for initial margin and that a portion of the CDS Guaranty Fund be U.S. dollar-based (determined based on the ratio between the dollar-denominated and Euro-denominated initial margin requirements for CDS). In addition, where the member's aggregate short position in sovereign CDS with respect to a sovereign exceeds a specified threshold, the Clearing House may decline to accept government bonds of that sovereign or any other sovereign bonds that exhibit certain correlations with such government bonds.

The Haircut Policy also addresses potential wrong-way risk arising from Permitted Cover more generally. The Clearing House will monitor collateral on a daily basis. Where the Clearing House considers there to be strong general wrong-way risk between a Clearing Member and the asset it is posting, the Clearing House will ask the member to change the composition of collateral to mitigate that risk.

The Haircut Policy establishes a VaR-based methodology for determining haircuts for Permitted Cover. Under the proposed Haircut Policy, the Clearing House will calculate six different estimations of VaR for each applicable risk factor. Each estimation is calculated using a 99.9% confidence interval (applicable to Permitted Cover posted with respect to all product categories). The proposed haircut will be based on the largest VaR of the 6 estimations. The policy specifies relevant price sources that will be used for the calculation of haircuts for each type of Permitted Cover. Haircuts will be determined using the bid prices of Permitted Cover assets, in order to account for higher liquidation costs in stressed markets. The applicable haircuts will be reviewed on a monthly basis, or more frequently where the risk management department deems it necessary.

Under the proposed policy, the risk management department may further adjust the haircut determined under the model as it determines prudent in light of additional qualitative and quantitative factors, including: the Clearing House's credit assessment of the issuer, current market conditions and volatility, expected future volatility, the liquidity of the underlying market for the asset, including bid/ask spread, wrong way risk considerations, VaR estimates determined for a period of stressed market conditions, and other factors that might affect the liquidity or value of an asset in stressed market conditions. ICE Clear Europe anticipates that such adjustments to the value calculated under the model would be used only in exceptional circumstances and would expect to use such adjustments to increase haircuts in stressed market circumstances. ICE Clear Europe has stated that it will make judicious use of current market information to override the model but anticipates exercising this ability in less than 5% of haircut rates.

The proposed Haircut Policy also sets a minimum haircut level of 3% in order to avoid pro-cyclical variation in haircuts and will review this minimum level annually under the Haircut Policy. In addition, a haircut add-on of up to 1% will be applied during the period until the next monthly review to issuers presenting increased credit risk. The add-on is applied once the issuer's CDS spread exceeds a specified level, and increases in steps of 0.25% up to a maximum of 1% where the CDS spread exceeds higher thresholds. The add-on is generally designed to anticipate potential haircut increases as part of the next monthly review cycle.

The proposed policy also imposes cross-currency haircuts to address the exchange rate risk faced by the Clearing House where the Permitted Cover is denominated in a different currency from the currency of the applicable margin requirement. Under the proposed Haircut Policy, cross-currency haircuts are determined using the same methodology described above for other haircuts, but are subject to a minimum haircut of 4.5%. Cross-currency haircuts will be applied in addition to any applicable haircut for the relevant form of Permitted Cover.

The Clearing House will monitor Permitted Cover on a daily and intraday basis. The Clearing House may, under its existing Rules and the Haircut Policy, take action to mitigate any change in risk, including by increasing haircuts, calling for additional collateral, reducing concentration limits and removing an asset from eligibility as Permitted Cover. The Clearing House will monitor the value of Permitted Cover deposited with it on a real time basis. Any change in a member's intra-day cover value that is greater than 3% will be flagged immediately by the Risk Management intraday monitoring system that is monitored by the Risk Management team throughout the business day. Any breach will be investigated and appropriate action taken where necessary. The Clearing House also will backtest haircuts based on price moves observed in the markets on a daily basis, and review haircut levels if a price move breaches an existing haircut. The Clearing House will prepare daily reports with respect to Permitted Cover for purposes of internal monitoring and provide monthly reports to the relevant Risk Committees and Board Risk Committee.

The Clearing House will review the Haircut Policy on an annual basis (which will include review by the Board Risk Committee) or where there is a material change to the risk exposure of the Clearing House. The Haircut Policy

[5] The Clearing House does not impose absolute or relative limits on the use of U.S. Treasury securities as Permitted Cover.

also will be independently reviewed annually under the Clearing House's model governance framework.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [6] directs the Commission to approve a proposed rule change of a self-regulatory organization if the Commission finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such self-regulatory organization. Section 17A(b)(3)(F) of the Act [7] requires, among other things, that the rules of a clearing agency are designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions and, in general, to protect investors and the public interest.

The Commission finds that the proposed rule change is consistent with Section 17A of the Act [8] and the rules thereunder applicable to ICE Clear Europe. The proposed Haircut Policy will codify the general principles and limitations for assets accepted by ICE Clear Europe as Permitted Cover. The proposed policy also provides a framework for ensuring that appropriate prices are used to value Permitted Cover and establishes a VaR-based methodology, utilizing six different estimations for each applicable risk factor and calculating each estimation using a 99.9% confidence interval, for determining haircuts to ensure that the value of Permitted Cover held by ICE Clear Europe is sufficient to cover the Clearing House's Margin and Guaranty Fund requirements. The policy also provides a methodology for setting absolute and relative concentration limits on particular bonds a Clearing Member may provide as Permitted Cover to guard against liquidity and concentration risks and establishes several measures designed to mitigate wrong-way-risk. In addition, the proposed policy provides procedures for the regular review and monitoring of Permitted Cover and associated haircuts and permits the Clearing House to respond promptly to changes in market conditions by modifying haircuts or other limits on Permitted Cover. Accordingly, the Commission believes that the Haircut Policy is designed to appropriately value Permitted Cover and enable ICE Clear Europe to efficiently and effectively liquidate all forms of accepted Permitted Cover to satisfy its payment obligations in the event of a Clearing Member default. The Commission therefore finds that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions and, in general, to protect investors and the public interest in accordance with Section 17A(b)(3)(F) of the Act.[9]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act [10] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (File No. SR–ICEEU–2015–007) be, and hereby is, approved.[12]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12032 Filed 5–18–15; 8:45 am]

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[6] 15 U.S.C. 78s(b)(2)(C).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 15 U.S.C. 78q–1.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78q–1.

[11] 15 U.S.C. 78s(b)(2).

[12] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74947; File No. SR–NYSEArca–2015–39]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services To Reduce Fees for Routing Certain Retail Orders to Away Market Centers

May 13, 2015.

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 April 30, 2015, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 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 Equities Schedule of Fees and Charges for Exchange Services (''Fee Schedule'') to reduce fees for routing certain retail orders to away market centers. The Exchange proposes to implement the changes on May 1, 2015. The text of the proposed rule change is available on the Exchange's Web site 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 Schedule to reduce fees for routing certain retail orders to away market centers. The Exchange proposes to implement the changes on May 1, 2015.

The Exchange currently charges $0.0029 per share for all orders in Tape A Securities that are routed outside the Book to the NYSE; and $0.0035 per share for all orders in Tape B Securities and Tape C Securities that are routed outside the Book to any away market center.

The Exchange proposes to reduce the fees for certain orders, *i.e.,* for Primary Until 9:45 Orders [4] and Primary After

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] A Primary Until 9:45 Order is an Order entered for participation on the primary market until 9:45 a.m. Eastern Time (6:45 a.m. Pacific Time) after

Continued

3:55 Orders [5] that are designated as retail orders and meet the requirements of Rule 7.44(a)(3), but which are not executed in the Retail Liquidity Program [6] (''Retail Orders''). Under Rule 7.44(a)(3), a Retail Order is an agency order or a riskless principal order that meets the criteria of Financial Industry Regulatory Authority, Inc. Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization (''RMO''),[7] provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. An ETP Holder may designate an order a Retail Order either (1) by designating certain order entry ports at the Exchange as ''Retail Order Ports'' and attesting, in a form and/or manner prescribed by the Exchange, that all orders submitted to the Exchange via such Retail Order Ports are Retail Orders; or (2) by means of a specific tag in the order entry message.[8]

Specifically, the Exchange proposes to charge a fee of $0.0010 per share for all Primary Until 9:45 Orders and Primary After 3:55 Orders that are designated as Retail Orders and that are routed to the primary listing market. The Exchange proposes to include this fee in three places in the Basic Rates section of the Fee Schedule for each of Tape A, Tape B, and Tape C securities by adding text following the existing rate for routing orders that provides ''except that Primary Until 9:45 Orders and Primary After 3:55 Orders that are designated as Retail Orders and routed to the primary listing market will be charged $0.0010 per share (fee).''

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, 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 Exchange believes that the proposed fee changes are reasonable as they are designed to attract additional retail order flow to the Exchange that include an instruction to route to the primary listing market at designated times. In addition, the proposed fees are equitable and not unfairly discriminatory because they will apply uniformly to all similarly situated ETP Holders.

The Exchange notes that a significant percentage of the orders of individual investors are executed over-the-counter.[11] While the Exchange believes that markets and price discovery optimally function through the interactions of diverse flow types, it also believes that growth in internalization has required differentiation of retail order flow from other order flow types. The proposed new fee is set at a level to incentivize ETP Holders to continue to direct a subset of Retail Orders to the Exchange, rather than to an over-the-counter market. The Exchange believes that, because Retail Orders are likely to reflect long-term investment intentions, they promote price discovery and dampen volatility. Accordingly, the presence of Retail Orders on the Exchange, or if routed, on the primary listing market for those securities, has the potential to benefit all market participants. For this reason, the Exchange believes that the proposed pricing is equitable and not unfairly discriminatory and would continue to encourage greater retail participation on the Exchange and other registered exchanges.

The pricing proposed herein is not designed to permit unfair discrimination, but instead to promote a competitive process around retail executions such that retail investors would receive better prices. The proposed change is also equitable and not unfairly discriminatory because it would contribute to investors' confidence in the fairness of their transactions and because it would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition. For these reasons, the Exchange believes that the proposal is consistent with the Act.

which time the order is cancelled on the primary market and entered on the NYSE Arca Book. The Primary Until 9:45 Order may be Day only and may not be designated as GTC or GTD. Orders that return to the NYSE Arca Book after routing to the primary market retain their original order attributes. *See* NYSE Arca Equities Rule 7.31(f)(2).

[5] A Primary After 3:55 Order is an Order entered for participation on the Exchange until 3:55 p.m. Eastern Time (12:55 p.m. Pacific Time) after which time the order is cancelled on the Exchange and an order is entered for participation on the primary market. The Primary After 3:55 Order may be Day only and may not be designated as GTC or GTD. Orders that route to the primary market at 3:55 p.m. Eastern Time retain their original order attributes. *See* NYSE Arca Equities Rule 7.31(f)(2) [sic].

[6] The Retail Liquidity Program is a pilot program designed to attract additional retail order flow to the Exchange for NYSE Arca-listed securities and securities traded pursuant to unlisted trading privileges (''UTP Securities'') while also providing the potential for price improvement to such order flow. *See* Rule 7.44. *See* Securities Exchange Act Release No. 71176 (December 23, 2013), 78 FR 79524 (December 30, 2013) (SR–NYSEArca–2013–107).

[7] ''RMO'' is defined in Rule 7.44(a)(2) as an ETP Holder that is approved by the Exchange to submit Retail Orders. However, an order designated as a Retail Order of an RMO for purposes of the Retail Liquidity Program is separate from the designation of an order as a Retail Order for purposes of existing pricing tiers in the Fee Schedule. *See* Securities Exchange Act Release No. 71722 (March 13, 2014), 78 [sic] FR 15376 (March 19, 2014) (SR–NYSEArca–2014–22) (''Arca Retail Approval Order'' [sic]). The proposed rule change solely concerns Retail Orders outside the Retail Liquidity Program that are currently defined in the Fee Schedule as ''Retail Orders''.

[8] *See, e.g.,* Securities Exchange Act Release No. 68322 (November 29, 2012), 77 FR 72425 (December 5, 2012) (SR–NYSEArca–2012–129). ETP Holders designating orders as Retail Orders by using a tag in the order entry message are required to have written policies and procedures reasonably designed to assure that it only designates orders as Retail Orders if all requirements of a Retail Order are met. The written policies and procedures require the ETP Holder to (i) exercise due diligence before entering a Retail Order to assure that entry as a Retail Order is in compliance with the requirements specified by the Exchange, and (ii) monitor whether orders entered as Retail Orders meet the applicable requirements. If the ETP Holder represents Retail Orders from another broker-dealer customer, the ETP Holder's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meets the definition of a Retail Order.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] *See* Concept Release on Equity Market Structure, Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (''Concept Release'') (noting that dark pools and internalizing broker-dealers executed approximately 25.4% of share volume in September 2009). *See also* Mary Jo White, Focusing on Fundamentals: The Path to Address Equity Market Structure (Speech at the Security Traders Association 80th Annual Market Structure Conference, Oct. 2, 2013) (available on the Commission's Web site) (''White Speech''); Mary L. Schapiro, Strengthening Our Equity Market Structure (Speech at the Economic Club of New York, Sept. 7, 2010) (available on the Commission's Web site) (''Schapiro Speech''). In her speech, Chair White noted a steadily increasing percentage of trading that occurs in ''dark'' venues, which appear to execute more than half of the orders of long-term investors. Similarly, in her speech, only three years earlier, Chair Schapiro noted that nearly 30 percent of volume in U.S.-listed equities was executed in venues that do not display their liquidity or make it generally available to the public and the percentage was increasing nearly every month.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed fees would increase competition for retail order flow among execution venues and encourage additional execution opportunities on the Exchange and other registered exchanges. The Exchange believes the proposed fee change also would not impose any burden on competition among market participants. To the contrary, because Primary Until 9:45 Orders and Primary After 3:55 Orders are designed to route to the primary listing market during designated times, the Exchange believes that the proposed fee would promote inter-exchange competition by proving an incentive for ETP Holders to route such orders to the Exchange, which would also benefit the primary listing markets that would receive the orders when routed.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change promotes a 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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[13] of the Act and subparagraph (f)(2) of Rule 19b–4[14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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)[15] 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–NYSEArca–2015–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2015–39. 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 Web site (*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 Web site 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2015–39 and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12062 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78f(b)(8).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, May 21, 2015 at 2:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be: Institution and settlement of injunctive actions; Institution and settlement of administrative proceedings; Adjudicatory matter; and Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: May 14, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–12183 Filed 5–15–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74952; File No. SR–BOX–2015–19]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adjust the Preferred Market Maker Quoting Obligations

May 13, 2015.

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 May 5, 2015, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''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 the Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule 7300 (Preferenced Orders) to adjust the Preferred Market Maker quoting obligations. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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 amend BOX Rule 7300 (Preferenced Orders) to revise the quoting obligations for Preferred Market Makers. Specifically, the Exchange proposes to (i) decrease the percentage of time a Preferred Market Maker is required to continuously quote from 99% to 90%; (ii) decrease the percentage of series the Preferred Market Maker is required to continuously quote; and (iii) modify the series the continuous quoting obligations apply to for Preferred Market Makers. Each of these changes, which are described in detail below, will make BOX's Preferred Market Maker obligations more consistent with the comparable market maker obligations at other options exchanges.[3]

BOX Rule 7300 currently provides that during trading hours, a Preferred Market Maker[4] must maintain a continuous two-sided market, pursuant to Rule 8050(c)(1), throughout the trading day, in option classes for which it accepts Preferenced Orders, for 99% of the time the Exchange is open for trading in each such option class; provided, however, that for purposes of this requirement, a Preferred Market Maker is not required to quote in intra-day add-on series or series that have a time to expiration of nine months or more in the classes for which it receives Preferenced Orders and a Market Maker may still be a Preferred Market Maker in any such series if the Market Maker otherwise complies with Rule 7300(a)(2).

The rule also provides that if a technical failure or limitation of a system of the Exchange prevents a Preferred Market Maker from maintaining, or prevents a Preferred Market Maker from communicating to the Exchange, timely and accurate electronic quotes in an option class, the duration of such failure will be disregarded in determining whether the Preferred Market Maker has satisfied this requirement. The Exchange may also consider other exceptions to this obligation based on a demonstrated legal or regulatory requirement or other mitigating circumstances.

The Exchange first proposes to reduce the percentage of time which a Preferred Market Maker is required to provide continuous quotes in an appointed options class to 90% of the time. The Exchange then proposes to amend the continuous quoting obligation for Preferred Market Makers from 100% to 99% of the options series of each class for which it accepts Preferenced Orders. Finally, the Exchange proposes to add the language ''non-adjusted options series'' to indicate that Preferred Market Maker will not be obligated to maintain continuous quotes in adjusted options series and to define the term adjusted options series. Compliance with the Preferred Market Maker's continuous quoting requirement will still be determined on a monthly basis; and this does not relieve a Preferred Market Maker from meeting this quoting requirement on a daily basis, nor does it prohibit the Exchange from taking disciplinary action against a Preferred Market Maker for failing to meet this requirement each trading day.

The Exchange does not believe that the proposed rule change will adversely affect the quality of the Exchange's market or lead to a material decrease in liquidity. Rather, the Exchange believes that lowering the continuous quoting requirements may increase liquidity by attracting more Preferred Market Makers to the Exchange. Preferred Market Makers will still have to meet heightened quoting requirements when compared to the quoting requirements of Market Makers on the Exchange.[5] Additionally, the Exchange Rules will continue to impose a number of other obligations on Preferred Market Makers to ensure that they create and maintain a fair and orderly market in the option classes to which they are assigned.[6]

The Exchange believes this proposal will make the quoting requirements of Preferred Market Makers more comparable to those at other options exchanges and is therefore essential for competitive purposes.[7]

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''), in general, and Section 6(b)(5) of the Act, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* MIAX Rule 514 and 604(e)(2); CBOE Rule 1.1(ccc); Phlx Rule 1014(b)(ii)(D)(1); and ISE Rule 804(e)(2)(iii).

[4] The term ''Preferred Market Maker'' means a Market Maker designated as such by a Participant with respect to an order submitted by such Participant to BOX. *See* BOX Rule 7300.

[5] Under BOX Rule 8050(e) on a daily basis a Market Maker must post valid quotes at least sixty percent (60%) of the time that the classes are open for trading.

[6] For example, in order to receive the allocation preference the Preferred Market Maker must also be quoting at the NBBO at the time the Preferenced Order was received.

[7] *See supra,* note 3.

general to protect investors and the public interest. In particular, the proposed rule change removes impediments to and perfects the mechanisms of a free and open market and a national market system because it is similar with the continuous quoting standards in place on other options exchanges. The Exchange believes the proposed rule change will not diminish, and in fact may increase market making activity and liquidity on the Exchange by establishing a quoting compliance standard that is reasonable and is similar to those already in place on other options exchanges. Specifically, the Exchange believes that the proposed quoting requirements will encourage greater participation by Market Makers to provide quotes on the Exchange as Preferred Market Makers. These additional responses should encourage greater competition on the Exchange, which should, in turn, benefit and protect investors and the public interest through the potential for greater volume of orders and executions.

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 not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change applies to all Preferred Market Makers. Additionally, the proposed rule change is substantially similar to the rules in place at other options exchanges,[8] which the exchange believes may enhance, rather than burden, competition among the options exchanges.

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 comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 for 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[9] and Rule 19b–4(f)(6) thereunder.[10]

At any time within 60 days of the filing of the 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 to determine whether the proposed rule 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–BOX–2015–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2015–19. 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 Web site (*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 Web site 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 filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2015–19, and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12029 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[8] *See supra,* note 3.

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the 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.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74954; File No. SR–Phlx–2015–29]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Amend and Restate Certain Rules That Govern the NASDAQ PSX

May 13, 2015.

On March 20, 2015, NASDAQ OMX PHLX LLC (''Phlx'') 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 proposed rule change to amend and restate certain Phlx rules that govern NASDAQ OMX PSX in order to provide a clearer and more detailed description of certain aspects of its functionality. The proposed rule change was published for comment in the **Federal Register** on April 6, 2015.[3] The Commission received no comment letters regarding the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74618 (March 31, 2015), 80 FR 18452.

[4] 15 U.S.C. 78s(b)(2).

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 for this filing is May 21, 2015.

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] and for the reasons stated above, the Commission designates July 5, 2015, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12031 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34- 74953; File No. SR–FINRA–2015–011]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Reporting Requirements of FINRA Rule 4530(a)(1)(H)

May 13, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 4530 (Reporting Requirements) to provide an exception from the requirements of paragraph (a)(1)(H) of the rule for dealings with a member or associated person subject to statutory disqualification, if that member or associated person has been approved (or is otherwise permitted pursuant to FINRA rules and the federal securities laws) to be a member or to be associated with a member.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA 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

FINRA Rule 4530 requires members to report to FINRA specified events, such as statutory disqualifications, and quarterly statistical and summary information regarding written customer complaints.[4] FINRA uses the information for regulatory purposes to identify and initiate investigations of firms, offices and associated persons that may pose a risk.

FINRA Rule 4530(a)(1)(H) requires a member to report whenever the member itself or an associated person of the member is subject to a ''statutory disqualification'' as defined in the Act. The rule also requires a member to report whenever the member or an associated person of the member is involved in the sale of any financial instrument, the provision of any investment advice or the financing of any such activities with any person that is subject to a ''statutory disqualification'' as defined in the Act. The report must include the name of the person subject to the statutory disqualification and details concerning the disqualification. In addition, the report must be submitted to FINRA within 30 calendar days after the member knows or should have known of the event.

The definition of ''statutory disqualification'' under the Act includes, among other events, findings by the SEC, Commodity Futures Trading Commission or a self-regulatory organization that a person: (1) Willfully violated the federal securities or commodities laws, or the Municipal Securities Rulemaking Board rules; (2) willfully aided, abetted, counseled, commanded, induced or procured such violations; or (3) failed to supervise another person who commits violations of such laws or rules.[5] Thus, for instance, a member is currently required to report under FINRA Rule 4530(a)(1)(H) each time the member is involved in the sale of any financial instrument, such as participating in a selling syndicate or selling group, with a member that has been found to have willfully violated the federal securities laws. This would be true even if the member that is subject to the willful violation has been approved, or is otherwise permitted pursuant to FINRA rules and the federal securities laws, to continue in membership notwithstanding the disqualification.[6]

For the following reasons, FINRA believes that there is no regulatory value

[4] The specified events and customer complaint information must be electronically reported to FINRA via an application on FINRA's Firm Gateway.

[5] *See* 15 U.S.C. 78c(a)(39).

[6] In general, persons subject to a statutory disqualification would be required to obtain approval from FINRA to enter or remain in the securities industry. A firm seeking to continue in membership, notwithstanding the existence of such a disqualification, generally would be required to file an MC–400A application with FINRA. Similarly, a firm seeking to sponsor (*i.e.,* employ or associate with) a disqualified person generally would be required to file an MC–400 application with FINRA. However, as described in *Regulatory Notice* 09–19 (April 2009), a firm would not be required to file an application for approval for specific disqualifying events. For instance, a firm that is subject to a statutory disqualification based on a willful violation of the federal securities laws would not be required to file an MC–400A application with FINRA if the sanction is no longer in effect. Such a firm would be permitted to continue in membership notwithstanding the disqualification and without having to file an application with FINRA for approval.

in requiring a firm to report dealings with a disqualified member or associated person that has been approved or is otherwise permitted to be a member or associated with a member. First, FINRA is aware of the statutory disqualification status of such members and associated persons. Second, disqualified members and associated persons that have been approved to be members or associated with members typically are subject to special supervisory conditions, and FINRA periodically examines them to ensure compliance with the supervisory conditions and to monitor for other problems.

Therefore, FINRA is proposing to amend Rule 4530(a)(1)(H) to exclude activities with a disqualified member or associated person that has been approved (or is otherwise permitted pursuant to FINRA rules and the federal securities laws) to be a member or associated with a member.

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date of the proposed rule change will be the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[7] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change will further these purposes by eliminating unnecessary reporting of information to FINRA and allowing FINRA to use its resources more efficiently. FINRA also believes that the proposed rule change will serve to reduce potential compliance burdens on firms without compromising the regulatory information available to FINRA.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposed rule change would reduce potential compliance burdens on firms by eliminating the requirement under FINRA Rule 4530(a)(1)(H) to report to FINRA each instance where a firm or an associated person is involved in a financial activity with a disqualified member or associated person that has been approved or is otherwise permitted to be a member or associated with a member.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[10] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA requested the Commission to waive the 30-day operative delay so it can implement the proposed rule change immediately. FINRA stated that waiver of the operative delay would eliminate unnecessary reporting requirements relating to dealings with members or associated persons that are subject to a statutory disqualification where FINRA already has access to information regarding the status of such persons and they have either been approved or are otherwise permitted to be a member or associated with a member. The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[12]

At any time within 60 days of the filing of the 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 to determine whether the proposed rule 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–FINRA–2015–011 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–FINRA–2015–011. 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 Web site (*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 Web site 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 FINRA. All comments received

[7] 15 U.S.C. 78*o*–3(b)(6).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with 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. FINRA has fulfilled this requirement.

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–011 and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12030 Filed 5–18–15; 8:45 am]

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74950; File No. SR–EDGX–2015–22]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of EDGX Exchange, Inc.

May 13, 2015.

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 April 30, 2015, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. 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 filed a to amend its fees and rebates applicable to Members[5] of the Exchange pursuant to EDGX Rule 15.1(a) and (c) (''Fee Schedule'') to: (i) decrease the rebate for orders yielding fee code BY, which routes to the BATS Y-Exchange, Inc. (''BYX'') and removes liquidity using routing strategies Destination Specific (''DIRC''), ROUC, or ROUE;[6] (ii) decrease the standard rate charged for removing liquidity from the Exchange from $0.0030 per share to $0.0029 per share; and (iii) make a few non-substantive clarifying changes. Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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 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 parts 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: (i) Decrease the rebate for orders yielding fee code BY, which routes to BYX and removes liquidity using routing strategies DIRC, ROUC, or ROUE; (ii) decrease the standard rate charged for removing liquidity from the Exchange from $0.0030 per share to $0.0029 per share; and (iii) make a few non-substantive clarifying changes.

Fee Code BY

In securities priced at or above $1.00, the Exchange currently provides a rebate of $0.00160 per share for Members' orders that yield fee code BY, which routes to BYX and removes liquidity using routing strategies DIRC, ROUC, or ROUE. The Exchange proposes to amend its Fee Schedule to decrease the rebate for orders that yield fee code BY to $0.00150 per share in securities priced at or above $1.00.[7] The proposed change represents a pass through of the rate BATS Trading, Inc. (''BATS Trading''), the Exchange's affiliated routing broker-dealer, is provided for routing orders to BYX that remove liquidity. The proposed change is in response to BYX's May 2015 fee change where BYX decreased its rebate from $0.00160 per share to $0.00150 per share for orders in securities priced at or above $1.00.[8] When BATS Trading routes to and removes liquidity from BYX, it will now receive a standard rebate of $0.00150 per share. BATS Trading will pass through the rebate provided by BYX to the Exchange and the Exchange, in turn, will pass through this rate to its Members.

Standard Removal Rate Change

In securities priced at or above $1.00, the Exchange currently charges a fee or $0.0030 per share when removing liquidity. The Exchange now proposes to decrease the standard rate charged for removing liquidity from the Exchange from $0.0030 per share to $0.0029 per share in securities priced at or above $1.00.[9] The standard removal rate applies unless a Member's transaction is assigned a fee code other than a standard fee code. If a Member's transaction is assigned a fee code other than a standard fee code, the rates listed in the Fee Codes table of the Fee Schedule will apply.

The standard rate for removing liquidity from the Exchange will be $0.0029 per share and no lower fees will be available if a Member qualifies for a tier included in footnote 1 of the Fee Schedule. Therefore, the Exchange proposes to make a series of changes to the Fee Schedule as a result of decreasing the standard rate to $0.0029 per share. First, the Exchange proposes to amend footnote 1 to remove references to reduced fees for removing or routing liquidity from the Exchange. Under footnote 1, if a Member satisfies the respective tier's criteria, they would be charged a reduced fee of: (i) $0.0029 per share under Mega Tier 1; (ii) $0.0029 per share under Mega Tier 2; or (iii) $$0.00295 per share under Mega

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer, or any person associated with a registered broker or dealer [sic], that has been admitted to membership in the Exchange. A Member will have the status of a ''member'' of the Exchange as that term is defined in Section 3(a)(3) of the Act.'' *See* Exchange Rule 1.5(n).

[6] The DIRC, ROUC, and ROUE routing strategies are set forth in Exchange Rule 11.11(g).

[7] The Exchange does not propose to amend its fee for orders that yield fee code BY in securities priced below $1.00.

[8] *See* BYX Exchange Fee Schedule Changes Effective May 1, 2015 *available at http://cdn.batstrading.com/resources/fee_schedule/2015/BATS-BYX-Exchange-BZX-Exchange-EDGA-Exchange-and-EDGX-Exchange-Fee-Schedule-Changes-Effective-May-1-2015.pdf.*

[9] The Exchange does not propose to amend its standard rate for orders in securities priced below $1.00.

Tier 3.[10] Going forward, Members will be charged the standard removal rate of $0.0029 per share regardless of whether they satisfy the criteria for Mega Tier 1 or Mega Tier 2. Members will also be charged the reduced standard removal rate of $0.0029 per share, rather than $0.00295 per share, if they satisfy the criteria for Mega Tier 3. Therefore, the Exchange proposes to delete the references under footnote 1 to reduced fees for removing of routing liquidity from the Exchange as Members will be charged the reduced standard removal rate regardless of whether they meet any of the above referenced tiers' criteria. As a result of the above changes, the Exchange also proposes to remove language from footnote 1 listing the fee codes eligible for reduced removal fees provided by the add volume tiers included in footnote 1 as this language would be no longer necessary.

Second, the Exchange proposes to delete references to footnote 1 from: (i) the standard rate for removing liquidity in securities priced above $1.00; and (ii) standard fee codes 6, 7, BB, N, RT, and W. These fee codes provide for the standard removal rate when removing liquidity from the Exchange. Footnote 1 references reduced fees charged for removing liquidity if the criteria included in the tiers within footnote 1 are satisfied. The Exchange believes references to footnote 1 discussed above are no longer necessary as the standard rate for removing liquidity from the Exchange will be $0.0029 per share and no lower fees will be available if a Member qualifies for a tier included in footnote 1.

Lastly, as a result of reducing the standard rate, the Exchange proposes to amend fee codes 5, EA, and ER to reduce the fee charged for internalized trades executed on the Exchange from $0.0005 per share to $0.00045 per share. For customer internalization, which occurs when two orders presented to the Exchange from the same Member (*i.e.,* MPID) are presented separately and not in a paired manner, but nonetheless inadvertently match with one another,[11] the Exchange currently charges $0.00050 per share per side of an execution (for adding liquidity and for removing liquidity) for fee codes 5, EA, and ER.[12] This charge occurs in lieu of the standard or tiered rebate/removal rates. Therefore, Members currently incur a total transaction cost of $0.0010 per share for both sides of an execution for customer internalization.

Prior to the proposed reduction of the standard removal rate proposed herein, the Exchange charged a standard rate of $0.0030 per share for orders that remove liquidity and a standard rebate of $0.0020 per share for orders that add liquidity resulting in a maker/taker spread of $0.0010 per share, equal to the total transaction cost of $0.0010 per share for both sides of an execution for customer internalization. Going forward, the Exchange proposes to charge a standard rate of $0.0029 per share for orders that remove liquidity and will continue to provide a standard rebate of $0.0020 per share for orders that add liquidity resulting in a maker/taker spread of $0.0009 per share.

In order to ensure that the internalization fee is in line with the proposed maker/taker spread of $0.0009 for the standard add rate (rebate of $0.0020) and standard removal rate (proposed $0.0029 fee per share), the Exchange proposes to reduce the fee charged for internalized trades executed on the Exchange from $0.00050 per share to $0.00045 per share under fee codes 5, EA, and ER. The amended fee of $0.00045 per share for fee codes 5, EA, and ER would result in total transaction cost of $0.0009 per share for both sides of an execution for customer internalization, equal to the maker/taker spread of $0.0009 for the standard add and removal rates discussed above. For both tiered and standard rates, the charge for Members inadvertently matching with themselves will continue to be no more favorable than each maker/taker spread.[13] The applicable rate for customer internalization thus allows the Exchange to continue to discourage potential wash sales.

Non-Substantive Changes

The Exchange also proposes to make the below non-substantive clarifying changes to its Fee Schedule. First, the Exchange proposes to remove '', Inc.'' from the reference to the Exchange in the heading of the Fee Schedule. This non-substantive change is intended to make the reference to the Exchange in the heading of the Fee Schedule consistent with the manner in which its affiliated exchanges[14] are referenced in their respective fee schedules. Second, the Exchange proposes to remove an incorrect reference to footnote 4 under the standard removal rate as footnote 4 provides for a rebate of $0.0034 per share for Members meeting criteria under the Exchange's Retail Order tier. Footnote 4 is, therefore, inapplicable to the standard removal rate. Third, the Exchange proposes to remove a reference to fee code PI from the Standard Rates table as fee code PI was previously removed from the Fee Codes and Associated Fees section of the Fee Schedule on January 16, 2015 and is no longer available.[15] Lastly, the Exchange proposes to add a reference to footnote 1 to fee code ZA, which provides for a rebate of $0.0032 per share for Retail Orders[16] that add liquidity. Footnote 1 states that the rebates to add liquidity provided by the add volume tiers listed in the footnote are applicable to various fee codes, including fee code ZA. Therefore, the Exchange believes that adding a reference to footnote 1 following fee code ZA will improve the understandability of the Exchange's Fee Schedule because footnote 1 does expressly apply to that fee code.

Implementation Date

The Exchange proposes to implement these amendments to its Fee Schedule immediately.

[10] The Exchange does not propose to amend the rebates provide by or the criteria necessary to satisfy Mega Tier 1, Mega Tier 2, or Mega Tier 3.

[11] Members are advised to consult Exchange Rule 12.2 respecting fictitious trading.

[12] Fee codes 5 provides for a fee of $0.0005 per share per each side of an internalized trade executed on the Exchange during the Pre-Market Trading Session and Post-Market Trading Session. Fee code EA also provides for a fee of $0.0005 per share for an internalized trade executed on the Exchange that adds liquidity during Regular Trading Hours. Fee code ER provides for a fee of $0.0005 per share for an internalized trade executed on the Exchange that removes liquidity during Regular Trading Hours.

[13] In addition, the Exchange notes that under footnote 7 of the Fee Schedule, a Member that adds 10,000,000 shares or more of average daily volume (''ADV'') would be charged a rate of $0.0001 per share per side for customer internalization. The Exchange has a variety of tiered rebates ranging from $0.0025–$0.0034 per share, which makes its maker/taker spreads range from $0.0006 (standard removal rate—Mega Tier 1 rebate), $0.00035 (standard removal rate—Market Depth Tier 1 rebate), $0.0003 (standard removal rate—Mega Tier 2, Mega Tier 3, Mega-Step-Up Tier 1,and Investor Tier rebate),), $0.0002 (standard removal rate—Ultra Tier rebate), $0.0001 (standard removal rate—Mega Step-Up Tier 2 rebate), $0 (standard removal rate—Market Depth Tier 2 rebate), −$0.0001 (standard removal rate—Mega Step-Up Tier 3 and Super Tier), −$0.0002 (standard removal rate—Tape B Step Up Tier), and −$0.0004 (standard removal rate—Growth Tier rebate). As a result of the customer internalization charge, Members who internalized would be charged $0.0001 per share per side of an execution (total of $0.0002 per share) or $0.0045 per share per side (total of $0.0009 per share) instead of capturing the maker/taker spreads resulting from achieving the tiered rebates.

[14] The Exchange's affiliated exchanges are BATS Exchange, Inc., BATS Y-Exchange, Inc., and EDGA Exchange, Inc. (''EDGA''). The Exchange understands that EDGX also intends to file a proposed rule change with the Commission making a similar change to how EDGA is referenced in the heading of its fee schedule.

[15] *See* Securities Exchange Act Release No. 74165 (January 28, 2015), 80 FR 5854 (February 3, 2015) (SR–EDGX–2015–04) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Make Non-Substantive Amendments and Clarifications to the Fee Schedule).

[16] ''Retail Order'' is defined under Exchange Rule 11.21(a).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[17] in general, and furthers the objectives of Section 6(b)(4),[18] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent [sic] market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

Fee Code BY

The Exchange believes that its proposal to decrease the rebate for orders that yield fee code BY represents an equitable allocation of reasonable dues, fees, and other charges among Members and other persons using its facilities. Prior to the BYX's May 2015 fee change, BYX provided BATS Trading a rebate of $0.00160 per share to remove liquidity in securities priced at or above $1.00, which BATS Trading passed through to the Exchange and the Exchange provided its Members. When BATS Trading routes to BYX, it will now be provided a rebate of $0.00150 per share. The Exchange does not levy additional fees or offer additional rebates for orders that it routes to BYX through BATS Trading. Therefore, the Exchange believes that the proposed change to fee code BY is equitable and reasonable because it accounts for the pricing changes on BYX, which enables the Exchange to provide its Members the applicable pass-through rebate. Lastly, the Exchange notes that routing through BATS Trading is voluntary and believes that the proposed change is non-discriminatory because it applies uniformly to all Members.

Standard Removal Rate Change

The Exchange believes that its proposal to lower the standard removal rate from $0.0030 per share to $0.0029 per share, as well as related changes made throughout the Fee Schedule, represent an equitable allocation of reasonable dues, fees and other charges as it will enable the Exchange to decrease trading cost for Members who remove liquidity from the Exchange. Decreasing the standard removal rate is designed to attract additional liquidity to the Exchange, thereby increasing depth of the Exchange's order book, resulting in improved price discovery for all investors. The rate is also equitable and reasonable as compared to the fees for removing liquidity charged by The Nasdaq Stock Market LLC (''Nasdaq'') (removal rate of $0.0030 per share) and NYSE Arca, Inc. (''NYSE Arca'') (removal rate of $0.0030 per share for Tape A and Tape C securities).[19] The Exchange believes references to footnote 1 as well as removing the fees to remove liquidity from Mega Tier 1, Mega Tier 2, and Mega Tier 3, as referenced above, are also equitable and reasonable because such provisions are no longer necessary as the standard rate for removing all liquidity from the Exchange will be $0.0029 per share, which is equal to or lower than the current removal rated provided for in those tiers. The proposed standard removal rate is also non-discriminatory in that it applies uniformly to all Members.

The Exchange believes that decreasing the fee for customer internalization from $0.00050 to $0.00045 per share per side of an execution for fee codes EA, ER, and 5 represents an equitable allocation of reasonable dues, fees, and other charges as it is designed to discourage Members from inadvertently matching with one another and potential wash sales. The revised fee also allows the Exchange to offset its administrative, clearing, and other operating costs incurred in executing such trades. Finally, the fee is equitable and reasonable because it total transaction cost of for both sides of an execution for customer internalization will continue to be equal to the maker/taker spread of $0.0009 for the standard add and removal rates discussed above.[20] The Exchange believes that the proposed rate is non-discriminatory in that it applies uniformly to all Members.

Non-Substantive Changes

The Exchange believes that the non-substantive clarifying changes to its Fee Schedule are reasonable because they are not designed to amend any fee, nor alter the manner in which it assesses fees or calculates rebates. These proposed changes to the Fee Schedule are intended to make the reference to the Exchange in the heading of the Fee Schedule consistent with the manner in which its affiliated exchanges are referenced in their respective fee schedules, while the clarifying changes to remove reference to footnote 4 under the standard removal rate and add a reference to footnote 1 to fee code ZA are intended to add clarity to the Fee Schedule and avoid investor confusion. Therefore, the Exchange believes these changes will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendments to its Fee Schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

Fee Code BY

The Exchange believes that its proposal to pass through the amended rebate for orders that yield fee code BY would increase intermarket competition because it offers customers an alternative means to route to BYX for the same rebate that they would be provided if they entered orders on that trading center directly. The Exchange believes that its proposal would not burden intramarket competition because the proposed rebate would apply uniformly to all Members.

Standard Removal Rate Change

The Exchange believes that its proposal to lower the standard removal

[17] 15 U.S.C. 78f.

[18] 15 U.S.C. 78f(b)(4).

[19] *See* Nasdaq, Price List—Trading & Connectivity, *available at http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2. See also* the NYSE Arca Schedule of Fees and Charges for Exchange Services, dated April 20, 2015 *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf.*

[20] In each case, the internalization fee is no more favorable to the Member than each prevailing maker/taker spread. The Exchange will continue to ensure that the internalization fee is no more favorable than each prevailing maker/taker spread.

rate from $0.0030 per share to $0.0029 per share will also assist in increasing competition in that its proposed rebate is lower than the standard fees for removing liquidity offered by Nasdaq (removal rate of $0.0030 per share) and NYSE Arca (removal rate of $0.0030 per share for Tape A and Tape C securities).[21]

The Exchange believes that its internalization rates for securities priced $1.00 and above will also not burden intermarket or intramarket competition as the proposed rates are no more favorable than Members achieving the maker/taker spreads between the standard add and remove rates on the Exchange.

Non-Substantive Changes

The Exchange believes that the proposed non-substantive clarifying changes to the Fee Schedule will not affect intermarket nor intramarket competition because these changes are not designed to amend any fee or alter the manner in which the Exchange assesses fees or calculates rebates.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[22] and paragraph (f) of Rule 19b–4 thereunder.[23] At any time within 60 days of the filing of the 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.

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–EDGX–2015–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2015–22. 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 Web site (*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 Web site 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2015–22 and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12027 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[21] *See supra* note 19.

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74949; File No. SR–EDGX–2015–18]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing of Proposed Rule Change To Establish Rules Governing the Trading of Options on the EDGX Options Exchange

May 13, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on April 30, 2015, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''SEC'' or ''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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to adopt rules to govern the trading of options on the Exchange (referred to herein as ''EDGX Options Exchange'' or ''EDGX Options''). As described more fully below, the EDGX Options Exchange will operate a fully automated, Customer priority/pro rata allocation model. The fundamental premise of the proposal is that the Exchange will operate its options market in a similar manner to the options exchange operated by the Exchange's affiliate, BATS Exchange, Inc. (''BZX Options''), with the exception of the proposed priority model and certain other limited differences.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt a series of rules in connection with EDGX Options, which will be a facility of the Exchange. EDGX Options will operate an electronic trading system developed to trade options (''System'') that will provide for the electronic display and execution of orders, as described below. All Exchange Members will be eligible to participate in EDGX Options provided that the Exchange specifically authorizes them to trade in the System. The System will provide a routing service for orders when trading interest is not present on EDGX Options, and will comply with the obligations of the Options Order Protection and Locked/Crossed Market Plan.

EDGX Options Members

The Exchange will authorize any Exchange Member who meets certain enumerated qualification requirements to obtain access to EDGX Options (any such Member, an ''Options Member'').

There will be two basic types of Options Members, Options Order Entry Firms (''OEFs'') and Options Market Makers. Options Market Makers, in turn, will be eligible to participate as Directed Market Makers, Primary Market Makers and Market Makers. OEFs will be those Options Members representing orders as agent on EDGX Options and non-market maker participants conducting proprietary trading as principal. Options Market Makers are Options Members registered with the Exchange as Options Market Makers.

To become an Options Market Maker, an Options Member is required to register by filing a written application with the Exchange, and then must register to make markets in individual series of options. Pursuant to proposed Rule 22.2, the Exchange may appoint one Primary Market Maker per option class. Market Makers may select from among any option issues traded on the Exchange to request appointment as a Primary Market Maker, subject to the approval of the Exchange. In considering the approval of the appointment of a Primary Market Maker in each security, the Exchange will consider: the Market Maker's preference; the financial resources available to the Market Maker; the Market Maker's experience, expertise and past performance in making markets, including the Market Maker's performance in other securities; the Market Makers [sic] operational capability; and the maintenance and enhancement of competition among Market Makers in each security in which they are registered, including pursuant to the performance standards set forth in proposed Rule 22.2(i).[3]

An unlimited number of Market Makers may be registered in each class unless the number of Market Makers registered to make a market in a particular option class should be limited whenever, in the Exchange's judgment, quotation system capacity in an option class or classes is not sufficient to support additional Market Makers in such class or classes. The Exchange will not restrict access in any particular option class until such time as the Exchange has submitted objective standards for restricting access to the SEC for its review and approval.

EDGX Options Market Makers will be required to electronically engage in a course of dealing to enhance liquidity available on EDGX Options and to assist in the maintenance of fair and orderly markets. Among other things, an Options Market Maker would have to satisfy the following responsibilities and duties during trading: (1) On a daily basis maintain a two-sided market on a continuous basis in at least 75% of the individual options series in which it is registered; (2) engage, to a reasonable degree under the existing circumstances, in dealings for their own accounts when there exists, or it is reasonably anticipated that there will exist, a lack of price continuity, a temporary disparity between the supply of (or demand for) a particular option contract, or a temporary distortion of the price relationships between option contracts of the same class; (3) compete with other Market Makers in all series in which the Market Maker is registered to trade; and (4) maintain minimum net capital in accordance with Commission and the Exchange rules. The Exchange proposes to specify numerically the meaning of ''continuous'' with respect to Market Makers' obligation to maintain continuous, two-sided quotes. For the purposes of Rule 22.6, the Exchange will consider the continuous quoting requirement fulfilled if a Market Maker provides two-sided quotes for 90% of the time the Market Maker is required to provide quotes in an appointed options series on a given trading day, or such higher percentage as the Exchange may announce in advance. Substantial or continued failure by an Options Market Maker to meet any of its obligations and duties, will subject the Options Market Maker to disciplinary action, suspension, or revocation of the Options Market Maker's registration in one or more options series.

Options Market Makers receive certain benefits for carrying out their duties. For example, a Market Maker may be designated by the Exchange as a Primary Market Maker or may have orders directed to it in its capacity as a Directed Market Maker, in each case receiving a priority advantage over other non-Customer orders to the extent applicable priority overlays have been implemented, as described below. In addition, a lender may extend credit to a broker-dealer without regard to the restrictions in Regulation T of the Board of Governors of the Federal Reserve System if the credit is to be used to finance the broker-dealer's activities as a specialist or market maker on a national securities exchange. Thus, an Options Market Maker has a corresponding obligation to hold itself out as willing to buy and sell options for its own account on a regular or continuous basis to justify this favorable treatment. The Exchange believes that the proposed 90% continuous quoting requirement for all Market Makers is consistent with that typically required of Primary Market Makers and market makers of similar status.

Every Options Member shall at all times maintain membership in another registered options exchange that is not registered solely under Section 6(g) of the Securities Exchange Act of 1934 or in FINRA. OEF's that transact business with customers must at all times be members of FINRA. Pursuant to proposed EDGX Rule 17.2(g), every Options Member will be required to have at least one registered Options Principal who satisfies the criteria of that Rule, including the satisfaction of a proper qualification examination. An OEF may only transact business with Public Customers if such Options Member also is an Options Member of another registered national securities exchange or association with which the Exchange has entered into an agreement under Rule 17d-2 under the Exchange Act pursuant to which such other exchange or association shall be the designated options examining authority for the OEF.

[3] The Exchange notes that proposed Rule 22.2 is based in part on BZX Options Rule 22.2 (paragraphs (a) and (b)) and in part on Amex Rule 923NY (paragraphs (c) through (i)).

As provided in EDGX Rule 16.2, existing Exchange Rules applicable to the EDGX equity market contained in Chapters I through XV of the Exchange Rules will apply to Options Members unless a specific Exchange Rule applicable to the options market (Chapters XVI through XXIX of the Exchange Rules) governs or unless the context otherwise requires. Options Members can therefore provide sponsored access to the EDGX Options Exchange to a nonmember (''Sponsored Participant'') pursuant to Rule 11.3 of the Exchange Rules.

Execution System

The Exchange's options trading system will leverage the Exchange's current state of the art technology, including its customer connectivity, messaging protocols, quotation and execution engine, order router, data feeds, and network infrastructure. This approach minimizes the technical effort required for existing Exchange Members to begin trading options on the EDGX Options Exchange. The EDGX Options Exchange will closely resemble the Exchange's affiliate, BZX Options, but will differ in that EDGX Options will maintain a pro rata allocation model with execution priority dependent on the capacity of an order (*e.g.,* Customer or non-Customer) as well as status as a Primary Market Maker or Directed Market Maker, as applicable. The proposed model for EDGX Options is similar to other options exchanges such as NYSE Amex Options (''Amex''), the MIAX Options Exchange (''MIAX''), and other exchanges, which are sometimes referred to as ''classic'' exchanges.

Like the Exchange system for equities, all trading interest entered into the System will be automatically executable. Orders entered into the System will be displayed either with attribution or anonymously. The Exchange will become an exchange member of the Options Clearing Corporation (''OCC''). The System will be linked to OCC for the Exchange to transmit locked-in trades for clearance and settlement.

Hours of Operation. The Exchange will begin accepting orders at 8:00 a.m. Eastern Time, as described below. The options trading system will operate between the hours of 9:30 a.m. Eastern Time and 4:00 p.m. Eastern Time, with all orders being available for execution during that timeframe.

Minimum Quotation and Trading Increments. The Exchange is proposing to apply the following quotation increments: (1) If the options series is trading at less than $3.00, five (5) cents; (2) if the options series is trading at $3.00 or higher, ten (10) cents; and (3) if the options series is trading pursuant to the Penny Pilot program one (1) cent if the options series is trading at less than $3.00, five (5) cents if the options series is trading at $3.00 or higher, except for QQQQ, SPY, or IWM where the minimum quoting increment will be one cent for all series. In addition, the Exchange is proposing that the minimum trading increment for options contracts traded on EDGX Options will be one (1) cent for all series. The Exchange also proposes to offer trading of Mini Options, and that the minimum trading increment for Mini Options shall be the same as the minimum trading increment permitted for standard options on the same underlying security.

Penny Pilot Program. Upon initial operation of EDGX Options the Exchange proposes to commence trading, pursuant to the Penny Pilot Program (the ''Penny Pilot''), all classes that are, on that date, traded by other options exchanges pursuant to the Penny Pilot, which is currently scheduled to expire on June 30, 2015, unless extended.

The Exchange represents that it has the necessary system capacity to support any additional series listed as part of the Penny Pilot.

The Exchange agrees to submit semi-annual reports to the Commission that will include sample data and written analysis of information collected from April 1 through September 30, and from October 1 through March 31, for each year, for the ten most active and twenty least active option classes added to the Penny Pilot. In addition, for comparison purposes, the reports include data from a control group consisting of the ten least active option classes from the initial group of 63 option classes in the program. This report will include, but is not limited to: (1) Data and written analysis on the number of quotations generated for options included in the report; (2) an assessment of the quotation spreads for the options included in the report; (3) an assessment of the impact of the Penny Pilot on the capacity of the Exchange's automated systems; (4) data reflecting the size and depth of markets; and (5) any capacity problems or other problems that arose related to the operation of the Penny Pilot and how the Exchange addressed them.

Additionally, the Exchange proposes that any Penny Pilot issues that have been delisted may be replaced on a semi-annual basis by the next most actively traded multiply listed options classes that are not yet included in the Penny Pilot, based on trading activity in the previous six months. The replacement issues, as applicable, would be added to the Penny Pilot Program on the second trading day following January 1 and July 1 of each year. The Exchange will employ the same parameters to prospective replacement issues as approved and applicable under the Penny Pilot Program, including excluding high-priced underlying securities. The replacement issues will be announced in Information Circulars distributed to Members.

Order Types. The proposed System will make available to Options Members the following order types: Limit Orders, Minimum Quantity Orders, Market Orders, Price Improving Orders, Book Only Orders, Post Only Orders, and Intermarket Sweep Orders, with characteristics and functionality similar to what is currently approved for use on BZX Options. Each of the proposed rules regarding the order types and order type modifiers described below is substantively identical to the applicable rule for a corresponding order type or order type modifier offered by BZX Options with the exception of the Post Only Order, to which the Exchange has proposed some substantive modification. The Exchange has also proposed minor corrections and improvements to the descriptions of the IOC and FOK time-in-force and Price Improving Orders, as compared to the corresponding BZX Options Rules. The Exchange notes that it has not proposed initially to adopt all of the order types and order type modifiers currently offered by BZX Options.[4] The Exchange has not proposed to adopt any new order types or order type modifiers that are not currently offered by BZX Options.

''Limit Orders'' are orders to buy or sell an option at a specified price or better. A limit order is marketable when, for a limit order to buy, at the time it is entered into the System, the order is priced at the current inside offer or higher, or for a limit order to sell, at the time it is entered into the System, the order is priced at the inside bid or lower.

''Minimum Quantity Orders'' are orders that require that a specified minimum quantity of contracts be obtained, or the order is cancelled. Minimum Quantity Orders will only execute against multiple, aggregated orders if such execution would occur simultaneously. The Exchange will only

[4] The Exchange has not proposed to adopt stop orders or stop limit orders, reserve orders, partial post only at limit orders or the WAIT time-in-force, each of which is offered by BZX Options.

honor a specified minimum quantity on a Book Only Order entered with a time-in-force designation of Immediate or Cancel and will disregard a minimum quantity on any other order.

''Market Orders'' are orders to buy or sell at the best price available at the time of execution. Market Orders to buy or sell an option traded on EDGX Options will be rejected if they are received when the underlying security is subject to a ''Limit State'' or ''Straddle State'' as defined in the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'').[5] Any portion of a Market Order that would execute at a price more than $0.50 or 5 percent worse than the national best bid and offer (''NBBO'') at the time the order initially reaches EDGX Options, whichever is greater, will be cancelled.

''Price Improving Orders'' are orders to buy or sell an option at a specified price at an increment smaller than the minimum price variation in the security. Price Improving Orders may be entered in increments as small as (1) one cent. Price Improving Orders shall be displayed at the minimum price variation in that security and shall be rounded up for sell orders and rounded down for buy orders. Unless a User[6] has entered instructions not to do so, Price Improving Orders will be subject to the ''display-price sliding process,'' as described below. The display-price sliding process is contained in proposed Rule 21.1(h).

''Book Only Orders'' are orders that are to be ranked and executed on the Exchange pursuant to Rule 21.8 (Order Display and Book Processing) or cancelled, as appropriate, without routing away to another options exchange. A Book Only Order will be subject to the display-price sliding process unless a User has entered instructions not to use the display-price sliding process.

''Post Only Orders'' are orders that are to be ranked and executed on the Exchange pursuant to proposed Rule 21.8 or cancelled, as appropriate, without routing away to another options exchange except that the order will not remove liquidity from the EDGX Options Book. A Post Only Order cannot be designated with instructions to use the display-price sliding process, and any such order will be rejected. A Post Only Order that is not subject to the Price Adjust process, as described below, that would lock or cross a Protected Quotation of another options exchange or the Exchange will be cancelled. The Exchange notes that Post Only Orders on BZX Options are permitted to remove liquidity under certain circumstances and can be designated for the display-price sliding process under BZX Options Rules. The Exchange has not proposed to adopt these features.

''Intermarket Sweep Orders'' or ''ISOs'' are orders that shall have the meaning provided in proposed Rule 27.1, which relates to intermarket trading. Such orders may be executed at one or multiple price levels in the System without regard to Protected Quotations at other options exchanges (*i.e.,* may trade through such quotations). The Exchange relies on the marking of an order by a User as an ISO order when handling such order, and thus, it is the entering Options Member's responsibility, not the Exchange's responsibility, to comply with the requirements relating to ISOs. ISOs are not eligible for routing pursuant to Rule 21.9.

Time in Force Designations. Options Members entering orders into the System may designate such orders to remain in force and available for display and/or potential execution for varying periods of time. Unless cancelled earlier, once these time periods expire, the order (or the unexecuted portion thereof) is returned to the entering party.

''Good Til Day'' or ''GTD'' shall mean, for orders so designated, that if after entry into the System, the order is not fully executed, the order (or the unexecuted portion thereof) shall remain available for potential display and/or execution for the amount of time during such trading day specified by the entering User unless canceled by the entering party.

''Immediate Or Cancel'' or ''IOC'' shall mean, for an order so designated, a limit order that is to be executed in whole or in part as soon as such order is received. The portion not so executed immediately on the Exchange or another options exchange is cancelled and is not posted to the EDGX Options Book. IOC limit orders that are not designated as Book Only Orders and that cannot be executed in accordance with Rule 21.8 on the System when reaching the Exchange will be eligible for routing away pursuant to Rule 21.9.

''DAY'' shall mean, for an order so designated, a limit order to buy or sell which, if not executed expires at market close.

''Fill-or-Kill'' or ''FOK'' shall mean, for an order so designated, a limit order that is to be executed in its entirety as soon as it is received and, if not so executed, cancelled. A limit order designated as FOK is not eligible for routing away pursuant to Rule 21.9.

One Second Exposure Period. Proposed Rule 22.12 would prohibit Options Members from executing as principal on EDGX Options orders they represent as agent unless (i) agency orders are first exposed on EDGX Options for at least one (1) second or (ii) the Options Member has been bidding or offering on EDGX Options for at least one (1) second prior to receiving an agency order that is executable against such bid or offer. As noted above, proposed Rule 22.12 would require Options Members to expose their customers' orders on the Exchange for at least one second under certain circumstances. During this one second exposure period, other Options Members will be able to enter orders to trade against the exposed order. In adopting a one-second order exposure period, the Exchange is proposing a requirement that is consistent with the Rules of other options exchanges, including BZX Options.[7] Thus, the exposure period will allow Options Members that are members of other options exchanges to comply with Rule 22.12 without programming separate time parameters into their systems for order entry or compliance purposes. The Exchange believes that market participants are sufficiently automated that a one second exposure period allows an adequate time for market participants to electronically respond to an order. Also, it is possible that market participants might wait until the end of the exposure period, no matter how long, before responding. Thus, the Exchange believes that any longer than one second would not further the protection of investors or market participants, but rather, would potentially increase market risk to investors and other market participants by creating a longer period of time for the exposed order to be subject to market risk.

The technology for the Exchange's trading system for EDGX Options will be comparable to the technology used for the trading system currently used for equities trading on the Exchange today. The Exchange has had ample experience with that trading system to believe that one second is an adequate exposure

[5] Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (order approving the Plan on a pilot basis).

[6] As proposed in Rule 16.1(a)(63), the term ''User'' means any Options Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3 (Access).

[7] *See, e.g.,* Chicago Board Options Exchange (''CBOE'') Rules 6.45A, 6.45B, 6.74A and 6.74B; International Securities Exchange (''ISE'') Rule 717(d); NOM Chapter VII, Sec. 12.

period. Further, the Exchange believes that many of its current Members will be Options Members and that such current Members have demonstrated an ability to respond to orders in a timely fashion.

Match Trade Prevention Modifiers. As is true for BZX Options, the Exchange will allow Options Members to use Match Trade Prevention (''MTP'') Modifiers. Any incoming order designated with an MTP modifier will be prevented from executing against a resting opposite side order also designated with an MTP modifier and originating from the same market participant identifier (''MPID''), Exchange Member identifier, trading group identifier, or Exchange Sponsored Participant identifier.

Re-Pricing Mechanisms. The Exchange, like BZX Options, proposes to offer two re-pricing mechanisms for Users of EDGX Options, the display-price sliding process and the Price Adjust process. In turn, under each type of price sliding, Users will be able to select between either single price sliding or multiple price sliding. The Exchange will offer display-price sliding (including multiple display-price sliding) and Price Adjust (including multiple Price Adjust) to ensure compliance with locked and crossed market rules relevant to participation on EDGX Options. The proposed display-price sliding functionality for EDGX Options is identical to functionality for BZX Options, with the exception of language related to Post Only Order functionality, which is not applicable. Specifically, as noted above, the Exchange omitted language regarding Post Only Orders contained in the BZX Options description of display-price sliding because the Exchange has proposed to reject orders that are designated as Post Only Orders and subject to display-price sliding. Similarly, because the Exchange has not proposed to adopt functionality that results in executions of Post Only Orders against resting liquidity under certain circumstances, the Exchange has omitted from the Exchange's proposed Price Adjust rule certain language contained in the corresponding BZX Options rule regarding such circumstances.

Market Opening Procedures. The System shall open options, other than index options, for trading after 9:30 a.m. Eastern Time as described below. With respect to index options, the System shall open such options for trading at 9:30 a.m. Eastern Time.

As proposed, the Exchange will accept market and limit orders and quotes for inclusion in the opening process (the ''Opening Process'') beginning at 8:00 a.m. Eastern Time or immediately upon trading being halted in an option series due to the primary listing market for the applicable underlying security declaring a regulatory trading halt, suspension, or pause with respect to such security (a ''Regulatory Halt'') and will continue to accept market and limit orders and quotes until such time as the Opening Process is initiated in that option series (the ''Order Entry Period''), other than index options. The Exchange will not accept IOC or FOK orders for queuing prior to the completion of the Opening Process. The Exchange will convert all ISOs entered for queuing prior to the completion of the Opening Process into non-ISOs.

After the first transaction on the primary listing market after 9:30 a.m. Eastern Time in the securities underlying the options as reported on the first print disseminated pursuant to an effective national market system plan (''First Listing Market Transaction'') or the Regulatory Halt has been lifted, the related option series will be opened automatically as described below. The System will determine a single price at which a particular option series will be opened (the ''Opening Price'') as calculated by the System within 30 seconds of the First Listing Market Transaction or the Regulatory Halt being lifted. Where there are no contracts in a particular series that would execute at any price, the System shall open such options for trading without determining an Opening Price. After establishing an Opening Price that is also a Valid Price,[8] orders and quotes in the System that are priced equal to or more aggressively than the Opening Price will be matched based on the Exchange's proposed priority rule, Rule 21.8. Matches will occur until there is no remaining volume or there is an imbalance of orders. All orders and quotes or portions thereof that are matched pursuant to the Opening Process will be executed at the Opening Price. An imbalance of orders on the buy side or sell side may result in orders that are not executed in whole or in part. Such orders will be handled in time sequence, beginning with the order with the oldest time stamp and may, in whole or in part, be placed on the EDGX Options Book, cancelled, executed, or routed in accordance with proposed Rule 21.9.

Order Display/Matching System. Other than the differences with respect to the market model described below, the System will be based upon technology and functionality currently approved for use in the Exchange's equities trading system and the Exchange's affiliate, BZX Options. Specifically, the System will allow Options Members to enter market orders and priced limit orders to buy and sell options listed on EDGX Options. The orders will be designated for display (price and size) in the order display service of the System.

Book Processing/Priority. After the opening, trades on the Exchange will occur when a buy order/quote and a sell order/quote match on the Exchange's order book. The System shall execute trading interest within the System in price priority, meaning it will execute all trading interest at the best price level within the System before executing trading interest at the next best price. Pursuant to proposed Rule 21.8(c), after considering price priority, all orders are matched according to pro-rata priority. In addition, Customer, Primary Market Maker and/or Directed Market Maker priority overlays are also available at the Exchange's discretion on a class-by-class basis pursuant to proposed Rule 21.8(d). For example, (i) the Customer Overlay provides Customers with priority over all non-Customer interest at the same price; (ii) the Directed Market Maker overlay (which may only be in effect if the Customer Overlay is also in effect) provides the Directed Market Maker with priority over other Market Makers for a certain percentage of contracts allocated at the same price (60% or 40% depending upon the number of other Market Makers at the NBBO) and for small size orders; and (iii) the Primary Market Maker overlay (which may only be in effect if the Customer Overlay is also in effect) provides Primary Market Makers with priority over other Market Makers for a certain percentage of contracts allocated at the same price (60% or 40% depending upon the number of other Market Makers at the NBBO) and for small size orders.

After executions resulting from the Priority Overlays described above, Orders and Quotes within the System for the accounts of non-Customers, including Professional Customers, have next priority. If there is more than one highest bid or more than one lowest offer in the Consolidated Book for the account of a non-Customer, then such bids or offers will be afforded priority on a ''size pro rata'' basis.

In allocating the participation entitlements set forth in proposed Rule 21.8 to the Directed Market Maker and the Primary Market Maker, the following shall apply. In a class of options where both the Primary Market

[8] Valid Price is defined in proposed Rule 21.7(a)(2).

Maker and the Directed Market Maker participation entitlements are in effect and an Options Member has directed an order to a Directed Market Maker: (a) if the Directed Market Maker's priority quote is at the NBBO, the Directed Market Maker's participation entitlement will supersede the Primary Market Maker's participation entitlements for an order directed to such Directed Market Maker; (b) if the Directed Market Maker's priority quote is not at the NBBO, the Primary Market Maker's participation entitlement will apply to that order, provided the Primary Market Maker's priority quote is at the NBBO: and (c) if neither the Directed Market Maker's nor the Primary Market Maker's priority quote is at the NBBO then executed contracts will be allocated in accordance with the pro-rata allocation methodology as described in paragraphs (c) and (e) above without regard to any participation entitlement. If an incoming order has not been directed to a Directed Market Maker by an Options Member, however, then the Primary Market Maker's participation entitlement will apply to that order, provided the Primary Market Maker's priority quote is at the NBBO.

As proposed and as noted above, the participation entitlements of proposed Rule 21.8 shall not be in effect unless the Customer Overlay is also in effect and the participation entitlements shall only apply to any remaining balance after Customer orders have been satisfied.

Neither the Primary Market Maker nor the Directed Market Maker may be allocated a total quantity greater than the quantity they are quoting at the execution price. If the Primary Market Maker's or the Directed Market Maker's allocation of an order pursuant to its participation entitlement is greater than its pro-rata share of priority quotes at the best price at the time that the participation entitlement is granted, neither the Primary Market Maker nor the Directed Market Maker shall receive any further allocation of that order.

In establishing the counterparties to a particular trade, the participation entitlements must first be counted against the Primary Market Maker's highest priority bids and offers or the Directed Market Maker's highest priority bids or offers.

The proposed participation entitlements only apply to the allocation of executions among competing Market Maker priority quotes existing on the EDGX Options Book at the time the order is received by the Exchange. No market participant is allocated any portion of an execution unless it has an existing interest at the execution price. Moreover, no market participant can execute a greater number of contracts than is associated with its interest at a given price. Accordingly, the Primary Market Maker and the Directed Market Maker participation entitlements contained in the proposed Rule are not guarantees.

The Exchange believes that proposed Rule 21.8 governing priority on the Exchange is consistent with other options exchanges that have similar market models, including Amex and MIAX.[9]

Routing. The EDGX Options Exchange will support orders that are designated to be routed to the NBBO as well as orders that will execute only within EDGX Options. Orders that are designated to execute at the NBBO will be routed to other options markets to be executed when the Exchange is not at the NBBO consistent with the Options Order Protection and Locked/Crossed Market Plan. Subject to the exceptions contained in proposed Rule 27.2(b), the System will ensure that an order will not be executed at a price that trades through another options exchange. An order that is designated by an Options Member as routable will be routed in compliance with applicable Trade-Through restrictions. Any order entered with a price that would lock or cross a Protected Quotation that is not eligible for either routing, or the display-price sliding process or the Price Adjust process will be cancelled.

EDGX Options shall route orders in options via BATS Trading, Inc. (''BATS Trading''), which serves as the Outbound Router of the Exchange, as defined in current Rule 2.11. The function of the Outbound Router will be to route orders in options listed and open for trading on EDGX Options to other options exchanges pursuant to EDGX Options rules solely on behalf of EDGX Options. The Outbound Router is subject to regulation as a facility of the Exchange, including the requirement to file proposed rule changes under Section 19 of the Act. Use of BATS Trading or Routing Services (as described below) to route orders to other market centers is optional. Parties that do not desire to use BATS Trading or other Routing Services provided by the Exchange must designate orders as not available for routing.

In the event the Exchange is not able to provide order routing services through its affiliated broker-dealer, the Exchange will route orders to other options exchanges in conjunction with one or more routing brokers that are not affiliated with the Exchange (''Routing Services'').

EDGX Options will offer a variety of routing options that will be identical to the routing options offered by BZX Options. Routing options may be combined with all available order types and times-in-force, with the exception of order types and times-in-force whose terms are inconsistent with the terms of a particular routing option. The System will consider the quotations only of accessible markets. The term ''System routing table'' refers to the proprietary process for determining the specific options exchanges to which the System routes orders and the order in which it routes them. The Exchange reserves the right to maintain a different System routing table for different routing options and to modify the System routing table at any time without notice. The proposed System routing options are Parallel D, Parallel 2D, Destination Specific and Directed ISO. The Exchange notes that Destination Specific and Directed ISO are both offered by BZX Options but that such options are currently listed in both the routing section and the order description section. The Exchange believes that these options are more appropriately listed as routing strategies, and thus has proposed to include them in Rule 21.9.

The Exchange also proposes to offer two optional Re-Route instructions, Aggressive Re-Route and Super Aggressive Re-Route, either of which can be assigned to routable orders. Pursuant to the Aggressive Re-Route instruction, to the extent the unfilled balance of a routable order has been posted to the EDGX Options Book, should the order subsequently be crossed by another accessible options exchange, the System shall route the order to the crossing options exchange. Pursuant to the Super Aggressive Re-Route instruction, to the extent the unfilled balance of a routable order has been posted to the EDGX Options Book, should the order subsequently be locked or crossed by another accessible options exchange, the System shall route the order to the locking or crossing options Exchange.

Data Feed; Anonymity. The System will include a proprietary data feed, Multicast PITCH, which will display depth of book quotations and execution information based on orders received by EDGX Options using the minimum price variation applicable to that security. The Exchange will make available to all market participants through the Options Price Reporting Authority (''OPRA'') an indication that there is Customer interest included in the best bid and

[9] *See, e.g.,* Amex Rule 964NY; MIAX Rule 514.

offer disseminated by the Exchange. The Exchange will also identify Customer orders and trades as such on messages disseminated by the Exchange through its Multicast PITCH data feed. To the extent a User has submitted an Attributable Order, which is the default property for all orders entered into the System, the Multicast PITCH data feed will indicate the User's MPID along with the price and size of their order or quote.

The intra-day transaction reports produced by the System will indicate the details of the transactions, and will not reveal contra party identities. However, the Exchange does anticipate generating daily, weekly and/or monthly reports containing aggregate information regarding Market Maker and Customer executions, and thus, has proposed to make clear in Rule 21.10 that such identifying information will be made available. The Exchange believes that this practice is common on other options exchanges that operate market models similar to that proposed by the Exchange.

Risk Monitor Mechanism. The Exchange also proposes to offer to all Users of EDGX Options the ability to establish certain risk control parameters via the Exchange's Risk Monitor Mechanism. The proposed Risk Monitor Mechanism is identical to that offered by BZX Options pursuant to Rule 21.16. The Risk Monitor Mechanism provides protection from the risk of multiple executions across multiple series of an option or across multiple options. The risk to Users is not limited to a single series in an option or even to all series of an option; Users that quote in multiple series of multiple options have significant exposure, requiring them to offset or hedge their overall positions.

In particular, the Risk Monitor Mechanism will be useful for EDGX Options Market Makers, who are required to continuously quote in assigned options. Quoting across many series in an option creates the possibility of ''rapid fire'' executions that can create large, unintended principal positions that expose the Market Maker to unnecessary market risk. The Risk Monitor Mechanism is intended to assist such Users in managing their market risk.

Though the Risk Monitor Mechanism will be most useful to Market Makers, the Exchange proposes to offer the functionality to all participant types. There may be other firms that trade on a proprietary basis and provide liquidity to the Exchange; these firms could potentially benefit, similarly to Market Makers, from the Risk Monitor Mechanism. The Exchange believes that the Risk Monitor Mechanism should help liquidity providers generally, market makers and other participants alike, in managing risk and providing deep and liquid markets to investors.

Options Order Protection and Locked/Crossed Market Plan Rules

The Exchange will participate in the approved Options Order Protection and Locked/Crossed Market Plan (''Plan''), and therefore will be required to comply with the obligations of Participants under the Plan. The Exchange proposes to adopt rules relating to the Plan that are substantially similar to the rules in place on all of the options exchanges that are Participants to the Plan.

The Plan replaced the Plan for the Purpose of Creating and Operating an Intermarket Option Linkage (''Old Plan''). The Old Plan required its participant exchanges to operate a stand-alone system or ''Linkage'' for sending order-flow between exchanges to limit trade-throughs, and the Linkage was operated by the Options Clearing Corporation (''OCC''). The Plan essentially applies the Regulation NMS price-protection provisions to the options markets. Similar to Regulation NMS, the Plan requires the Plan Participants to adopt rules ''reasonably designed to prevent Trade-Throughs,'' while exempting Intermarket Sweep Orders (''ISOs'') from that prohibition. The Plan's definition of an ISO is essentially the same as under Regulation NMS. The remaining exceptions to the trade-through prohibition, discussed more specifically below, either track those under Regulation NMS or correspond to unique aspects of the options market, or both.

The Rules in proposed Chapter XXVII conform to the requirements of the Plan. Rule 27.1 sets forth the defined terms for use under the Plan. Rule 27.2 prohibits trade-throughs and exempts ISOs from that prohibition. Rule 27.2 also contains additional exceptions to the trade-through prohibition that track the exceptions under Regulation NMS or correspond to unique aspects of the EDGX Options Exchange, or both.

Proposed Rule 27.3 sets forth the general prohibition against locking/crossing other eligible exchanges as well as several exceptions that permit locked markets in limited circumstances; such exceptions have been approved by the Commission for inclusion in the rules of other options exchanges. Specifically, the exceptions to the general prohibition on locking and crossing occur when (1) the locking or crossing quotation was displayed at a time when the Exchange was experiencing a failure, material delay, or malfunction of its systems or equipment; (2) the locking or crossing quotation was displayed at a time when there is a Crossed Market; or (3) the Member simultaneously routed an ISO to execute against the full displayed size of any locked or crossed Protected Bid or Protected Offer.

Securities Traded on EDGX Options

General Listing Standards. The Exchange proposes to adopt listing standards for Options traded on EDGX Options (Chapter XIX) as well as for Index Options (Chapter XXIX) that are identical to the approved rules of BZX Options.[10] The Exchange will join the Options Listings Procedures Plan and will list and trade options already listed on other options exchanges. The Exchange will gradually phase-in its trading of options, beginning with a selection of actively traded options. At least initially, the Exchange does not plan to develop new options products or listing standards.

$1 Strike Program. Pursuant to proposed Rule 19.6, Supplementary Material .02, the interval between strike prices of series of options on individual stocks may be $1.00 or greater (''$1 Strike Prices'') provided the strike price is $50 or less, but not less than $1. The listing of $1 strike prices shall be limited to option classes overlying no more than one hundred fifty (150) individual stocks (the ''$1 Strike Price Program'') as specifically designated by EDGX Options. As proposed, EDGX Options may list $1 Strike Prices on any other option classes if those classes are specifically designated by other national securities exchanges that employ a similar $1 Strike Price Program under their respective rules.

To be eligible for inclusion into the $1 Strike Price Program, an underlying security must close below $50 in the primary market on the previous trading day. After a security is added to the $1 Strike Price Program, EDGX Options may list $1 Strike Prices from $1 to $50 that are no more than $5 from the closing price of the underlying on the preceding day. For example, if the underlying security closes at $13, EDGX Options may list strike prices from $8 to $18. EDGX Options may not list series with $1 intervals within $0.50 of an existing strike price in the same series, except that strike prices of $2, $3, $4, $5 and $6 shall be permitted within $0.50 of an existing strike price for classes also selected to participate in the $0.50 Strike Program. Additionally, for an option class selected for the $1 Strike Price Program, EDGX Options may not

[10] *See* Rules of BZX Options, Chapters XIX and XXIX.

list $1 Strike Prices on any series having greater than nine (9) months until expiration. A security shall remain in the $1 Strike Price Program until otherwise designated by EDGX Options.

For options classes selected to participate in the $1 Strike Program, the Exchange will, on a monthly basis, review series that were originally listed under the $1 Strike Program with strike prices that are more than $5 from the current value of an options class and delist those series with no open interest in both the put and the call series having a: (1) strike higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (2) strike lower than the lowest strike price with open interest in the put and/or call series for a given expiration month. If the Exchange identifies series for delisting pursuant to this policy, the Exchange shall notify other options exchanges with similar delisting policies regarding the eligible series for delisting, and shall work jointly with such other exchanges to develop a uniform list of series to be delisted so as to ensure uniform series delisting of multiply listed options classes.

Notwithstanding the above delisting policy, the Exchange may grant member requests to add strikes and/or maintain strikes in series of options classes traded pursuant to the $1 Strike Program that are eligible for delisting.

In addition to $1 strikes as proposed above, the Exchange proposes to offer options trading on series of options with $0.50, $2.50 and $5.00 strike price intervals, consistent with other options exchanges, including BZX Options.

With regard to the impact on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority have the necessary systems capacity to handle the additional traffic associated with the listing and trading of option series that may be listed and traded in the strike price intervals described above, including $0.50, $1, $2.50 and $5.00 strikes.

Mini Options. After an option class on a stock, Exchange-Traded Fund Share, Trust Issued Receipt, Exchange Traded Note, and other Index Linked Security with a 100 share deliverable has been approved for listing and trading on the Exchange, the Exchange proposes to permit listing of series of option contracts with a 10 share deliverable on that stock, Exchange-Traded Fund Share, Trust Issued Receipt, Exchange Traded Note, and other Index Linked Security for all expirations opened for trading on the Exchange. Pursuant to proposed Interpretation and Policy .07 to Rule 19.6, Mini Option contracts could be listed on SPDR S&P 500 (''SPY''), Apple Inc. (''AAPL''), SPDR Gold Trust (''GLD''), Google Inc. (''GOOG''), and Amazon.com Inc. (''AMZN''). Strike prices for Mini Options shall be set at the same level as for regular options. For example, a call series strike price to deliver 10 shares of stock at $125 per share has a total deliverable value of $1250 and the strike price will be set at 125. No additional series of Mini Options may be added if the underlying security is trading at $90 or less. The underlying security must trade above $90 for five consecutive days prior to listing Mini Options contracts in an additional expiration month.

Quarterly Options Series Program. Pursuant to proposed Rule 19.6, Interpretation and Policy .04 and proposed Rule 29.11(g) the Exchange may list and trade options series that expire at the close of business on the last business day of a calendar quarter (''Quarterly Options Series''). As proposed, the Exchange may list Quarterly Options Series for up to five (5) currently listed options classes that are either options on exchange traded funds (''ETF'') or index options. In addition, the Exchange may also list Quarterly Options Series on any options classes that are selected by other securities exchanges that employ a similar program under their respective rules.

The Exchange may list series that expire at the end of the next consecutive four (4) calendar quarters, as well as the fourth quarter of the next calendar year. For example, if the Exchange is trading Quarterly Options Series in the month of May 2016, it may list series that expire at the end of the second, third, and fourth quarters of 2016, as well as the first and fourth quarters of 2017. Following the second quarter 2016 expiration, the Exchange could add series that expire at the end of the second quarter of 2017.

For each class of ETF options selected for the Quarterly Options Series program, the Exchange may list strike prices within $5 from the previous day's closing price of the underlying security at the time of initial listing. Subsequently, the Exchange may list up to 60 additional strike prices that are within thirty percent (30%) of the previous day's close, or more than 30% away from the previous day's close provided demonstrated customer interest exists for such series.

The Exchange has also proposed a delisting policy with respect to Quarterly Options Series in ETF options. On a monthly basis, the Exchange will review series that are outside of a range of five (5) strikes above and five (5) strikes below the current price of the ETF, and delist series with no open interest in both the call and the put series having a (1) strike higher than the highest price with open interest in the put and/or call series for a given expiration month; and (2) strike lower than the lowest strike price with open interest in the put and/or the call series for a given expiration month. Notwithstanding the delisting policy, customer requests to add strikes and/or maintain strikes in Quarterly Options Series eligible for delisting shall be granted.

The Exchange also may list Quarterly Option Series based on an underlying index pursuant to similar provisions in Rule 29.11. There are two noteworthy distinctions between the rules for listing Quarterly Options Series based on an ETF versus Quarterly Options Series based on an index. First, whereas the initial listing of Quarterly Options Series based on an underlying ETF is restricted to strike prices within $5 from the previous day's closing price of the underlying security, the initial listing of strikes for Quarterly Options Series based on an underlying index is restricted to: (i) a price that is within thirty percent (30%) of the current index value, and (ii) no more than five strikes above and five strikes below the value of the underlying index. Second, whereas the Exchange may list up to 60 additional strike prices for each Quarterly Options Series based on an ETF, there is no firm cap on the additional listing of strikes for Quarterly Options Series based on an underlying index; rather, additional strike prices may be listed provided the new listings do not result in more than five strike prices on the same side of the underlying index value as the new listings.

The interval between strike prices on Quarterly Options Series shall be the same as the interval for strike prices for series in that same options class that expire in accordance with the normal monthly expiration cycle.

With regard to the impact on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority have the necessary systems capacity to handle the additional traffic associated with the listing and trading of options series pursuant to the above-described Quarterly Options Series program.

Short Term Option Series Program. The Exchange plans to operate a Short-Term Options Series Program similar to other Short Term Options Programs, including that of BZX Options. Pursuant

to proposed Rule 19.6, Interpretation and Policy .05 for equity options and Rule 29.11(h) for index options in, the Exchange intends to open for trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') series of options on that class that expire on each of the next five (5) Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire (''Short Term Option Expiration Dates''). As proposed, the Exchange may have no more than a total of five Short Term Option Expiration Dates. If EDGX Options is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if EDGX Options is not open for business on the Friday that the options are set to expire, the Short Term Option Expiration Date will be the first business day immediately prior to that Friday.

As proposed, the Exchange may select up to fifty (50) option classes in which Short Term Option Series may be traded. In addition to those fifty option classes the Exchange may also list Short Term Option Series on any option classes that are selected by other securities exchanges that employ a similar program. For each option class eligible for participation in the Short Term Option Series Program, the Exchange may open up to thirty (30) Short Term Option Series for each expiration date in that class. The Exchange may also open Short Term Option Series that are opened by other securities exchanges in option classes selected by such exchanges under their respective short term option rules.

As noted above, the remaining parameters of the proposed Short Term Options Program are identical to those of BZX Options and similar to those operated by other options exchanges.

With regard to the impact on system capacity, the Exchange has analyzed its capacity and represents that it and the Options Price Reporting Authority have the necessary systems capacity to handle the additional traffic associated with the listing and trading of option series pursuant to the Short Term Option Series Program.

Conduct and Operational Rules for Options Members

EDGX proposes to adopt rules that are nearly identical to the approved rules of other options exchanges, including BZX Options. Thus, EDGX proposes to adopt rules that are based on the rules of BZX Options regarding: Business Conduct Rules (Chapter XVIII); exercises and deliveries (Chapter XXIII); records, reports and audits (Chapter XXIV); minor rule violations (Chapter XXV); doing business with the public (Chapter XXVI); and margin (Chapter XXVIII).

The Exchange notes that certain requirements that will be applicable to Options Members are contained in other sections of the Exchange's existing Rules. For example, the Exchange has included applicable rules requiring options principal registration into proposed EDGX Rule 17.2(g) but also proposes to include reference to applicable registration requirements that are already contained in EDGX Rule 2.5. The Exchange also proposes to expand EDGX Rule 2.5 to clearly include options principal registration. The Exchange intends to require Authorized Traders of Options Members to comply with existing Exchange registration requirements applicable to all Authorized Traders.[11] Accordingly, the Exchange has not proposed specific rules applicable to registration of representatives other than options principals.

As is true for BZX Options, with respect to Position Limits (Rule 18.7) and Exercise Limits (Rule 18.9), the Exchange is proposing to apply the limits established pursuant to the rules of the CBOE, although the Exchange will establish such limits for products not traded on the CBOE. By expressly incorporating an already-approved limit, the Exchange will ensure that an appropriate limit is in place at all times without the need to continually adjust its rule manually or to disrupt the operations of its Members.

National Market System

The EDGX Options Exchange will operate as a full and equal participant in the national market system for options trading established under Section 11A of the Exchange Act, just as its equities market participates today. The EDGX Options Exchange will become a member of OPRA, the Options Linkage Authority (''OLA''), the Options Regulatory Surveillance Authority (''ORSA''), and the Options Listing Procedures Plan (''OLPP'').

The Exchange expects to participate in those plans on the same terms currently applicable to current members of those plans, and it expects little or no plan impact due to the fact that the Exchange's market will operate in a manner similar to several other existing options exchanges.

[11] *See* Exchange Rule 2.5, Interpretation and Policy .01 and Exchange Rule 11.4.

Regulation

The Exchange will leverage many of the structures it established to operate a national securities exchange in compliance with Section 6 of the Exchange Act. As described in more detail below, there will be three elements of that regulation: (1) the Exchange will join the existing options industry agreements pursuant to Section 17(d) of the Exchange Act, as it has with respect to its equities market, (2) the Exchange's Regulatory Services Agreement (''RSA'') with FINRA will govern many aspects of the regulation and discipline of Members that participate in options trading, just as it does for equities market regulation, and (3) the Exchange will perform options listing regulation, as well as authorize Options Members to trade on EDGX Options, and conduct surveillance of options trading as it does today for equities.

Section 17(d) of the Exchange Act and the related Exchange Act rules permit SROs to allocate certain regulatory responsibilities to avoid duplicative oversight and regulation. Under Exchange Act Rule 17d–1, the SEC designates one SRO to be the Designated Examining Authority, or DEA, for each broker-dealer that is a member of more than one SRO. The DEA is responsible for the financial aspects of that broker-dealer's regulatory oversight. Because EDGX Options Members also must be members of at least one other SRO, the Exchange would generally not be designated as the DEA for any of its members.

Rule 17d–2 under the Act permits SROs to file with the Commission plans under which the SROs allocate among each other the responsibility to receive regulatory reports from, and examine and enforce compliance with specified provisions of the Act and rules thereunder and SRO rules by, firms that are members of more than one SRO (''common members''). If such a plan is declared effective by the Commission, an SRO that is a party to the plan is relieved of regulatory responsibility as to any common member for whom responsibility is allocated under the plan to another SRO.

All of the options exchanges and FINRA have entered into the Options Sales Practices Agreement, a Rule 17d–2 agreement. Under this Agreement, the examining SROs will examine firms that are common members of the Exchange and the particular examining SRO for compliance with certain provisions of the Act, certain of the rules and regulations adopted thereunder, certain examining SRO rules, and certain EDGX

Options Rules. In addition, EDGX Options Rules contemplate participation in this Agreement by requiring that any Options Member also be a member of at least one of the examining SROs.

For those regulatory responsibilities that fall outside the scope of any Rule 17d–2 agreements, the Exchange will retain full regulatory responsibility under the Exchange Act. However, as noted above, the Exchange has entered into an RSA with FINRA, pursuant to which FINRA personnel operate as agents for the Exchange in performing certain of these functions. As is the case with the EDGX equities market, the Exchange will supervise FINRA and continue to bear ultimate regulatory responsibility for the EDGX Options Exchange. The Exchange intends to amend the existing RSA in order to capture certain aspects of regulation specifically applicable to EDGX Options and the regulation and discipline of Options Members.

As a member of the Intermarket Surveillance Group, the Exchange will comply with the specifications of the Consolidated Options Audit Trail System (''COATS'') in submitting data for purposes of creating a consolidated audit trail. The Exchange will also receive COATS data for purposes of its surveillance operations.

Consistent with the Exchange's existing regulatory structure, the Exchange's Chief Regulatory Officer shall have general supervision of the regulatory operations of EDGX Options, including responsibility for overseeing the surveillance, examination, and enforcement functions and for administering all regulatory services agreements applicable to EDGX Options. Similarly, the Exchange's existing Regulatory Oversight Committee will be responsible for overseeing the adequacy and effectiveness of Exchange's regulatory and self-regulatory organization responsibilities, including those applicable to EDGX Options.

Finally, as is true with respect to equities, the Exchange, and FINRA pursuant to the RSA referenced above, will perform automated surveillance of trading on EDGX Options for the purpose of maintaining a fair and orderly market at all times. Specifically, EDGX Options will be monitored to identify unusual trading patterns and determine whether particular trading activity requires further regulatory investigation by FINRA.

In addition, the Exchange will oversee the process for determining and implementing trade halts, identifying and responding to unusual market conditions, and administering the Exchange's process for identifying and remediating ''obvious errors'' by and among its Options Members. EDGX proposed rules (Chapter XX) regarding halts, unusual market conditions, extraordinary market volatility, obvious errors, and audit trail are identical to the approved rules of BZX Options.[12]

The Exchange notes that the obvious error rule of BZX Options was recently approved [13] and that other options exchanges are in the process of implementing similar rules. The Exchange has not proposed any changes as compared to the recently approved obvious error rule of BZX Options. Thus, in addition to the general provisions for reviewing and handling transactions that potentially qualify for adjustment or nullification as Obvious Errors or Catastrophic Errors, the Exchange proposes to adopt Interpretation and Policy .01 to provide for how the Exchange will treat Obvious and Catastrophic Errors in response to the Limit Up-Limit Down Plan, which is applicable to all NMS stocks, as defined in Regulation NMS Rule 600(b)(47).[14] As proposed, during a pilot period to coincide with the pilot period for the Plan, including any extensions to the pilot period for the Plan, an execution will not be subject to review as an Obvious Error or Catastrophic Error pursuant to paragraph (c) or (d) of the Proposed Rule if it occurred while the underlying security was in a ''Limit State'' or ''Straddle State,'' as defined in the Plan. During a Limit or Straddle State, options prices may deviate substantially from those available immediately prior to or following such States. Thus, determining a Theoretical Price in such situations would often be very subjective, creating unnecessary uncertainty and confusion for investors. Because of this uncertainty, the Exchange is proposing to provide in Rule 20.6 that the Exchange will not review transactions as Obvious Errors or Catastrophic Errors when the underlying security is in a Limit or Straddle State.

The Exchange represents that it will conduct its own analysis concerning the elimination of the Obvious Error and Catastrophic Error provisions during Limit and Straddle States and agrees to provide the Commission with relevant data to assess the impact of this proposed rule change. As part of its analysis, the Exchange will evaluate (1) the options market quality during Limit and Straddle States, (2) assess the character of incoming order flow and transactions during Limit and Straddle States, and (3) review any complaints from Members and their customers concerning executions during Limit and Straddle States. The Exchange also agrees to provide to the Commission data requested to evaluate the impact of the inapplicability of the Obvious Error and Catastrophic Error provisions, including data relevant to assessing the various analyses noted above.

In connection with this proposal, the Exchange will provide to the Commission and the public a dataset containing the data for each Straddle State and Limit State in NMS Stocks underlying options traded on the Exchange beginning in the month during which the proposal is approved, limited to those option classes that have at least one (1) trade on the Exchange during a Straddle State or Limit State. For each of those option classes affected, each data record will contain the following information:

- Stock symbol, option symbol, time at the start of the Straddle or Limit State, an indicator for whether it is a Straddle or Limit State.
  - For activity on the Exchange:
  - Executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer;
  - high execution price, low execution price;
  - number of trades for which a request for review for error was received during Straddle and Limit States;
  - an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's Limit or Straddle State compared to the last available option price as reported by OPRA before the start of the Limit or Straddle State (1 if observe 30% and 0 otherwise). Another indicator variable for whether the option price within five minutes of the underlying stock leaving the Limit or Straddle state (or halt if applicable) is 30% away from the price before the start of the Limit or Straddle State.

In addition, the Exchange shall provide to the Commission and the public assessments relating to the impact of the operation of the Obvious Error rules during Limit and Straddle States as follows: (1) Evaluate the statistical and economic impact of Limit and Straddle States on liquidity and market quality in the options markets; and (2) Assess whether the lack of Obvious Error rules in effect during the Straddle and Limit States are problematic. The timing of this submission would coordinate with Participants' proposed time frame to submit to the Commission assessments as required under Appendix B of the Plan. The Exchange notes that the pilot

[12] *See* BZX Options Rules Chapter XX; *see also* Rules of NOM, Chapter V, and BOX, Chapter V.

[13] *See* Securities Exchange Act Release No. 74556 (March 20, 2015), 80 FR 16031 (March 26, 2015) (SR–BATS–2014–067).

[14] 17 CFR 242.600(b)(47).

program is intended to run concurrent with the pilot period of the Plan, which currently expires to October 23, 2015. The Exchange proposes to reflect this date in the Proposed Rule.

Minor Rule Violation Plan

The Exchange's disciplinary rules, including Exchange Rules applicable to ''minor rule violations,'' are set forth in Chapter VIII of the Exchange's current Rules. Such disciplinary rules will apply to Options Members and their associated persons.

The Commission approved the EDGX Exchange's Minor Rule Violation Plan (''MRVP'') in 2010.[15] The Exchange's MRVP specifies those uncontested minor rule violations with sanctions not exceeding $2,500 that would not be subject to the provisions of Rule 19d–1(c)(1) under the Act [16] requiring that an SRO promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[17] The Exchange's MRVP includes the policies and procedures included in Exchange Rule 8.15 (Imposition of Fines for Minor Violation(s) of Rules) and in Rule 8.15, Interpretation and Policy .01.

The Exchange proposes to amend its MRVP and Rule 8.15, Interpretation and Policy .01 to include proposed Rule 25.3 (Penalty for Minor Rule Violations).[18] The rules included in proposed Rule 25.3 as appropriate for disposition under the Exchange's MRVP are: violations of applicable Position Limit and Exercise Limit rules; order entry violations regarding restrictions on orders entered by Market Makers; violations of Market Maker continuous bid and offer rules; violations of rules applicable to expiring exercise declarations; and violations of Exchange requirements to provide trade data. The rules included in Rule 25.3 are the same as the rules included in the MRVPs of BZX Options and other options exchanges.[19]

Upon implementation of this proposal, the Exchange will include the enumerated options trading rule violations in the Exchange's standard quarterly report of actions taken on minor rule violations under the MRVP. The quarterly report includes: the Exchange's internal file number for the case, the name of the individual and/or organization, the nature of the violation, the specific rule provision violated, the sanction imposed, the number of times the rule violation has occurred, and the date of disposition.

Although the Exchange has not proposed fees for EDGX Options in connection with this proposal, the Exchange does anticipate filing a separate proposal prior to the launch of EDGX Options to establish applicable fees. The Exchange notes that pursuant to both the Act and existing Exchange Rule 15.1, the Exchange has the authority to prescribe dues, fees, assessments and other charges (collectively, ''Fees'') so long as such Fees are equitably allocated, reasonable and not unreasonably discriminatory.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of the Act,[20] in general and with Section 6(b)(5) of the Act,[21] in particular, in that it is designed 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 mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the fundamental premise of the proposal is that the Exchange will operate its options market in a similar manner to its affiliated options exchange, BZX Options, with the exception of the priority model and certain other limited differences. The Exchange believes that EDGX Options will benefit individual investors, options trading firms, and the options market generally. The entry of an innovative, low-cost competitor such as EDGX Options will promote competition, spurring existing markets to improve their own execution systems and reduce trading costs.

The basis for the majority of the rules of EDGX Options are [sic] the approved rules of BZX Options, which have already been found to be consistent with the Act. For instance, the Exchange does not believe that any of the proposed order types or order type functionality raise any new or novel issues that have not previously been considered. Thus, the Exchange further believes that the functionality that it proposes to offer is consistent with Section 6(b)(5) of the Act,[22] because the System is designed to be efficient and its operation transparent, thereby facilitating transactions in securities, removing impediments to and perfecting the mechanism of a free and open market and a national market system. As noted above, the Exchange will participate in the approved Options Order Protection and Locked/Crossed Market Plan, and therefore will be required to comply with the obligations of Participants under the Plan.

Similarly, the Exchange proposes to adopt initial and continued listing standards for equity and index options that are substantially similar to the listing standards adopted by BZX Options and other options exchanges. The Exchange has also proposed to adopt rules that are substantially similar to those of BZX Options with respect to the Penny Pilot Program and various other strike price programs, including the program regarding the listing of $0.50, $1, $2.50 and $5.00 strikes, the Quarterly Options Series Program and the Short Term Options Series program. The Exchange believes that general consistency amongst options exchanges with respect to the series of options available for listings and trading is consistent with Section 6(b)(5) of the Act,[23] in particular, in that it is designed 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 mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest by avoiding unnecessary confusion.

The Exchange believes that the rules of EDGX Options as well as the proposed method of monitoring for

[15] *See* Release No. 34–62036 (May 5, 2010), 75 FR 26822 (May 12, 2010) (File No. 4–594) (''MRVP Order'').

[16] 17 CFR 240.19d–1(c)(1).

[17] The Commission adopted amendments to paragraph (c) of Rule 19d-1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Release No. 34–21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to such a plan filed with and declared effective by the Commission will not be considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[18] In the MRVP Order, the Commission noted that the Exchange proposed that any amendments to Rule 8.15.01 made pursuant to a rule filing submitted under Rule 19b–4 of the Act would automatically be deemed a request by the Exchange for Commission approval of a modification to its MRVP. *See* MRVP Order, *supra* note 15, at note 5.

[19] *See* BZX Options Rule 25.3; *see also,* NOM, Chapter X, Section 7, and BOX, Chapter X, Section 2.

[20] 15 U.S.C. 78a *et seq.*

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78f(b)(5).

compliance with and enforcing such rules is also consistent with the Act, particularly Sections 6(b)(1), 6(b)(5) and 6(b)(6) of the Act, which require, in part, that an exchange have the capacity to enforce compliance with, and provide appropriate discipline for, violations of the rules of the Commission and of the exchange.[24] The Exchange has proposed to adopt rules necessary to regulation Options Members that are nearly identical to the approved Rules of BZX Options as well as numerous other options exchanges. The Exchange proposes to regulate activity on EDGX Options in the same way it regulates activity on its equities market, specifically through various Exchange specific functions, an RSA with FINRA, as well as participation in industry plans, including plans pursuant to Rule 17d–2 under the Exchange Act.

More specifically, the Exchange's MRVP, as proposed to be amended, is also consistent with Sections 6(b)(1), 6(b)(5) and 6(b)(6) of the Act, which require, in part, that an exchange have the capacity to enforce compliance with, and provide appropriate discipline for, violations of the rules of the Commission and of the exchange.[25] In addition, because amended Rule 8.15 will offer procedural rights to a person sanctioned for a violation listed in proposed Rule 25.3, the Exchange will provide a fair procedure for the disciplining of members and associated persons, consistent with Section 6(b)(7) of the Act.[26] The proposal to include the rules listed in proposed Rule 25.3 in the Exchange's MRVP is also consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[27] because it should strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as an SRO in cases where full disciplinary proceedings are unsuitable in view of the minor nature of the particular violation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in an intensely competitive global marketplace for transaction services. Relying on its array of services and benefits, the Exchange competes for the privilege of providing market services to broker-dealers. The Exchange's ability to compete in this environment is based in large part on the quality of its trading systems, the overall quality of its market and its attractiveness to the largest number of investors, as measured by speed, likelihood and cost of executions, as well as spreads, fairness, and transparency.

The Exchange notes that most U.S. options exchanges are owned and operated by companies that operate more than one options exchange.[28] The primary reason to operate multiple options exchanges, as is true with respect to the proposed launch of EDGX Options, is that it allows an exchange operator to offer multiple market models, including a price-time market and a pro rata market, often with Customer priority as a critical component of the latter. Accordingly, the proposed rule change is intended to enhance competition by allowing the Exchange to compete with existing options exchanges that operate models based on Customer priority and pro rata allocations.

The proposed rule change will reduce overall trading costs and increase price competition, both pro-competitive developments, and will promote further initiative and innovation among market centers and market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

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 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–EDGX–2015–18 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–EDGX–2015–18.* 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2015–18 and should be submitted on or before June 9, 2015.

[24] 15 U.S.C. 78f(b)(1), 78f(b)(5) and 78f(b)(6).

[25] 15 U.S.C. 78f(b)(1), 78f(b)(5) and 78f(b)(6).

[26] 15 U.S.C. 78f(b)(7).

[27] 17 CFR 240.19d–1(c)(2).

[28] The IntercontinentalExchange Group, Inc. (''ICE'') operates two options exchanges, Amex and Arca; NASDAQ OMX Group, Inc. operates three options exchanges, NOM, Phlx and NASDAQ OMX BX; International Securities Exchange Holding, Inc. operates two options exchanges, ISE and ISE Gemini; and CBOE Holdings operates two options exchanges, CBOE and C2 Options Exchange.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12022 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74946; File No. SR–NASDAQ–2015–052]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify NASDAQ Rule 7018 Governing Fees and Credits Assessed For Execution and Routing

May 13, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 7, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''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.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to modify NASDAQ Rule 7018(a)(1), (2), and (3), governing fees and credits assessed for execution and routing securities listed on NASDAQ (subsection 1), the New York Stock Exchange (''NYSE'') (subsection 2) and on exchanges other than NASDAQ and NYSE (subsection 3). NASDAQ will implement the proposed fees on May 1, 2015.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.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 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

NASDAQ is proposing to amend NASDAQ Rule 7018(1), (2) and (3) to modify fees assessed for execution and routing securities listed on NASDAQ (''Tape C''), NYSE (''Tape A'') and on exchanges other than NASDAQ and the NYSE (''Tape B''), respectively, (together, the ''Tapes''). The Exchange is proposing two categories of changes to credits paid regarding midpoint liquidity: (1) Changes to the calculation of Equity and Options-linked volume when the Exchange pays rebates to members that provide liquidity via midpoint orders that are executed; and (2) adding a tier of credits for midpoint liquidity provided via non-displayed orders that are executed. These changes are described in greater detail below.

Equity and Options-Linked Volume. With respect to credits paid for members adding liquidity via midpoint orders, the Exchange currently pays a credit of $0.0030 per share executed for members (i) with shares of liquidity provided in all securities during the month representing at least 0.40% of Consolidated Volume during the month, through one or more of its Nasdaq Market Center MPIDs, and (ii) that qualifies for the Nasdaq Options Market Customer and Professional Rebate to add Liquidity in Penny Pilot Options Tier 8 under Chapter XV, Section 2 of the Nasdaq Options Market rules during the month through one or more of its Nasdaq Options Market MPIDs. The Tier 8 program requires that a ''Participant adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 0.75% or more of total industry customer equity and ETF option ADV contracts per day in a month.'' The Tier 8 credit is designed to reward members that add liquidity broadly across NASDAQ's equity and options trading platform whether for trading NASDAQ, NYSE or Amex or other exchange-listed securities.

NASDAQ is proposing to retain the credit rate of $0.0030 for this activity tier and to modify the volume calculations for both equity and options volume for securities on all three Tapes. First, the Exchange is increasing the required percentage of Consolidated Volume of equities executed from 0.40 percent to 0.60 percent per member for one or more of that member's MPIDs. Second, NASDAQ is retaining the existing link between equities and options trading, but it is modifying the measure of options volume. Specifically, the Exchange is modifying the rule to incorporate language from the Liquidity in Penny Pilot Options Tier 8 under Chapter XV, Section 2 of the Nasdaq Options Market. Additionally, the Exchange plans to credit members that add liquidity of 1.25 percent or more of average daily volume (''ADV'') for the industry in the customer clearing range[3] in Equity and ETF Options[4] based upon volume added by that member in the Customer,[5] Professional,[6] Firm,[7] Non-NOM Market Maker[8] and Broker-Dealer[9] classifications as those classifications are defined in NOM rules.

Non-Displayed Volume. Currently, NASDAQ Rule 7018 provides for credits for the execution of non-displayed liquidity (other than via Supplemental

[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''customer clearing range'' refers to a clearing designation determined by the Options Clearing Corporation that applies throughout the options industry.

[4] This proposed rule change applies to the same categories of options (Penny Pilot, Non-Penny Pilot, Equity and ETF options) and the same participant liquidity (Customer, Professional, Firm, Non-NOM Market Maker and Broker-Dealer) that are identified in Chapter XV, Section 2 of the Nasdaq Options Market Rules, Tier 8.

[5] As defined in Chapter XV of the Nasdaq Options Market Rules, the term ''Customer'' or (''C'') applies to any transaction that is identified by a Participant for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of broker or dealer or for the account of a ''Professional'' (as that term is defined in Chapter I, Section 1(a)(48)).

[6] As defined in Chapter XV of the Nasdaq Options Market Rules, the term ''Professional'' or (''P'') means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s) pursuant to Chapter I, Section 1(a)(48). All Professional orders shall be appropriately marked by Participants.

[7] As defined in Chapter XV of the Nasdaq Options Market Rules, the term ''Firm'' or (''F'') applies to any transaction that is identified by a Participant for clearing in the Firm range at OCC.

[8] As defined in Chapter XV of the Nasdaq Options Market Rules, the term ''Non-NOM Market Maker'' or (''O'') is a registered market maker on another options exchange that is not a NOM Market Maker. A Non-NOM Market Maker must append the proper Non-NOM Market Maker designation to orders routed to NOM.

[9] As defined in Chapter XV of the Nasdaq Options Market Rules, the term ''Broker-Dealer'' or (''B'') applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

Orders) when the member provides certain levels of liquidity and also provides certain levels of options liquidity simultaneously. The credits currently range from $0.0025 to $0.0005 depending upon the orders types used and the amount of liquidity provided, where midpoint liquidity is highest valued.

The Exchange is modifying three rebate tiers and adding a new rebate tier across Tapes A and B only; Tape C securities will remain unmodified. Specifically, the Exchange will raise the credit from $0.0020 to $0.0022 per share executed for midpoint orders if the member provides an average daily volume of 6 million or more shares through midpoint orders during the month, and from $0.0017 to $0.0020 per share executed for midpoint orders if the member provides an average daily volume between 5 million and less than 6 million shares through midpoint orders during the month. Additionally, the Exchange is adding a new rebate tier of $0.0018 per share executed for midpoint orders if the member provides an average daily volume between 1 million and less than 5 million shares through midpoint orders during the month Finally, the Exchange is retaining the rebate tier of $0.0014 per share executed for midpoint orders but lowering the volume requirement from 5 million to 1 million shares average daily volume of midpoint liquidity provided during the month.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[10] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

NASDAQ believes that the changes across all tapes to the calculation of the Equity and Options-linked credit of $0.0030 for members that provide midpoint liquidity are reasonable, equitably allocated and not unfairly discriminatory. First, it is reasonable and equitable to increase the required percentage of Consolidated Volume of equities executed from 0.40 percent to 0.60 percent per member for one or more of that member's MPIDs. This change is designed to create incentives for members to add additional liquidity to the NASDAQ Market Center. Liquidity is critical to the trading efficiency and quality of the exchange, and changes to enhance liquidity should be viewed favorably by all participants. This change will be applied equally to all similarly situated members and therefore should not be considered discriminatory, much less unfairly discriminatory.

NASDAQ also believes that it is reasonable, equitably allocated and not unfairly discriminatory to retain the existing link between equities and options trading, to modify the measure of options volume. As with the previous change, the Exchange is requiring members to add additional liquidity (1.25 versus 0.75 percent of ADV), and to apply the same numerator (volume added by that member in the Customer, Professional, Firm, Non-NOM Market Maker and Broker-Dealer classifications) and denominator (total volume in the customer clearing range in Equity and ETF Options) for that calculation. Again, it is important for the Exchange to encourage members to add liquidity to the platforms NASDAQ operates and fair to modify fees to accomplish that important goal.

The Exchange also believes it is reasonable, equitably allocated and not unfairly discriminatory to adjust rebate tiers for non-displayed liquidity for Tapes A and B. NASDAQ notes that each of the four changes results in higher rebates per executed share in the future for the same volume of shares previously executed. Three of the four changes are modifications to existing tiers and the fourth is the insertion of a new volume tier, each of which is designed to reward more generously the provision of midpoint liquidity on NASDAQ. Midpoint liquidity is valuable to the efficient operation and competitiveness of the Exchange, and particularly beneficial to investors matching at the midpoint.

NASDAQ believes it is not unfairly discriminatory to apply these changes to Tapes A and B versus Tape C because they will be absolute rather than relative requirements. As an absolute standard, the liquidity requirements will apply uniformly to all Market Makers eligible to participate in the program. All members have incentives available and equal opportunity to earn the higher rebates for adding more liquidity in Tapes A and B securities. NASDAQ has determined that modifying the incentives is more necessary for Tape A and B securities than for Tape C securities due to differences in NASDAQ's share of trading and the total volume traded in the market. If NASDAQ's determination is incorrect, NASDAQ would expect its share of trading in Tape C securities to decline due to intense competition in the market.

Further, all participants may qualify to be eligible for these rebates, provided they transact the requisite amount of liquidity. It is reasonable to emphasize customer liquidity in options trading because it offers unique benefits to the market, which benefits all market participants. Customer liquidity benefits all options market participants by providing more trading opportunities, which attracts market makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[12] NASDAQ notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, NASDAQ must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, NASDAQ believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the changes to liquidity credits for midpoint liquidity and to equity and options-lined credits do not impose a burden on competition because NASDAQ's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. In sum, if the changes proposed herein are unattractive to market participants, it is likely that NASDAQ will lose market share as a result. Accordingly, NASDAQ does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] 15 U.S.C. 78f(b)(8).

their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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–NASDAQ–2015–052 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2015–052. 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 Web site (*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 Web site 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 filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2015–052, and should be submitted on or before June 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12015 Filed 5–18–15; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Interagency Task Force on Veterans Small Business Development; Federal Register Meeting Notice

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Interagency Task Force meeting.

DATES: *Date and Time:* June 11, 2015, from 9:00 a.m. to 12:00 noon.

ADDRESSES: SBA Headquarters, 409 3rd Street SW., Washington, DC 20416, in the Eisenhower Conference Room B, Concourse Level.

SUMMARY:

Purpose: This public meeting is to discuss recommendations identified by the Interagency Task Force (IATF) to further enable veteran entrepreneurship policy and programs. In addition, the Task Force will allow public comment regarding the focus areas.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development. The Task Force is established pursuant to Executive Order 13540 and focused on coordinating the efforts of Federal agencies to improve capital, business development opportunities and pre- established Federal contracting goals for small business concerns owned and controlled by veterans (VOB's) and service-disabled veterans (SDVOSB'S). Moreover, the Task Force shall coordinate administrative and regulatory activities and develop proposals relating to ''six focus areas'': (1) Access to capital (loans, surety bonding and franchising); (2) Ensure achievement of pre-established contracting goals, including mentor protégé and matching with contracting opportunities; (3) Increase the integrity of certifications of status as a small business; (4) Reducing paperwork and administrative burdens in accessing business development and entrepreneurship opportunities; (5) Increasing and improving training and counseling services; and (6) Making other improvements to support veteran's business development by the Federal government.

Additional Information: Advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Task Force must contact Cheryl Simms by June 5, 2015 by email in order to be placed on the agenda. Comments for the record should be applicable to the ''six focus areas'' of the Task Force and emailed prior to the meeting for inclusion in the public record. Comments will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Cheryl Simms, Program Liaison for the Task Force, Office of Veterans Business Development at *vetstaskforce@sba.gov*. If participants need accommodations because of a disability or require additional information, please contact Cheryl Simms, Program Liaison at (202) 205-6773, or by email at *vetstaskforce@sba.gov*. For more information, please visit our Web site at *www.sba.gov/vets*.

Dated: May 8, 2015.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–12042 Filed 5–18–15; 8:45 am]

BILLING P

SMALL BUSINESS ADMINISTRATION

Meeting of the Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs. The meeting will be open to the public.

DATES: Wednesday, June 10, 2015 from 9 a.m. to 4 p.m.

ADDRESSES: U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

Room: Eisenhower Conference room A, located on the Concourse Level Floor.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The Advisory Committee on Veterans Business Affairs serves as an independent source of advice and policy recommendation to the Administrator of the U.S. Small Business Administration.

Purpose: The full committee meeting will focus on business opportunities for veterans and service disabled veterans. Several topics include government procurement and business development. For information regarding our veterans' resources and partners, please visit our Web site at *www.sba.gov/vets*.

Additional Information: The meeting is open to the public, however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Advisory Committee must contact Cheryl Simms, by June 4, 2015, by email below in order to be placed on the agenda. Comments for the Record including verbal presentations, should be emailed prior to the meeting for inclusion in the public record comments will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Cheryl Simms, Program Liaison, Office of Veterans Business Development, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

Additionally, if participants need accommodations because of a disability or require additional information, please contact Cheryl Simms, Designated Federal Official for the Advisory Committee on Veterans Business Affairs at (202) 205–6773; or by email at *cheryl.simms@sba.gov*. For more information, please visit our Web site at *www.sba.gov/vets*.

Dated: May 8, 2015.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–12037 Filed 5–18–15; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2015–15]

Petition for Exemption; Summary of Petition Received; Gus Christopher Toulatos

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before June 8, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–0646 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation.
- (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Keira Jones (202) 267–4024, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on May 14, 2015.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–0646
Petitioner: Gus Christopher Toulatos
Section(s) of 14 CFR Affected: §§ 61.17 (b)(1), 61.39 (b)(1), and 61.156

Description of Relief Sought

Mr. Toulatos seeks relief from § 61.17(b)(1) to allow for the reinstatement of his expired temporary airman certificate so that he may obtain a permanent ATP certificate with an airplane category multiengine class rating. Mr. Toulatos also requests relief from § 61.39(b)(1) to allow for the validation of his successful completion of the practical test for an ATP certificate even though it was completed with an expired knowledge test report. As an alternative to the relief requested for §§ 61.17 and 61.39, Mr. Toulatos seeks relief from § 61.156 to enable him to apply for the knowledge test for an ATP certificate with an airplane category multiengine class rating without completing the ATP CTP. Mr. Toulatos would then complete a new ATP certificate check.

Project No.: AFS–15–877–E
Project Officer:

ARM–101:KJones:3/20/2015:Doc# 43190
ARM–1/100/104:Program Office AFS–200
MR. GREGORY WINSTON, ESQ.
COUNSEL FOR GUS TOULATOS
GUS CHRISTOPHER TOULATOS
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ANNAPOLIS, MARYLAND 21401

[FR Doc. 2015–12089 Filed 5–18–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2015–0008]

Manual for Assessing Safety Hardware (MASH) Transition

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice; request for comment.

SUMMARY: In issuing Federal-aid eligibility letters for roadside safety hardware, the Federal Highway Administration (FHWA) currently makes determinations of continued eligibility for modifications to devices tested to the National Cooperative Highway Research Program Report 350 (NCHRP 350). In an effort to facilitate the implementation of the Manual for Assessing Safety Hardware (MASH), FHWA intends to discontinue issuing eligibility letters for requests received after December 31, 2015, for modified NCHRP 350-tested devices that do not involve full scale crash testing to the MASH. Modifications to NCHRP 350-tested devices that have, in the past, been based on engineering analysis or finite element modeling will no longer receive FHWA eligibility letters. Effective January 1, 2016, all changes to NCHRP 350-tested devices will require testing under MASH in order to receive a Federal-aid eligibility letter from FHWA.

DATES: Data and information must be submitted to FHWA on or before June 18, 2015.

ADDRESSES: Mail or hand deliver data and information to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or fax comments to (202) 493–2251. Alternatively, you may submit or retrieve information online through the Federal eRulemaking portal at *http://www.regulations.gov.* The Web site is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site. An electronic copy of this document may also be downloaded from the Government Printing Office's Web site at: *http://www.gpoaccess.gov* and the Office of the Federal Register's Web site at: *http://www.archives.gov/federal_register.* Please note that the Federal eRulemaking portal is unable to receive videos or any document larger than 10MB. If you would like to submit a video or a document that is 10MB or larger, please directly contact one of the individuals identified in this notice. All data and information must include the docket number that appears in the heading of this document. All data and information received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of data and information must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all information in any one of our dockets by the name of the individual submitting the information (or signing the information, if submitted on behalf of an association, business, or labor union). The DOT solicits comments from the public to better inform its activities. The DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Michael Griffith, Office of Safety, 202–366–9469, *mike.griffith@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. For legal questions, please contact Jennifer Mayo, Assistant Chief Counsel, FHWA Office of the Chief Counsel, (202) 366–1523, or via email at *jennifer.mayo@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Background

Guardrails, guardrail end terminals, and other roadside safety hardware are tested to criteria established by the American Association of State Highway and Transportation Officials (AASHTO) through its committee structure in which FHWA participates. The States are guided by the AASHTO Roadside Design Guide (RDG) in their decisions regarding what roadside safety hardware to install on their roadways. In order for a State to receive FHWA reimbursement for roadside safety hardware, the hardware must be crashworthy, meaning that it meets the testing and evaluation guidelines in effect at the time that hardware was developed.

Roadside safety hardware guidelines and testing criteria have evolved over the last several decades with changes in the vehicle fleet and the emergence of new hardware designs. From 1981 until 1993, NCHRP 230 guidelines were used. From 1993 until 2011, NCHRP 350 guidelines were used. The MASH was published in 2009 and since January 1, 2011, all new or significantly changed devices must meet the MASH criteria.

Not unlike other industries, each successive version of guidelines is meant to encourage manufacturers to advance the state of roadside safety hardware and to develop devices that work with a changing vehicle fleet under a wider range of conditions. Because of the extensive development and testing required, it typically takes many years after roadside safety hardware guidelines are established for products meeting those guidelines to be widely available on the market. Accordingly, when AASHTO adopted MASH, it did not intend or require that devices designed to meet previous criteria would need to be retested to meet the newly developed criteria. Instead, a new generation of devices would need to be developed to meet the newly adopted criteria. In the six years since the MASH was published, however, there have not been a significant number of MASH-tested devices developed and brought to market. As a result and to encourage the development and installation of MASH-compliant devices, FHWA and AASHTO agree it is time to begin the transition to requiring that new installations of roadway safety hardware comply with the MASH criteria.

Purpose of This Notice

The FHWA provides technical assistance to States by issuing Federal-aid eligibility letters for devices deemed crashworthy. The FHWA also makes determinations of continued eligibility for modified devices that have existing eligibility letters. The purpose of this notice is to seek the input of industry, State Departments of Transportation, and the broader highway community on the impact of FHWA no longer issuing eligibility letters after December 31, 2015, for modified NCHRP 350-tested devices that do not involve full scale crash testing to MASH. Modifications to NCHRP 350-tested devices that have, in the past, been based on engineering analysis or finite element modeling will no longer receive FHWA eligibility letters. Please provide any information that FHWA should be aware of regarding impacts of this change.

By taking this action, FHWA believes it will facilitate the implementation of MASH. Later this year, AASHTO is expected to take action regarding a schedule for requiring that new installations of roadway safety hardware comply with the MASH criteria.

Authority: 23 U.S.C. 148 and 315.

Issued on: May 13, 2015.

Gregory G. Nadeau,

Deputy Administrator, Federal Highway Administration.

[FR Doc. 2015–12021 Filed 5–18–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Unified Carrier Registration Plan Board of Directors Meeting.

TIME AND DATE: The meeting will be held on June 10, 2015, from 9:00 a.m.to 12:00 Noon, Eastern Daylight Time.

PLACE: This meeting will be open to the public at the Read House Hotel, 827 Broad Street, Chattanooga, TN 37402 and via conference call. Those not attending the meeting in person may call 1–877–422–1931, passcode 2855443940, to listen and participate in this meeting.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the Board) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement and to that end, may consider matters properly before the Board.

FOR FURTHER INFORMATION CONTACT: Mr. Avelino Gutierrez, Chair, Unified Carrier Registration Board of Directors at (505) 827–4565.

Issued on: May 12, 2015.

Larry W. Minor,

Associate Administrator, Office of Policy, Federal Motor Carrier Safety Administration.

[FR Doc. 2015–12209 Filed 5–15–15; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Vehicle Theft Prevention Standard; Jaguar Land Rover North America, LLC

AGENCY: National Highway Traffic Safety Administration, NHTSA, Department of Transportation, DOT.

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Jaguar Land Rover North America LLC's, (Jaguar Land Rover) petition for an exemption of the Jaguar XF vehicle line in accordance with 49 CFR part 543, *Exemption from the Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541).

DATES: The exemption granted by this notice is effective beginning with model year (MY) 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Hisham Mohamed, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, W43–437, 1200 New Jersey Avenue SE., Washington, DC 20590. Mr. Mohamed's phone number is (202) 366–0307. His fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: In a petition dated March 23, 2015, Jaguar Land Rover requested an exemption from the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541) for the MY 2016 Jaguar XF vehicle line. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for an entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, Jaguar Land Rover provided a detailed description and diagrams of the identity, design, and location of the components of the antitheft device for the XF vehicle line. Jaguar Land Rover stated that its XF vehicles will be equipped with a passive, transponder based, electronic engine immobilizer device as standard equipment beginning with the 2016 model year. Key components of its antitheft device will include a power train control module (PCM), instrument cluster, body control module (BCM), remote frequency receiver (RFR), remote frequency actuator (RFA), immobilizer antenna unit (IAU), Smart Key, door control units (DCU), and a visual and audible perimeter alarm system. Jaguar Land Rover also stated that the audible and visual perimeter alarm system will be installed as standard equipment and can be armed with the Smart Key or programmed to be passively armed. Jaguar Land Rover further stated that the siren will sound and the vehicle's exterior lights will flash if unauthorized entry is attempted by opening the hood, doors or luggage compartment. Jaguar Land Rover's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

Jaguar Land Rover stated that the Smart Key is programmed and synchronized to the vehicle through means of an identification key code and a randomly generated secret code that are unique to each vehicle. Jaguar Land Rover further stated that the immobilizer device is armed automatically when the Smart Key is removed from the vehicle.

Jaguar Land Rover also stated that there are three methods the driver can approach the vehicle and start the engine. Method one is through automatic detection of the Smart Key via a remote frequency challenge response sequence. Jaguar stated that when the driver approaches the vehicle and pulls the driver's door handle (after authentication of the correct Smart Key), the doors will unlock. Specifically, when the ignition start button is pressed, a search to find and authenticate the Smart Key commences within the vehicle interior. If successful, this information is passed by a coded data transfer to the BCM via the Remote Function Actuator. The BCM in turn, will pass the ''valid key'' status to the instrument cluster, via a coded data transfer. The BCM sends the key valid message to the PCM which initiates a coded data transfer authorizing the engine to start. Method two is accomplished by unlocking the vehicle with the Smart Key unlock button. As the driver approaches the vehicle, the Smart Key unlock button is pressed and the doors will unlock. Once the driver presses the ignition start button, the operation process is the same as method one. Method three is accomplished by using the emergency key blade. If the Smart Key has a discharged battery or is damaged, there is an emergency key blade that can be removed from the Smart Key and used to unlock the doors. When the ignition start button is pressed a search is commenced to find and authenticate the Smart Key within the vehicle. Once the Smart Key is docked in the correct position and the ignition start button is pressed again, the BCM and Smart key completes a coded data exchange via the IAU. If successful, the BCM passes the valid key status to the instrument cluster, via a coded data transfer. The BCM then sends the key valid message to the PCM which initiates a coded data transfer. If

successful, the engine will be authorized to start.

In addressing the specific content requirements of 543.6, Jaguar Land Rover provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Jaguar Land Rover conducted tests based on its own specified standards. Jaguar Land Rover provided a detailed list of the tests conducted (*i.e.,* temperature and humidity cycling, high and low temperature cycling, mechanical shock, random vibration, thermal stress/shock tests, material resistance tests, dry heat, dust and fluid ingress tests). Jaguar Land Rover stated that it believes that its device is reliable and durable because it complied with specified requirements for each test. Additionally, Jaguar Land Rover stated that its key recognition sequence includes more than a billion code combinations, which include encrypted data that are secure against copying. Jaguar Land Rover also stated that the coded data transfer between its modules use a unique secure identifier, a random number and a secure public algorithm. Jaguar Land Rover further explained that since its XF vehicle line will utilize push button vehicle ignition, it does not have a conventional mechanical key barrel and therefore believes that forcibly bypassing the key-locking system would be virtually impossible.

Jaguar Land Rover also stated that the current generation Jaguar XF vehicle line produced since MY 2009, is installed with an engine immobilizer device as standard equipment. Jaguar Land Rover noted that since the current generation Jaguar XF vehicles have only been available with an engine immobilizer, there is no comparative data available for the XF vehicle line without an immobilizer. However, Jaguar Land Rover stated that the immobilizer is substantially similar to the antitheft device installed on the Jaguar XK, Jaguar XJ, Land Rover LR2, Land Rover Range Rover Evoque, and Land Rover Discovery Sport vehicle lines previously granted an exemption by the agency. Jaguar Land Rover stated that based on the MY 2012 final theft data published by NHTSA, the Jaguar Land Rover vehicles equipped with immobilizers had a theft rate of 0.76 per thousand vehicles, comparatively below NHTSA's overall theft rate of 1.13 thefts per thousand vehicles for MY 2012 passenger vehicles stolen in CY 2012. The theft rates for the Jaguar XK, XJ, Land Rover Evoque, and Land Rover LR2 using an average of 3 MY's data are 1.0803, 0.9199, 0.5501 and 0.4141, respectively. Jaguar Land Rover believes these low theft rates further demonstrate the effectiveness of its immobilizer device. Additionally, as further evidence of the effectiveness of its immobilizer device, Jaguar Land Rover submitted a Highway Loss Data Institute news release (July 19, 2000) showing an average reduction in theft losses of about 50 percent for vehicles installed with an immobilizer device.

Based on the supporting evidence submitted by Jaguar Land Rover on its device, the agency believes that the antitheft device for the XF vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR 541). The agency concludes that the device will provide the five types of performance listed in § 543.6(a)(3): promoting activation; attracting attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7 (b), the agency grants a petition for exemption from the parts-marking requirements of part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Jaguar Land Rover has provided adequate reasons for its belief that the antitheft device for its XF vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Jaguar Land Rover provided about its device.

For the foregoing reasons, the agency hereby grants in full Jaguar Land Rover's petition for exemption for the Jaguar Land Rover XF vehicle line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR part 543.7(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If Jaguar Land Rover decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Jaguar Land Rover wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, part 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis,* it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Under authority delegated in 49 CFR part 1.95.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2015–12072 Filed 5–18–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 3949–A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 3949–A, Information Referral.

DATES: Written comments should be received on or before July 20, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, room 6129, 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 R. Joseph Durbala, (202) 317–5746, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Information Referral.

OMB Number: 1545–1960.

Form Number: 3949–A.

Abstract: Form 3949–A is used by certain taxpayer/investors to wishing to report alleged tax violations. The form will be designed capture the essential information needed by IRS for an initial evaluation of the report. Upon return, the Service will conduct the same back-end processing required under present IRM guidelines. Submission of the information to be included on the form is entirely voluntary on the part of the caller and is not a requirement of the Tax Code.

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: Individuals and Households.

Estimated Number of Respondents: 215,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 53,750.

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: May 11, 2015.

Christie Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–11998 Filed 5–18–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Information Collection; Comment Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before July 20, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: To obtain additional information, or copies of the information collection and instructions, or copies of any comments received, contact Elaine Christophe, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *Elaine.H.Christophe@irs.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and the Internal Revenue Service, as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to take this opportunity to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 *et seq.*).

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments will become a matter of public record. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the agency's functions, including whether the information has 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 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 the requested information. Currently, the IRS is seeking comments concerning the following forms, and reporting and record-keeping requirements:

Title: Income, Excise, and Estate and Gift Taxes Effective Dates and Other Issues Arising Under the Employee Benefit Provisions of the Tax Reform Act of 1984.

OMB Number: 1545–0916.

Regulation Project Number: T.D. 8073 (temporary regulations) and EE–96–85 (noticed of proposed rulemaking).

Abstract: The regulations provide rules relating to effective dates and certain other issues arising under sections 91, 223, and 511–561 of the Tax Reform Act of 1984. The regulations affect qualified employee benefit plans, welfare benefit funds, and employees receiving benefits through such plans.

Current Actions: There are no changes being made at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, and individuals.

Estimated Number of Respondents: 7,800.

Estimated Time per Respondent: 31 minutes.

Estimated Total Annual Burden Hours: 4,000.

Title: Excise Tax Under Section 4980B, 4980D, 4980E & 4980G.

OMB Number: 1545–2146.

Regulation Project Number: TD 9457 (REG–120476–07).

Abstract: This final regulation provide the requirement for filing of the return and the time for filing a return for the payment of the excise taxes under section 4980B, 4980D, 4980E, and 4980G.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit organizations, and individuals.

Estimated Number of Respondents: 5,000.

Estimated Time per Respondent: .50 hours.

Estimated Total Annual Burden Hours: 2,500.

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.

Approved: May 11, 2015.

Christie A. Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–12127 Filed 5–18–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5452

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 5452, Corporate Report of Nondividend Distributions.

DATES: Written comments should be received on or before July 20, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 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 R. Joseph Durbala at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 317–5746, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Corporate Report of Nondividend Distributions.

OMB Number: 1545–0205.

Form Number: 5452.

Abstract: Form 5452 is used by corporations to report their nontaxable distributions as required by Internal Revenue Code section 604(d)(2). The information is used by IRS to verify that the distributions are nontaxable as claimed.

Current Actions: There are no changes to the burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 1,700.

Estimated Number of Respondents: 34 hours, 3 minutes.

Estimated Total Annual Burden Hours: 57,885.

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: May 11, 2015.

Christie Preston,

IRS, Reports Clearance Office.

[FR Doc. 2015–12002 Filed 5–18–15; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 80 Tuesday,

No. 96 May 19, 2015

Part II

Department of Labor

Office of the Secretary

29 CFR Part 18

Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges; Final Rule

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 18

RIN 1290–AA26

Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges

AGENCY: Office of the Secretary, Labor.

ACTION: Final rule.

SUMMARY: This is the final text of regulations governing practice and procedure for proceedings before the United States Department of Labor, Office of Administrative Law Judges (OALJ). The regulations were first published as a final rule in 1983 and were modeled on the Federal Rules of Civil Procedure (FRCP). A Notice of Proposed Rulemaking was published in the **Federal Register** on December 4, 2012 requesting public comment on proposed revisions to and reorganization of these regulations. The revisions make the regulations more accessible and useful to parties. The revisions also harmonize administrative hearing procedures with the current FRCP and with the types of claims now heard by OALJ, which increasingly involve whistleblower and other workplace retaliation claims, in addition to a longstanding caseload of occupational disease and injury claims. The Department received sixteen comments to the proposed rule. This rule responds to those comments and establishes the final text of the revised regulations.

DATES:

Effective Date: This rule is effective June 18, 2015.

Compliance Date: This rule is effective June 18, 2015.

FOR FURTHER INFORMATION CONTACT: Todd Smyth at the U.S. Department of Labor, Office of Administrative Law Judges, 800 K Street NW., Suite 400-North, Washington, DC 20001–8002; telephone (202) 693–7300.

SUPPLEMENTARY INFORMATION:

I. Background

On December 4, 2012, the Department published a Notice of Proposed Rulemaking (NPRM) with a request for comments amending 29 CFR part 18, subpart A. Rules of Practice and Procedure for Hearings Before the Office of Administrative Law Judge, 77 FR 72142 (Dec. 4, 2012). The Department proposed to amend comprehensively its procedural rules to reflect the changes to civil litigation since the OALJ promulgated its rules in 1983. Moreover, the need to update the OALJ's procedural rules was evident as the OALJ's authority to hear whistleblower cases increased. The new procedural rules are analogous to the FRCP used in the United States district courts and are intended to provide more guidance and clarity to parties practicing before the OALJ.

The Department provided an opportunity for the public to comment even though the changes are to rules of agency organization, procedure and practice, which are exempt from the notice and public comment requirements of the Administrative Procedure Act (APA). *See* 5 U.S.C. 553(b)(3)(A). The comment period ended on February 4, 2013. The Department reviewed and responded to each pertinent comment submitted. *See infra Part 3*. Accordingly, the NPRM amending 29 CFR part 18, subpart A, that was published on December 4, 2012, is being adopted as a final rule with the changes made below.

The Department has found that a handful of departmental specific program regulations reference these rules, and that these references may now be inaccurate due to shifts in numbering. The Department plans to correct these references in the near future through technical corrections, which will be published in the **Federal Register**.

II. Summary of General Comments on the Notice of Proposed Rulemaking

The Department received several general comments regarding the proposed changes to the OALJ rules of practice and procedure. Each comment is addressed as follows:

Compliance with the APA. The Department stated in the NPRM that while the proposed changes consist of amendments to rules of agency organization, procedure and practice that are exempt from the notice and public comment requirements of the APA, the Department wished to provide the public with an opportunity to comment on any aspect of the proposed rule. Accordingly, the proposed changes were published in the **Federal Register**, and public comment was invited. Two commenters challenged the Department's reference to the APA's procedural rules exception and claimed that the Department thus misinformed the public and chilled the pool of public comment on the proposed rule changes. These commenters asserted that the public harm resulting from this alleged error could only be remedied by withdrawing the proposed rules and reissuing them in conformity with the full notice and comment protections of the APA. One commenter argued that because the rules contain provisions for sanctions, they ''substantially alter the rights and interests of parties'' which triggers the APA's requirements for public notice and comment. This comment principally relied on the vacated decision of the Court of Appeals for the District of Columbia in *Air Transp. Ass'n of Am.* v. *Dep't of Transp.,* 900 F.2d 369 (1990), *cert. granted,* 498 U.S. 1023 (1991), *vacated,* 933 F.2d 1043 (1991). The other commenter stated that the OALJ rules of practice and procedure constitute agency rules with the ''force and effect of law'' that must be published for public comment in accordance with the Supreme Court's decisions in *United States* v. *Mead Corp.,* 533 U.S. 218 (2001), and *Christensen* v. *Harris Cnty.,* 529 U.S. 576 (2000).

The Department disagrees with these claims. In decisions issued subsequent to its vacated ruling in *Air Transp. Ass'n of Am.,* the D.C. Circuit has stressed that the '' 'critical feature' '' of a rule that satisfies the so-called ''procedural exception 'is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.' '' *James V. Hurson Assoc., Inc.* v. *Glickman,* 229 F.3d 277, 280 (2000) (quoting *JEM Broad Co.* v. *FCC,* 22 F.3d 320, 326 (D.C. Cir. 1994)). The Court further held in *Hurson* that ''an otherwise procedural rule does not become a substantive one, for notice and comment purposes, simply because it imposes a burden on regulated parties.'' *Id.* at 281. As nothing in the new rules alters the ''substantive criteria'' by which claims and complaints are adjudicated in the hearing before the OALJ, they are within the procedural rules exemption. *See* id. at 280–81; *JEM Broad Co.,* 22 F.3d at 237; *Nat'l Whistleblower Ctr.* v. *Nuclear Regulatory Comm'n,* 208 F.3d 256, 262 (D.C. Cir. 2000), *cert. denied,* 531 U.S. 1070 (2001). The Supreme Court's decisions in *Mead Corp.* and *Christensen* cited by the other commenter respectively address whether a U.S. Customs Service classification ruling and Department of Labor opinion letter, neither of which were issued after APA notice and comment rulemaking, are entitled to deference under *Chevron, U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837 (1984). These decisions do not address the scope of the APA's procedural rules exception.

The Department moreover voluntarily published the rule changes in

accordance with the notice and comment requirements of the APA consistent with the procedure recommended by the Administrative Conference of the United States to avoid controversy over the scope of the APA's notice and comment exceptions. *See* The Procedural and Practice Rule Exemption from the APA Notice-and-Comment Rulemaking Requirements, 1 CFR 305.92–1 (1995) (ACUS Recommendation 92–1, available at *www.acus.gov/sites/default/files/documents/92-1/pdf*). The commenters provided no evidence to support their claim that the Department's voluntary compliance with the APA's notice and comment requirements in accordance with the ACUS recommendation in any manner chilled or otherwise influenced public comment. They also cited no legal authority for their position that the Department's mere reference to the procedural rules exception vitiated the NPRM. The Department's receipt of multiple comments indicates that the public was neither ''chilled'' nor deterred from submitting items for consideration. Thus, there is no basis for withdrawing and reissuing the rules changes.

Conflicts with the LHWCA and BLBA. Two commenters argued that several provisions in the new rules providing for imposition of sanctions conflict with provisions of the Longshore and Harbor Workers' Compensation Act (LHWCA), 33 U.S.C. 901–950, which are also applicable to claims adjudicated under the Black Lung Benefits Act (BLBA), 30 U.S.C. 901–945, and therefore those provisions should either be deleted or rewritten to specifically state that they are not applicable to proceedings under the LHWCA and BLBA. The commenters identified sections 926, 927(b) and 931 of the LHWCA, 33 U.S.C. 926, 927(b), 931, as conflicting with the new rules containing sanction provisions. One commenter also suggested that some of the new rules may contravene section 923(a) of the LHWCA, 33 U.S.C. 923(a). The Department believes however that any conflicts between the rules and the LHWCA and, for that matter, any other statute governing administrative hearing proceedings before the OALJ, are already addressed appropriately in the rules and do not warrant either wholesale rescission or rewriting. The Department also believes that the commenters overstated the alleged conflicts between the new rules and the LHWCA.

Section 923(a) of the LHWCA provides that officials conducting hearings ''shall not be bound by common law or statutory rules of evidence or by technical or formal rules of procedure, except as provided by this chapter; but may make such investigation or inquiry or conduct such hearing in such manner as to best ascertain the rights of the parties.'' 33 U.S.C. 923(a). *See also* 20 CFR 702.339, 725.455(b). The Benefits Review Board (BRB) and courts of appeals have nevertheless applied provisions of the OALJ Rules of Practice and Procedure, particularly in regard to discovery issues, in proceedings governed by section 923(a) of the LHWCA in the absence of any conflict with a particular LHWCA or BLBA rule. *See, e.g., Johnson* v. *Royal Coal Co.,* 326 F.3d 421, 426 (4th Cir. 2003); *Keener* v. *Peerless Eagle Coal Co.,* 23 Black Lung Rep. (Juris) 1–229, 1–243 (Ben. Rev. Bd. 2007) (*en banc*); *Cline* v. *Westmoreland Coal Co.,* 21 Black Lung Rep. (Juris) 1–69, 1–76 (Ben. Rev. Bd. 1997); *see also Prince* v. *Island Creek Coal Co.,* BRB No. 01–0448 BLA, 2002 WL 34707263 (Ben. Rev. Bd. Jan. 24, 2002) (reading 29 CFR 18.14 and 20 CFR 725.455 as complementary rules providing the ALJ with broad discretion to direct discovery), *aff'd,* 76 Fed.Appx. 67, 2003 WL 22176988 (6th Cir. Sept. 19, 2003). It would be inappropriate and contrary to well-established precedent to add a textual exception to all of the proposed disclosure and discovery rules for LHWCA and BLBA cases. Moreover, § 18.10(a) provides that ''[t]o the extent that these rules may be inconsistent with a governing statute, regulation, or executive order, the latter controls.'' 29 CFR 18.10(a).

Section 926 of the LHWCA provides that ''[i]f the court having jurisdiction of proceedings in respect of any claim or compensation order determines that the proceedings in respect of such claim or order have been instituted or continued without reasonable ground, the costs of such proceedings shall be assessed against the party who has so instituted or continued such proceedings.'' 33 U.S.C. 926. Congress intended claimants to be subject to costs ''if they brought their unreasonable claims into court'' when it enacted section 926. *Metro. Stevedore Co.* v. *Brickner,* 11 F.3d 887, 890 (9th Cir. 1993). The Department recognizes that federal courts have the exclusive power to impose section 926 sanctions when a party brings a frivolous claim under the LHWCA. *Id.* at 890–91; *see also Boland Marine & Mfg. Co.* v. *Rihner,* 41 F.3d 997, 1004 (5th Cir. 1995). However, to the extent that any of the new rules conflict with section 926, the latter controls. *See* 29 CFR 18.10(a). There is therefore no conflict between section 926 and any of the new rules.

Section 927(b) in relevant part provides that if any person in a LHWCA proceeding ''disobeys or resists any lawful order or process, or misbehaves during a hearing or so near the place thereof as to obstruct the same, or neglects to produce, after having been ordered to do so, any pertinent book, paper, or document, or refuses to appear after having been subpoenaed, or upon appearing refuses to take the oath as a witness, or after having taken the oath refuses to be examined according to law,'' the adjudicatory official ''shall certify the facts to the district court having jurisdiction in the place in which he is sitting (or to the United States District Court for the District of Columbia'' for summary contempt proceedings). 33 U.S.C. 927(b). The Department agrees with the commenters that section 927(b) provides the district courts with the exclusive power to punish contumacious conduct consisting of a refusal to comply with a judge's order, lawful process or subpoena, or hearing room misbehavior in proceedings under the LHWCA. *See Goicochea* v. *Wards Cove Packing Co.,* 37 Ben. Rev. Bd. Serv. (MB) 4, 6 (2003) (vacating dismissal of claim as sanction for claimant's refusal to comply with a judge's discovery order). To the extent that any of the new rules conflict with section 927(b), the latter controls. *See* 29 CFR 18.10(a). However, there are several situations addressed by the new rules involving conduct that likely would fall outside the categories of contumacy requiring certification to a district court for a section 927(b) summary contempt proceeding. *See A–Z Intn'l* v. *Phillips,* 323 F.3d 1141, 1146–47 (9th Cir. 2003) (holding that the district court lacked section 927(b) jurisdiction over conduct that did not involve a refusal ''to comply with a summons, writ, warrant, or mandate issued by the ALJ''). *See, e.g.,* 29 CFR 18.35(c) (sanctions for violations of § 18.35(b) relating to the representations made when presenting a motion or other paper to the judge), 18.50(d)(3) (sanctions for violations of § 18.50(d)(1) pertaining to certifications made when signing disclosures and discovery requests, responses and objections), 18.56(d)(1) (sanctions for violations of the duty under § 18.56(c)(1) to protect a person subject to a subpoena from undue burden), 18.57(c) (sanctions for failures to disclose information, supplement an earlier response or to admit as required by §§ 18.50(c), 18.53 and 18.63(a)), 18.57(d) (sanctions for a party's failure to attend its own deposition, serve

answers to interrogatories, or respond to a request for inspection), 18.64(d)(2) (sanctions for impeding, delaying or frustrating a deposition), 18.64(g) (sanctions for failing to attend or proceed with a deposition or serve a subpoena on a non-party deponent when another party, expecting the deposition to be taken, attends), 18.72(h) (sanctions for submitting in bad faith an affidavit or declaration in support of or in opposition to a motion for summary decision). To the extent these provisions address violations of the procedural rules falling outside the scope of section 927(b), there is no conflict with the statute.

The Department also rejects the commenters' argument that section 927(b) provides the exclusive remedy for any misconduct or rules violation occurring in LHWCA and BLBA proceedings. Section 927(b), 44 Stat. 1438 (Mar. 4, 1927) (codified as amended at 33 U.S.C. 927), was originally enacted in 1927, decades before the passage of the APA which also governs adjudications under the LHWCA and the BLBA. 33 U.S.C. 919(d); 30 U.S.C. 932(a); *Dir., OWCP, Dep't of Labor* v. *Greenwich Collieries,* 512 U.S. 267, 280–81 (1994); *see also Lane* v. *Hollow Coal Co.* v. *Dir., OWCP, Dep't of Labor,* 137 F.3d 799, 802–03 (4th Cir. 1998) (requiring ALJ's decision to contain findings and conclusions, in accordance with 5 U.S.C. 557(c)(3)(A)); *Cole* v. *East Kentucky Collieries,* 20 Black Lung Rep. (Juris) 1–50, 1–54 (Ben. Rev. Bd. 1996) (discussing statutory mechanism whereby APA applies to BLBA claims); *Toyer* v. *Bethlehem Steel Corp.,* 28 Ben. Rev. Bd. Serv. (MB) 347, 351 (1994) (emphasizing APA applicability in all LHWCA adjudications). Notably, the APA's grant of authority to ''regulate the course of the hearing,'' 5 U.S.C. 556(c)(5), provides a judge with an independent basis to take such actions as are necessary to ensure parties a fair and impartial adjudication. Such authority includes the power to compel discovery and impose sanctions for non-compliance pursuant to the OALJ rules of practice and procedure. *See Williams* v. *Consolidation Coal Co.,* BRB No. 04–0756 BLA, 2005 WL 6748152, at *8 (Ben. Rev. Bd. Aug. 8, 2005), *appeal denied,* 453 F.3d 609 (4th Cir. 2006), *cert. denied,* 549 U.S. 1278 (2007). The bifurcation of general adjudicatory authority and contempt powers between administrative law judges and the district courts under the LHWCA is analogous to adjudication in the federal courts after passage of the Federal Magistrates Act, 28 U.S.C. 604, 631–39, under which magistrate judges have general authority to order non-dispositive discovery sanctions while contempt charges must be referred to a district court judge. *See Grimes* v. *City and County of San Francisco,* 951 F. 2d 236, 240–41 (9th Cir. 1991) (discussing the scope and limits of magistrate judges' sanction authority); *see also Dodd* v. *Crown Cent. Petroleum Corp.,* 36 Ben. Rev. Bd. Serv. (MB) 85, 89 n.6 (2002) (affirming, as not inconsistent with section 927(b), judge's imposition of sanctions pursuant to 29 CFR 18.6(d)(2) for claimant's noncompliance with a discovery order). The Department therefore believes that the commenters' proposal to exempt LHWCA and BLBA proceedings from the judge's authority under the APA to regulate the course of the hearing is neither warranted by the statute nor consistent with the efficient and impartial conduct of administrative hearings.

Section 931(a)(1) of the LHWCA provides that ''[a]ny claimant or representative of a claimant who knowingly and willfully makes a false statement or representation for the purpose of obtaining a benefit or payment under this chapter shall be guilty of a felony, and on conviction thereof shall be punished by a fine not to exceed $10,000, by imprisonment not to exceed five years, or by both.'' 33 U.S.C. 931(a)(1). Section 931(c) similarly provides that ''[a] person including, but not limited to, an employer, his duly authorized agent, or an employee of an insurance carrier who knowingly and willfully makes a false statement or representation for the purpose of reducing, denying, or terminating benefits to an injured employee, or his dependents pursuant to section 909 of this title if the injury results in death, shall be punished by a fine not to exceed $10,000, by imprisonment not to exceed five years, or by both.'' 33 U.S.C. 931(c). As there is no provision in the new rules that authorizes a judge to impose a fine or other penalty for a knowing and willfully false statement or representation for the purpose of obtaining or opposing a benefit under the LHWCA, there is no conflict between section 931 and any of the new rules.

Authority to Regulate the Conduct of Administrative Proceedings; Sanctions. The Department announced in the NPRM that it intended to bring the OALJ rules of practice and procedure into closer alignment with the FRCP. Doing so takes advantage of the mature precedent the federal courts have developed and the broad experience they have in applying the FRCP. Choosing which portions to adopt and which to omit allows for flexible case management, given the less formal nature of administrative proceedings, which never involve juries. These changes offer greater clarity and uniformity so parties can focus on the merits of their disputes with less distraction from litigating points of procedure. To attain these objectives, the new rules contain a number of provisions, similar to their FRCP counterparts, which authorize judges to take actions necessary to regulate and ensure the integrity of the hearing process. *See* 29 CFR 18.12(b)(10), 18.35(c), 18.50(d)(3), 18.56(c)(1), 18.57(a)(2)(A), 18.57(b), 18.57(c), 18.57(d)(1), 18.57(d)(3), 18.57(e), 18.57(f), 18.64(d)(2), 18.64(g), 18.72(h), 18.87. Two commenters asserted that these litigation sanction provisions exceed a judge's authority under the APA, and attempt to arrogate contempt power and claim ''inherent judicial authority'' that is vested exclusively in the Article III courts. The Department believes these assertions misunderstand the challenged rules and their intent.

The prior rules authorized judges to sanction a broad range of inappropriate conduct during the course of an administrative proceeding. A judge could overrule an objection to a discovery request (such as request for admission or an interrogatory) and compel a response. 29 CFR 18.6(d)(1). If that objecting party thereafter failed to answer or answered evasively, the judge could order that a matter be treated as admitted. *Id.* If a party failed to comply with a subpoena, discovery order or any other order, the judge could take other just actions, including (i) drawing adverse inferences; (ii) ruling that the matter concerning which the subpoena or order was issued be taken as established adversely to a non-complying party; (iii) excluding evidence a non-complying party offered; (iv) ruling that a non-complying party could not object to the use of secondary evidence to establish what evidence it withheld should have shown; or (v) ruling that all or part of a pleading be stricken, or that a decision be rendered against the non-complying party. 29 CFR 18.6(d)(2). The prior rules also recognized that judges have ''all powers necessary to the conduct of fair and impartial hearings including, but not limited to . . . [w]here applicable, take any appropriate action authorized by the Rules of Civil Procedure for the United States District Courts, issued from time to time and amended pursuant to 28 U.S.C. 2072. . . .'' 29 CFR 18.29(a)(8). The new rules preserve

this longstanding authority to impose appropriate litigation sanctions, *see* 29 CFR 18.12(b)(10), 18.57(b), and additional provisions for sanctions were made as discussed above in §§ 18.35(c), 18.50(d)(3), 18.56(c)(1), 18.57(c), 18.57(d), 18.64(d)(2), 18.64(g), 18.72(h). The new rules provide greater clarity and direction on the scope and limitations on a judge's authority to sanction a party's unjustified failure to carry out duties that the procedural rules establish.

The Department's appellate boards and judges have no Article III status or powers. *See, e.g., Temp. Emp't Serv.* v. *Trinity Marine Group, Inc.,* 261 F.3d 456, 460–61 (5th Cir. 2001); *Schmit* v. *ITT Fed. Elec. Int'l,* 986 F.2d 1103, 1109–10 (7th Cir. 1993); *Gibas* v. *Saginaw Mining Co.,* 748 F.2d 1112, 1117 (6th Cir. 1984). The APA vests no contempt powers in ALJs. The Department acknowledges that FRCP 11 itself does not vest ALJs with authority to impose the sanctions embodied in that rule because it is a rule of the Article III trial courts. Nor was it clear whether FRCP 11 had been generally incorporated into the prior rules by 29 CFR 18.1(a). *Metro. Stevedore Co.* v. *Brickner,* 11 F.3d 887, 891 (9th Cir. 1993) (expressing in dicta doubts about incorporation). FRCP 11 was unavailable for incorporation in Longshore claims, however. *Boland Marine & Mfg. Co.* v. *Rihner,* 41 F.3d 997 (5th Cir. 1995) (Section 26 of the Longshore Act confines an award of costs when proceedings are ''instituted or continued without reasonable grounds'' to proceedings that have made their way into the Article III courts. Therefore, neither FRCP 11 nor section 26(f) may be incorporated into Longshore Act proceedings at the Department through the text of 29 CFR 18.1(a) on the theory that the ''situation [is] not provided for or controlled by statute.''); *Metro. Stevedore Co.,* 11 F.3d at 891 (finding that under section 26 of the Longshore Act only courts can assess costs against a claimant who institutes or continues a proceeding in the courts without reasonable grounds); *R.S. [Simons]* v. *Va. Int'l Terminals,* 42 Ben. Rev. Bd. Serv. (MB) 11, 14 (2008) (rejecting an argument that an ALJ could assess attorney's fees against an employer that were unavailable under section 28 of the Longshore Act by using FRCP 11 instead); *Valdez* v. *Crosby & Overton,* 34 Ben. Rev. Bd. Serv. (MB) 69, 77 (2000) (applying the holdings in *Boland Marine & Mfg. Co.* and *Metro. Stevedore Co.*); *Crum* v. *Wolf Creek Collieries,* 18 Black Lung Rep. (Juris) 1–80, 1–83 (Ben. Rev. Bd. 1994). Though the new rules use the term ''sanction'' to describe remedies that can be applied when a party fails to fulfill its duties, these remedies do not extend to the full panoply of powers available to Article III judges under their inherent powers or under FRCP 11, which encompass the authority to require an errant lawyer to participate in seminars or education programs, or order a fine payable to the court. *See* Fed. R. Civ. P. 11 advisory committee's note (discussion of 1993 amendments).

Nonetheless, the APA empowers ALJs, ''[s]ubject to published rules of the agency and within its powers . . . to regulate the course of a hearing.'' 5 U.S.C. 556(a)(3), (c)(5). That authority is statutorily explicit. The appellate courts moreover have upheld orders that impose litigation sanctions on parties who violate an administrative agency's procedural rules. *See Roadway Exp., Inc.* v. *U.S. Dept. of Labor,* 495 F.3d 477, 484 (7th Cir. 2007) (''[A]gency's rules unambiguously permit the ALJ to impose, as a discovery sanction, an order excluding evidence that a non-complying party wishes to introduce in support of its claim.''); *In re Bogese,* 303 F.3d 1362, 1367–68 (Fed. Cir. 2002) (Patent and Trademark Office, like other administrative agencies, may impose reasonable deadlines and requirements on parties appearing before it and has broad authority to sanction undue delay by holding a patent unenforceable); *Atlantic Richfield Co.* v. *U.S. Dep't of Energy,* 769 F.2d 771, 793 (D.C. Cir. 1984) (rejecting argument that administrative agency ''cannot impose evidentiary sanctions—of course, short of a fine or imprisonment—when necessary to preserve the integrity of an authorized adjudicative proceeding''). As the court of appeals in *Atlantic Richfield Co.* stated,

> It seems to us incongruous to grant an agency authority to adjudicate—which involves vitally the power to find the material facts—and yet deny authority to assure the soundness of the fact finding process. Without an adequate evidentiary sanction, a party served with a discovery order in the course of an administrative adjudicatory proceeding has no incentive to comply, and often times has every incentive to refuse to comply.

769 F.2d at 796. The adjudicatory duties of an ALJ are in many ways ''functionally comparable'' to those of a federal district court judge. *Butz* v. *Economou,* 438 U.S. 478, 513–14 (1978). It would be incongruous to deprive an ALJ of any procedural tools that assure the integrity and soundness of the adjudicative process. The tools include the authority to impose litigation sanctions that do not conflict with the substantive statute applicable to the proceeding for procedural violations that frustrate efficient administrative adjudication. The Department's ALJs used a broad range of sanctions for the nearly 30 years under the prior rules, including the dismissal of a claim or defense, as well as lesser evidentiary sanctions. *Curley* v. *Grand Rapids Iron & Metal Co.,* ARB No. 00–013, ALJ No. 1999–STA–39 (ARB Feb. 9, 1999) (affirming ALJ's authority to dismiss employment protection claim for abandonment, based on complainant's failure to participate in prehearing conference or reply to order to show cause why the matter should not be dismissed for failure to comply with a lawful order); *see also Dodd* v. *Crown Cent. Petroleum Corp.,* BRB No. 02–0821, slip op. at 9–10 (Ben. Rev. Bd. Aug. 7, 2003) (affirming the dismissal for abandonment of a pro se litigant's claim under the authority of 29 CFR 18.29(a), which affords ALJs ''all necessary powers to conduct fair and impartial hearings and to take any appropriate action authorized by the Federal Rules of Civil Procedure,'' where claimant failed to attend the final hearing, stated he would not participate, sustained objections to discovery the claimant sought, and denied the claimant's motion to recuse the ALJ); *Matthews* v. *LaBarge, Inc.,* ARB No. 08–038, ALJ No. 2007–SOX–56 (ARB Nov. 26, 2008) (adopting ALJ's decision to dismiss under 29 CFR 18.6(d)(2) because ALJ found that pro se complainant failed to comply with discovery orders repeatedly, willfully, intentionally, and in bad faith); *Administrator* v. *Global Horizons Manpower, Inc.,* ARB No. 09–016, ALJ No. 2008–TAE–3 (ARB Dec. 21, 2010) (affirming ALJ's order granting, as a discovery sanction under 29 CFR 18.6(d)(2)(v) and 18.29(a)(8), all the back pay and civil penalties the Administrator of the Wage and Hour Division had sought against employer for ''willful, contumacious disregard of the discovery process as well as disregard of the ALJ's multiple warnings and orders''); *Administrator* v. *Global Horizons, Inc.,* ARB No. 11–058, ALJ No. 2005–TAE–1 & 2005–TLC–6, 2013 WL 2450031, at *4–8 (DOL Admin. Rev. Bd. May 31, 2013) (affirming an ALJ's summary judgment awarding worker's back pay, repayment of impermissible deductions from pay, and awarding the Administrator civil penalties, which were based in large part on 145 factual allegations deemed admitted as the result of three orders that imposed sanctions for misconduct in discovery). *But see Goichochea* v. *Wards Cove*

Packing Co., 37 Ben. Rev. Bd. Serv. (MB) 4, 7 (2003) (holding that in a claim for Longshore disability compensation benefits, the remedy for disobeying an order compelling discovery is the procedure described in section 27(b) of the Longshore Act).

The Department kept in mind the limits on the authority of an administrative agency to impose sanctions when it fashioned the litigation sanction provisions. Section 558(b) of the APA, cited by some commenters, states that ''[a] sanction may not be imposed or a substantive rule or order issued except within the jurisdiction delegated to the agency and authorized by law.'' 5 U.S.C. 558(b); *see also Am. Bus. Ass'n* v. *Slater,* 231 F.3d 1, 7 (D.C. Cir. 2000) (holding that the Department of Transportation lacked statutory authority to require a bus company to pay monetary damages to disabled passengers they failed to accommodate); *Windhauser* v. *Trane,* ARB No. 05–127, OALJ No. 2005–SOX–17, 2007 WL 7139497, at *2–3 (DOL Admin. Rev. Bd. Oct 31, 2007) (reversing ALJs imposition of monetary sanctions against whistleblower complainant because such sanctions ''are, by statute, in the jurisdiction of the federal district courts''). The *Slater* court distinguished between sanctions that require express statutory authority under section 558(d) of the APA because they are directed at modifying ''primary conduct,'' such as a bus company's failure to accommodate disabled passengers, and litigation sanctions designed to protect the integrity of the agency's administrative processes. *Id.* The *Slater* court recognized an agency has ''a limited power to impose sanctions that are not expressly authorized by statute, but only ones designed to 'protect the integrity of its own processes.' '' *Id.* (quoting *Touche Ross & Co.* v. *SEC,* 609 F.2d 570, 582 (2d Cir. 1979)); *see also Davy* v. *SEC,* 792 F.2d 1418, 1421 (9th Cir. 1986). The provisions for the limited sanctions in the new rules are not directed to any party's primary conduct—which would be the subject matter of the proceeding—but to violations of procedural rules that compromise the integrity of the administrative hearing process. These litigation sanctions are consistent with the Department's regulatory authority under section 556(c)(5) of the APA, do not require additional express statutory authorization under section 558(b) of the APA, and do not amount to an exercise of Article III courts' contempt or sanction powers.

Remedial Purpose of Whistleblower Adjudications. The Department received a comment regarding whistleblower adjudications generally, which suggested that the procedural rules should reflect the remedial purpose of the whistleblower statutes under the OALJ's jurisdiction. The Department notes that the new rules are procedural rules intended to apply to all proceedings before OALJ and not any specific class of proceeding. To the extent a particular agency seeks the application of specific procedural rules, it is incumbent on that agency to incorporate such rules into its own regulations. For instance, proceedings under the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1132, define specific procedures at 29 CFR 2570, subpart C.

The Department received a similar comment suggesting that the OALJ ''should strive for better whistleblower protection than U.S. District Courts'' because the OALJ has garnered specialized knowledge and the process is less formal in an agency adjudication. The comment however did not offer any concrete proposal for changes to the text of the new rules. Any program-specific change moreover should be addressed to the particular agency charged with administering the particular program.

Effect on Pro Se Litigants. One commenter asserted that the new rules will make litigation of whistleblower claims harder on pro se parties. The commenter noted that, although the OALJ rules of practice and procedure are analogous to the FRCP, there are some differences: For example, whistleblowers do not ordinarily have to plead a claim through a complaint. The commenter remarked that the Administrative Review Board (ARB) and other appellate authorities have construed pro se complainants' positions liberally and with a degree of judicial latitude. The commenter also suggested that the Department's comments should make clear that decisions on the merits are the goal, and compliance with procedural rules should ''bend where necessary to meet that goal.''

The Department agrees that concerns relating to the ability of pro se litigants to submit and litigate complaints deserve consideration. As the ARB has enunciated, a pro se litigant's presumed lack of familiarity with litigation procedures may require accommodation. For example, a pro se litigant must be informed of the consequences of failing to respond to dispositive motions, *Motarjemi* v. *Metro. Council, Metro. Transit Div.*, ARB No. 08–135, ALJ No. 2008–NTS–2 (ARB Sept. 17, 2010), and an untimely filing may be considered, *Wallum* v. *Bell Helicopter Textron, Inc.,* ARB No. 12–110, ALJ No. 2009–AIR–20 (Sept. 19, 2012). The new rules provide uniform procedures for case management, but simultaneously permit judges the flexibility to tailor procedures to specific cases through appropriate orders. So, for example, where a pro se complainant requires additional guidance, under the new rule the judge may issue more focused or detailed orders, as necessary. The new rules provide more detailed procedural information (particularly regarding discovery and other pre-hearing requirements) than had been the case previously. The Department therefore declines to adopt the commenter's suggestion.

Discovery Rules Regarding Electronically Stored Information. One commenter voiced some general concerns that the rules should clarify issues related to discovery of electronically stored information (ESI), specifically providing that both sides have access to discovery of ESI and that ESI is treated the same as paper documents. The Department believes those concerns are adequately addressed in § 18.61, which states that there is no differentiation in the access to ESI or paper discovery. Thus, the rule provides the ALJ with the ability to manage discovery and minimize gamesmanship in discovery of both paper documents and ESI.

Electronic Filing. One commenter urged that the OALJ adopt and implement electronic case filing (ECF) or, in the alternative, allow facsimile filing and remove the maximum page limitation on faxes. Those concerns were also specifically raised in the comments to proposed § 18.30 and are fully addressed in that response. However, the general answer is that the implementation of ECF is a resource constrained policy decision. Until the Department implements ECF, promulgating rules about ECF would lead to confusion.

Offer of Judgment. One commenter suggested that the OALJ's rules should include one analogous to FRCP 68, Offer of Judgment, and should expressly cut off attorney's fees and other litigation costs when a claimant refuses an offer and fails to obtain a more favorable result.

The Department declines to adopt the commenter's suggestion. An offer of judgment is significant matter that could affect an otherwise successful complainant's right to recover attorneys' fees as costs. *Marek* v. *Chesny,* 473 U.S. 1 (1985). No analog to FRCP 68 appears in the OALJ's previous rules. The Department stated its intention to align

its procedural rules more closely with the FRCP, but did not give any notice that an offer of judgment rule was contemplated. The Department believes the final rule should not include an offer of judgment provision for three interrelated reasons.

First, doing so would not have given interested parties sufficient notice that such a rule was contemplated, and it is unclear that doing so now could be regarded a logical outgrowth of the rules proposed. *See* 5 U.S.C. 553(b)(3); *Ass'n of Private Sector Colls. & Univs.* v. *Duncan,* 681 F.3d 427, 461 (D.C. Cir. 2012). Second, the OALJ issues no judgments; it is not a court, although it shares many attributes with Article III federal courts. FRCP 68 would have to be substantially altered to adapt to the context of administrative adjudication, as there is no clerk who could enter a judgment in the way FRCP 68(a) contemplates (''The clerk must then enter judgment.''). Finally, FRCP 68 is subject to varying interpretations in the courts of appeals on how the defense should address attorney's fees in the text of an offer, when the substantive statute at issue directs the adjudicator to assess those fees as an item of costs. *See* Charles Alan Wright et al., Federal practice and Procedure § 3005.1 (3d ed. 2014). Any rule the Department adopts should make a choice between the competing theories, to make the rule nationally uniform, and as useful to litigants as possible. Those choices will not be made without the benefit of public comment.

III. Summary of Specific Comments on the Notice of Proposed Rulemaking

The Department received several comments regarding specific sections in the NPRM. Each comment is addressed as follows:

§ 18.10 Scope and purpose. One commenter expressed concern that the principles expressed in section 923 of the LHWCA, providing that the LHWCA hearing process is not bound by formal rules of evidence but conducted in a manner to best ascertain the rights of the parties, may be circumvented by procedural rules not addressed in the LHWCA and BLBA and respective implementing regulations. The commenter suggested part 18 explains what sections do not apply to LHWCA or BLBA proceedings ''to avoid confusion.'' Another commenter suggested adding a paragraph ''(d)'' to § 18.10, which would specifically state that in proceedings under the LHWCA and BLBA the following list of proposed rules would not apply: §§ 18.12, 18.23, 18.35, 18.50, 18.56, 18.57, 18.64, 18.70, 18.72, 18.80, and 18.87.

Future statutory and regulatory changes in the numerous administered programs, including the LHWCA, BLBA, employment discrimination, ''whistleblower'' and immigration cannot be foreseen. For instance, recent litigation has highlighted a BLBA-specific issue—one involving the disclosure of non-testifying expert opinions—that may deserve further consideration. *See generally Fox* v. *Elk Run Coal Co.,* 739 F.3d 131 (4th Cir. 2014). Nothing in these rules would prevent the Department from adopting a procedural rule that applies only in BLBA claim adjudications or other program-specific contexts. Moreover, listing variations in procedural requirements for the numerous programs in each new rule defeats the purpose of the new rules and would require constant rulemaking activity to reflect legislative changes. The Department thus disagrees with the submitted proposals to individually identify superseding statutory, regulatory or executive order provisions collectively in the new § 18.10 or separately in those new rules where a conflict may exist.

One commenter suggested that the lack of an appeal process in regard to a judge's decision to modify, waive or suspend a procedural rule in new § 18.10(c) ''appears arbitrary and capricious.'' The Department disagrees. First, while the case is at the OALJ, no rule may be waived, modified or suspended without notice to the parties. Second, doing so requires the judge to make two determinations: That the specific alteration of the rule ''will not prejudice a party,'' and ''will serve the ends of justice.'' Finally, a party may raise before the appropriate appellate authority on direct review of the final order any error in modifying a rule.

§ 18.12 Proceedings before administrative law judge. The Department combined the designation provisions of prior § 18.25 and the authority provisions of prior § 18.29(a). The Department specifically clarified in the NPRM that the enumerated powers mirrored those set forth in section 556 of the APA and that the enforcement provision of prior § 18.29(b) was deleted due to its contents of referring contumacious conduct to an appropriate federal court is set forth in applicable statutes, such as Section 927(b) of the LHWCA.

One commenter proposed that prior § 18.29(b) should not be deleted ''even though the content is contained in applicable statutes [because] this provision clearly delineates an administrative law judge's restricted powers, especially under statutes like the LHWCA.'' The Department disagrees with the comment that the provision on referring contumacious conduct to federal court should be retained in the new rules since controlling program statutes provide for such referral action when appropriate. *See, e.g.,* 20 CFR 725.351(c).

The commenter also proposed deleting § 18.12(b)(10) listing the authority of an ALJ to ''take actions authorized by the FRCP'' because the language would include all sanctions authorized by the FRCP and penalty sanctioning authority is reserved to the federal courts by the LHWCA and BLBA. Section 18.12(b)(10) was a succinct restatement of prior § 18.29(a)(8). The Department agrees that the brevity in which prior § 18.29(a)(8) was restated could be construed as excessively broad. To ensure consistency, the new § 18.12(b)(10) is rewritten to closely align with prior § 18.29(a)(8) by returning the words ''where applicable'' to the rule.

§ 18.22 Representatives. The Department narrowed the rule on representatives appearing before OALJ to reflect the two classes of representatives who routinely appear—attorneys and non-attorney representatives. The rule sets forth the qualifications required to appear as a representative of a party, the minimum duties required of a representative, and prohibited actions of any representative. One comment suggested that the proposed rule setting forth the qualifications for an attorney representative is overreaching and conflicts with 5 U.S.C. 500(b). That provision states in relevant part: ''An individual who is a member in good standing of the bar of the highest court of a State may represent a person before an agency on filing with the agency a written declaration that he is currently qualified as provided by this subsection and is authorized to represent the particular person in whose behalf he acts.'' *Id.* The commenter suggested nothing more should be required of an attorney representative seeking to represent a party before OALJ. The commenter believed that the proposed § 18.22 (a)–(d) imposed additional requirements inconsistent with 5 U.S.C. 500(b).

The Department has made revisions to the new rule in response to this comment. The Department deleted the following sentence from § 18.22(a): ''The notice of appearance shall also include the statements and documentation required for admission to appear for the applicable category of representation found in subdivision (b) of this section.''

The Department has added the following in its place: ''Any attorney representative must include in the notice of appearance the license registration number(s) assigned to the attorney.'' Essentially the only requirement that an attorney representative must follow in order to represent a party before the Department is to file a notice of appearance and include the appropriate attorney license registration number. Filing the notice of appearance by the attorney representative will constitute an attestation that: (a) The attorney is a member of a bar in good standing of the highest court of a State, Commonwealth, or Territory of the United States, or the District of Columbia; and (b) no disciplinary proceeding is pending against the attorney in any jurisdiction where the attorney is licensed to practice law. The Department has amended § 18.22(b)(1)(i) to reflect this change.

The Department disagrees with the comment that sections (c) and (d) conflict with 5 U.S.C. 500. Section (c) sets forth the minimum requirements expected of any representative during the course of a proceeding before the Department, and section (d) delineates prohibited actions of any representative appearing in a proceeding before the Department. Neither section prescribes any additional requirements for an attorney representative to appear on behalf of a party before the Department.

The Department set forth the minimum duties required of all representatives appearing before the OALJ in § 18.22(c). These duties originate from the rules of conduct and standards of responsibility imposed by the Social Security Administration (SSA) on representatives appearing before the SSA. *See* 20 CFR 404.1740(b). While the Department realizes that the non-adversarial nature of SSA hearings may require more detailed procedures, the basic duties included in the new rule are elementary to any hearing process and serve as a baseline foundation for conducting hearings promptly, efficiently, and fairly. The new rule also states that an attorney representative must adhere to the rules of conduct applicable where the attorney is licensed to practice law. In setting forth this standard, the Department understands that hearings often occur outside of a jurisdiction where an attorney may be licensed to practice law, and imposing an unfamiliar standard of conduct on an attorney would not be ideal.

One comment suggested that paragraph (c) should be stricken because requiring attorneys to adhere to the rules of conduct in their licensing jurisdictions ''could result in the different standards for the submission of evidence, discovery, and other substantive and procedural matters.'' The Department disagrees. Rules of professional conduct are generally considered rules of reason and should be interpreted with reference to the law itself. Different rules of conduct should not apply based on specific substantive or procedural law. At a minimum, attorneys should always be held to the standards of conduct where they are licensed to practice law. The Department declines to strike the paragraph.

The new rule also defines prohibited actions of all representatives appearing before the Department in paragraph (d). The prohibited actions include such things as: threatening, coercing or intimidating a party; knowingly making false or misleading statements; or causing unreasonable delay. These again derive from the SSA regulations. 20 CFR 404.1740(c). One comment suggested that the paragraph should be stricken because it adds confusion and may require attorneys to act contrary to the interests of their clients or the rules of conduct required by their licensing jurisdictions. The Department declines to strike the paragraph.

§ 18.23 Disqualification and discipline of representatives. The proposed rule contemplated two paths for disqualification and disciplinary proceedings of attorney representatives appearing before the OALJ. One path regulated lawyers who were authorized to practice before the Department through admission to the bar of the highest court of a state or similar governmental unit, but lost the right to practice law in their licensing jurisdiction because of a criminal conviction or proven professional misconduct. The second path involved misconduct of a representative before the OALJ. One comment questioned the Department's authority to initiate disciplinary proceedings at all. The NPRM spells out the Department's authority to discipline attorneys in great detail and need not be restated herein. The Supreme Court has recognized such authority as early as 1923 in a case involving the Board of Tax Appeals where it upheld the Board's power to adopt rules of practice for professionals to protect the integrity of its administrative procedures and the public generally. *See Goldsmith* v. *United States Bd. of Tax Appeals,* 270 U.S. 117 (1926). Other comments suggested that the wording of the rule was not clear and suggested that as drafted, it appeared that the OALJ would be making the initial determination as to whether an attorney had committed any enumerated criminal act or professional misconduct.

The Department considered the comments and has amended the rule by consolidating the grounds upon which an attorney or representative may be disqualified or disciplined into one section—new § 18.23(a)(1). New § 18.23(a)(1) now sets forth three distinct grounds for disqualification: (1) suspension of a license to practice law by any court or agency of the United States, or by the highest court of a State or similar governmental unit; (2) disbarment from the practice of law by consent or resignation from the bar of a court or agency while an investigation into allegations of misconduct is pending; or (3) committing an act, omission, or contumacious conduct that violates the procedural rules, an applicable statute, an applicable regulation, or a judge's order(s). Accordingly, the previous sections providing for disqualification upon conviction of a felony (proposed § 18.23(a)(1)(i)) or certain enumerated misdemeanors (proposed § 18.23(a)(1)(ii)) are removed from the new rule. Such conduct however may still be grounds for disqualification in the new rules to the extent that new § 18.23(a)(1)(i) through (iii) apply.

The Department also consolidated the disqualification and discipline procedure into one section—new § 18.23(a)(2). The new consolidated ''Disqualification procedure'' states that in all instances the Chief Judge provides notice and an opportunity to be heard prior to taking any action. The provision deletes language pertaining to requests for hearing but also recognizes that, in appropriate instances, additional proceedings may be necessary, within the Chief Judge's discretion.

Other comments questioned the timeline for disciplinary proceedings and the status of cases while disciplinary proceedings are pending against an attorney. The Department notes that the new rule contemplates a fast track with an initial response time of 21 days. The Department believes that the Chief Judge should have the discretion to decide whether an attorney can continue to represent a party before the Department during the pendency of any disciplinary proceeding on a case-by-case basis.

Two commenters suggested that the Department maintain a national database of non-attorney representatives disciplined by the Department. The Department declines to amend the part 18 regulations to establish such a database because OALJ already

publishes formal disciplinary decisions on its Web site in the same manner as other judge decisions. *See, e.g., In the Matter of the Qualifications of Edwin H. Rivera,* 2009–MIS–2 (ALJ Feb. 6, 2009) (denying non-attorney representative the authority to appear in a representative capacity before OALJ).

§ 18.24 Briefs from amicus curiae. The proposed rule sets forth the general procedure for accepting a brief from an amicus curiae. The Department received two comments suggesting that the deadline for an amicus brief is too short. The proposed rule required such briefs by the close of the hearing unless otherwise directed by the presiding judge. The comments pointed out that no transcript is immediately available when the hearing closes and it may be better for an amicus curiae to review the brief of the party the amicus supports to allow the amicus curiae to focus on new arguments. The Department considered the comments and agrees that setting the deadline at the close of the hearing is impractical. The Department has amended the new rule by deleting any specific deadline for an amicus brief, and instead states that the deadline will be set by the presiding judge.

The Department has also received comments suggesting that it require amicus curiae to make disclosures similar to those found in U.S. Supreme Court Rule 37.4. Such disclosures include whether counsel for a party authored any part of an amicus brief and the identity of anyone who made monetary contributions to the preparation of the brief other than the amicus curiae or its members. The Department declines to adopt the specialized disclosure requirements. Any specialized requirement can be considered by the presiding judge and made part of a briefing order depending on the facts of any particular case.

§ 18.30 Service and filing. Commenters suggested that the list of documents not to be filed until used in the proceeding or ordered by a judge (§ 18.30(b)(1)) should be amended to add the notice and copy of ''documents only'' subpoenas that are required to be served on other parties by § 18.56(b)(1). That suggested change is consistent with the purpose of both the prior and proposed rule and reflects current common practice. The new rule is thus changed to add paragraph (b)(1)(vi) with the following language: ''the notice (and the related copy of the subpoena) that must be served on parties under rule 18.56(b)(1) before a 'documents only' subpoena may be served on the person commanded to produce the material.''

Several commenters argued that the OALJ's rules do not adequately accommodate electronic filing and service, which is now commonplace in federal courts and adjudicatory agencies. Commenters urged that the OALJ adopt an electronic filing system, or at least adopt a more liberal stance toward accepting email and facsimile transmissions.

The Department acknowledges that implementation of a dedicated electronic filing system and electronic service system for OALJ adjudications would be beneficial. However, because the OALJ does not have a dedicated electronic filing and service system, the rules of practice and procedure necessarily focus on traditional filing and service.

Several commenters urged that, in the absence of the availability of electronic filing, OALJ accept documents filed by email. The Department declines to adopt a regulation that permits filing by email for routine filings with the OALJ. Email is not a substitute for a dedicated electronic filing system in which administrative issues such as document management, storage, security, and access can be systematically addressed. The proposed regulation at § 18.30(b)(4) accommodates special circumstances by authorizing the judge to ''allow papers to be filed, signed, or verified by electronic means.''

Alternatively, several commenters urged that the OALJ accept documents filed by facsimile transmission without a page limitation. The Department declines to adopt a regulation that permits filing by facsimile for routine filings with the OALJ. Facsimile technology is not a substitute for traditional mail or hand delivery of filings or for a dedicated electronic filing system. When § 18.3 of the prior rules was amended in 1994 to permit filing by facsimile in certain circumstances, the Department discussed why, although the use of facsimile machines is often convenient to parties, it is not administratively practical for routine matters. *See* Amendment of Filing and Service Requirements in Proceedings Before the Office of Administrative Law Judges, 59 FR 41874 (Aug. 15, 1994). Although information technology has advanced considerably since 1994, it is still true that most filings before the OALJ are not time sensitive and that the Department is not in a position to bear the cost of receiving and printing large numbers of facsimile transmissions. The new rule at § 18.30(b)(3)(i) accommodates special circumstances by allowing a party to file by facsimile if permitted by the judge.

One commenter stated a concern that a judge could reject a facsimile filing that exceeded 12 pages. The 12 page limitation stated in § 18.30(b)(3)(i)(A) is confined to situations in which the party is unable to obtain prior permission to file by facsimile because the judge is unavailable. The 12 page limitation is a sensible limitation to discourage reliance on last hour filings by facsimile. Thus, the Department declines to revise § 18.30(b)(3)(i)(A) to remove the 12 page limitation on facsimile filings made without the judge's permission.

One commenter suggested that the OALJ's rules of practice and procedure provide for electronic service between parties, stating that if a representative wishes to receive all service by email, that individual should be able to so state in the record and then receive all subsequent service by email. Section 18.30(a)(2)(ii)(E) already accommodates this suggestion. That regulation states that ''[a] paper is served under this section by . . . sending it by electronic means if the person consented in writing—in which event service is complete upon transmission, but is not effective if the serving party learns that it did not reach the person to be served . . . .''

One commenter stated that the rule, as written, creates a paradox that a time sensitive filing could be filed with the OALJ by facsimile, but served by mail on the opposing party. This commenter suggested that adopting a service requirement that allows for email service would resolve this problem. As noted above, the regulation permits parties to agree to receipt of service of papers by electronic means. The Department declines to revise the rule to require electronic service on another party in situations where the filing party was granted permission to file a paper with the OALJ electronically.

§ 18.31 Privacy protection for filings and exhibits. One commenter suggested that the privacy requirement should be inapplicable to any document created prior to the effective date of the final rule in BLBA cases. The commenter stated that medical records containing social security numbers and other protected information are created long before a claim is filed and it would be burdensome to redact this information.

The FRCP Advisory Committee noted in its comments to FRCP 5.2 that ''[i]t is electronic availability, not the form of the initial filing, that raises the privacy and security concerns addressed in the E-Government Act.'' Fed. R. Civ. P. 5.2 advisory committee's note (discussion of 2007 amendments). The FRCP focuses on electronic records, but applies the same restrictions to hard-copy documentation, reasoning that the

number of paper filings will diminish over time.

The Department declines to adopt the commenter's suggestion. The privacy interests of individuals whose personal records appear before the OALJ outweigh the burden placed on those who represent them. Many of these records can be scanned and searched for the sensitive information, reducing the time and effort required to complete this redaction. The commenter's suggestion that this rule apply only to records created after the effective date of the final rule would severely limit its utility. The parties may choose to waive the protection of the rule if it would be unduly burdensome to redact the records, or the parties may petition the judge for a waiver of the rule.

§ 18.32 Computing and extending time. Commenters noted that setting 4:30 p.m. as the default deadline for filing on a specific date is inconsistent with other rules of practice and sets a trap for the unwary practitioner who may reasonably expect that the deadline would be 11:59 p.m. They suggested changing the time to 11:59 p.m.

The FRCP allows for electronic filing up to 11:59 p.m., but still sets the close of local business hours as the deadline for hardcopy delivery. The commenters' suggestions primarily relate to online and facsimile filing. The OALJ continues to rely on hardcopy delivery as the default authorized means of filing and allows electronic or facsimile filing only as authorized by order or regulation. Since both e-filing and facsimile filing include time stamps that show exactly when a document arrived at the facsimile machine or server of the recipient, the office need not be open to determine when a document arrives. Since e-filing or facsimile filing is only allowed with the permission of the judge, counsel can request extended filing hours when they request permission to file in that manner. The Department therefore declines to adopt the suggestion.

Commenters also observed that the language at (a)(4) including as a legal holiday any other day declared a holiday by the President or Congress is overly broad and should be amended to include in the definition the provision that federal offices are closed to normal business. They suggested providing for extensions where a party is prevented from filing or requesting an extension by local circumstances, such as natural disasters or other events that require closure of government facilities.

FRCP 6(a)(3) addresses the problem by including a provision for the inaccessibility of the clerk's office. The new rules allow for judges to grant ex post facto delays in such cases. However, changing the term ''legal holiday'' to include any day on which the district office in which the document is to be filed is closed or otherwise inaccessible to the filing party would provide a clearer standard and avoid uncertainty over whether an ex post facto delay may be granted. The new rule is thus changed as follows:

(4) ''Legal holiday'' defined. ''Legal holiday'' means the day set aside by statute for observing New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, or Christmas Day, any day declared a holiday by the President or Congress, *and any day on which the office in which the document is to be filed is closed or otherwise inaccessible*.

§ 18.35 Signing motions and other papers; representations to the judge; sanctions. New § 18.35 is modeled after FRCP 11. It states the standards attorneys and parties must meet when filing motions or other documents with OALJ and provides sanctioning authority for violations of this section.

Several commenters pointed out that the LHWCA and BLBA contain specific statutory provisions dealing with resistance to an order, misconduct during hearings, and discovery violations. They suggest amending § 18.35(c) to state that the sanctions provisions are not applicable to LHWCA and BLBA cases. The Department declines to adopt the commenters' suggestion for the reasons detailed above in section II, ''*Conflicts with the LHWCA and BLBA*.''

Several commenters objected to § 18.35(c) in its entirety, suggesting that the section is essentially an attempt by the OALJ to exercise contempt power, which is limited to courts and may not be conferred upon administrative agencies. Section 18.35(c) however is not identical to FRCP 11(c)(4) and does not seek to invest OALJ judges with powers beyond the APA's grant of authority to impose appropriate sanctions where necessary to regulate and ensure the integrity of the hearing process. Thus, for the reasons detailed above in section II, ''*Authority to Regulate the Conduct of Administrative Proceedings; Sanctions,*'' the Department declines to delete § 18.35(c).

One commenter argued that there is no authority to hold a law firm jointly responsible for a violation committed by its partner, associate, or employee and failing to further define the circumstance that would justify an exception. The provision for law firm joint responsibility in § 18.35(c)(1) is taken directly from the corresponding federal rule, which was revised in 1993 after the U.S. Supreme Court ruled that the previous language could not be interpreted to include a named offender's firm. *Pavelic & LeFlore* v. *Marvel Entm't Grp.,* 493 U.S. 120 (1989). Thus, the provision is in accord with federal practice and the Department declines to strike or modify the provision in § 18.35(c)(1) concerning law firm joint responsibility.

One commenter observed that § 18.35(c)(4) provides no guidance as to what type of sanction ''suffices to deter repetition of the conduct or comparable conduct.'' The Department agrees that § 18.35(c)(4) should be amended to provide more specific guidance. Paragraph (c)(4) of the rule is revised, containing the following language: ''A sanction imposed under this section may include, but is not limited to, striking part or all of the offending document, forbidding the filing of any further documents, excluding related evidence, admonishment, referral of counsel misconduct to the appropriate licensing authority, and including the sanctioned activity in assessing the quality of representation when determining an appropriate hourly rate and billable hours when adjudicating attorney fees.''

§ 18.50 General provisions governing disclosure and discovery. Under the new rule, a party may seek discovery at any time after a judge issues an initial notice or order and, unless the judge on motion orders otherwise, the methods of discovery may be used in any sequence regardless of the discovery conducted by other parties. The parties' required initial disclosures would be made within 21 days after entry of an initial notice or order acknowledging that the case has been docketed for adjudication, and the rule includes a provision exempting certain proceedings and parties from the initial disclosure requirements. The Department received two comments focusing on the timing of disclosures and discovery in LHWCA and BLBA cases. One commenter urged that discovery should be available following transfer of the case to the OALJ or at any time upon stipulation of the parties, asserting that initial notices and orders have historically taken three months to issue and that discovery during this period of time will be unavailable under the new rule, resulting in unnecessary delay. This commenter also suggested that the timing for initial disclosures be set at 35 days following transfer of the case to the OALJ. Citing similar concerns about delay, the other commenter suggested that discovery should be available at any time after a claim is filed.

The Department disagrees with these proposals. The use of a judge's initial notice or order as the case event allowing parties to commence discovery promotes uniformity and predictability as it is the first reliable indication to the parties that the case is actually before the OALJ. The Department believes that use of the date of transfer from the District Director, Office of Workers' Compensation Programs is potentially confusing because this procedure is only applicable in LHWCA and BLBA cases. *See* 20 CFR 702.317, 725.421. The transfer or referral is an internal administrative function that lacks the clarity of the initial notice of order from the judge in terms of informing parties that a case has been docketed for adjudication. The Department further believes that allowing discovery at any time after a claim is filed is problematic as this would inevitably lead to development of discovery disputes before the case is assigned to a judge. While the Department is sensitive to the expressed concern regarding delays in the issuance of an initial notice or order, this is a matter that is better addressed through internal policy directives rather than creation of a special rule of procedure or exception. Finally, the Department believes that the new disclosure and discovery rules, taken as a whole, provide parties with sufficient flexibility to ensure that all authorized and appropriate discovery will be available prior to adjudication.

One comment raised a concern with the sequence of discovery in LHWCA cases by asserting that the logical first step is for a claimant to produce a medical report followed by the deposition of the report's author. The commenter suggested that the new rule could allow a claimant to manipulate the discovery process by delaying production of a medical report which might result in a respondent having insufficient time to identify a rebuttal expert. To blunt this potential tactic, the commenter proposed that the rule require a claimant to produce a medical report and disclose any experts early in the process. The Department believes that this concern is adequately addressed in the provisions of the rule governing disclosure of experts, *see* 29 CFR 18.50(c)(2)and through the judge's broad discretion to oversee disclosure and discovery in an impartial manner that affords all parties a full and fair opportunity to be heard. Moreover, adoption of this proposal would create a special rule, applicable only in benefit cases such as those arising under the LHWCA and BLBA, which is inconsistent with the Department's objective of promulgating a uniform set of procedural rules.

One comment proposes that pro se parties be included in the list of parties who are exempted from the required initial disclosures under paragraph (c)(1)(iii) unless an ALJ orders the party to provide disclosures. The Department rejects this proposal as inconsistent with the efficient, impartial and fair adjudication of cases. The FRCP provides no such exemption for pro se litigants aside from those persons in government custody. *See* Fed. R. Civ. P. 26(a)(1)(B)(iii). Having a separate set of rules for unrepresented parties or requiring a judge to provide them with legal guidance is inappropriate. *See Pik* v. *Credit Suisse AG,* ARB No. 11–034, ALJ No. 2011–SOX–6 (ARB May 31, 2012) (citing *Rays Lawn & Cleaning Sys.,* ARB No. 06–112, ALJ No. 2005–SCA–7 (ARB Aug. 29, 2008)); *Olsen* v. *Triple A Mach. Shops, Inc.,* 25 Ben. Rev. Bd. Serv. (MB) 40, 46 n.4 (1991), *aff'd mem. sub nom. Olsen* v. *Dir., OWCP,* 996 F.2d 1226 (9th Cir. 1993).

Two comments expressed a concern that it is burdensome and/or irrelevant to require an expert witness's written report to list all other cases in which the witness testified as an expert during the previous four years and the amount he or she was paid. *See* General Provisions Governing Disclosure and Discovery, 77 FR 72159 (proposed Dec. 4, 2014) (proposed § 18.50(c)(2)(ii)(E) and (F)). These commentators stated that parties are not likely to have this information. The Department disagrees. While the parties themselves may not have such information, surely an expert witness would. Moreover, the rule allows for an exception to this requirement where stipulated or ordered by the judge. This exception could be invoked in those unusual cases where the required information might not be reasonably obtainable. These requirements track FRCP 26(a)(2)(B), and the Department is not persuaded by these comments that any deviation in the OALJ rules is justified.

Two commenters urged adoption of a rule that would require parties to provide ESI in a searchable electronic format rather than paper copies when the requested information is available in electronic form. The commentators cited federal case law in support, stating that parties have been required to provide ESI in electronic format when requested in that form. While acknowledging the cited precedent, the Department rejects the proposal for a rule mandating production of ESI in electronic format whenever requested in that form. First, such a rule may violate the principle recognized in the NPRM that discovery of ESI should be proportional to what is at stake in the litigation. 77 FR 72146 (citing FRCP 26(b)(2)(C)(iii)) (citing The Sedona Conference, The Sedona Principles: Second Edition, Best Practices Recommendations & Principles for Addressing Electronic Document Production 17 (Jonathan M. Redgrave et al. ed., 2d ed. 2007) (''Electronic discovery burdens should be proportional to the amount in controversy and the nature of the case. Otherwise, transaction costs due to electronic discovery will overwhelm the ability to resolve disputes fairly in litigation.'')). Second, the proposal would override paragraph (b)(3)(iii), which is based on FRCP 26(f)(3)(C) making any issues about disclosure or discovery of ESI, including the form or forms in which it should be produced, a required item in discovery plans. This proposal also conflicts with § 18.51(b)(2) which, like FRCP 26(b)(2)(B) upon which it is based, provides that ESI discovery issues are to be determined by the judge on a motion to compel or for protective order. In sum, the Department's new rules on disclosure and discovery of ESI track the provisions in the FRCP which were developed after consideration of the competing interests at stake with regard to ESI, and the Department is not persuaded that a different approach is necessary or desirable in proceedings before the OALJ.

The Department received one comment concerning the timing of initial disclosures for parties who are served or joined later. The commenter proposed adding the following sentence to the end of paragraph (c)(1)(v): ''Copies of all prior disclosures shall be served on the newly joined party within 14 days of the joinder.'' Such an addition is helpful because it is common in LHWCA and BLBA cases for additional parties to be joined after the commencement of the OALJ proceeding. Therefore, the Department has added the following sentence to the end of paragraph (c)(1)(v) in the final rule: *Copies of all prior disclosures must be served on a newly served or joined party within 21 days of the service or joinder.*

Two comments advocated adoption of early discovery protocols similar to the pilot project that has been implemented by some federal district courts to streamline discovery and reduce costs in certain employment discrimination cases. *See* Federal Judicial Center, Pilot Project Regarding Initial Discovery Protocols for Employment Cases Alleging Adverse Action (2011), available at *www.fjc.gov/public/pdf.nsf/lookup/discempl.pdf/$file/discempl.pdf.* Incorporating a pilot

project designed for a limited class of cases into a set of uniform rules of practice and procedure is not desirable. To the extent such initiatives may be beneficial in certain cases, the Department has concluded that the determination to adopt such procedures is best left to the discretion of individual judges and/or discovery plans developed by parties pursuant to paragraph (b)(3).

One comment proposed that paragraph (d)(3) should be revised to explicitly state that it does not apply to LHWCA and BLBA proceedings because 33 U.S.C. 927(b) expressly provides a procedure (*i.e.,* certification of facts to a federal district court for summary contempt proceedings) for addressing discovery violations. A party's failure to comply with the certification requirements likely would not involve refusal to comply with an order and, therefore would not be cognizable as contempt subject to section 927(b). *See A–Z Intn'l* v. *Phillips,* 323 F.3d 1141, 1146–47 (9th Cir. 2003) (holding that the district court lacked section 927(b) jurisdiction over conduct that did not involve a refusal ''to comply with a summons, writ, warrant, or mandate issued by the ALJ.''). The Department therefore rejects this proposal and has not made any change to paragraph (d)(3).

§ 18.51 Discovery scope and limits. One comment suggested that the language of paragraph (a) defining the scope of discovery could be read as precluding discovery of prior medical records. The commenter focused this concern on the second sentence of the rule which states that ''the judge may order discovery of any matter relevant to the subject matter involved in the proceeding.'' The commenter preferred language limiting discovery to matters ''relevant to the subject matter of the proceeding'' and, alternatively, suggested that the record should clearly state that prior medical records are relevant to a party's claim or defense when medical questions are at issue. The Department rejects this proposal as essentially seeking a substantive determination that prior medical records are discoverable without limitation in all proceedings as long as there is some medical issue in play. While such records may well be relevant and discoverable in many cases where medical issues are raised, it is not difficult to foresee situations where production of a person's prior medical records might not be required. In the Department's view, determinations as to the scope of discovery with respect to specific categories of information cannot be properly addressed in a general procedural rule and, instead, must be left to case-by-case adjudication.

Another comment stated that the exceptions established by paragraph (d)(3)(i) through (iii) to the general rule embodied in paragraphs (c)(1) and (2) which protect against disclosure of communications between a party's representative and an expert witness are not adequate to ensure access to evidence of fraud, abuse or influence such as a party's attorney writing the expert's report. The commenter suggested that the exceptions should be broadened to ensure disclosure of such evidence or that paragraphs (c)(1) and (c)(2) should be eliminated. The Department's new rules addressing disclosure of communications between a party's representative and an expert track the provisions of FRCP 26(b)(3) and (4), which were revised in 2010. While the Civil Rules Advisory Committee stated that the revisions to FRCP 26 were intended to alter pre-amendment case law that required disclosure of all attorney-expert communications and draft reports in favor of limiting disclosure to communications of a factual nature in order to protect the theories and mental impressions of counsel, the Advisory Committee emphasized that the ''facts or data'' exception should be interpreted broadly to require disclosure of ''any facts or data 'considered' by the expert in forming the opinions to be expressed, not only those relied upon by the expert.'' Fed. R. Civ. P. 26 advisory committee's note (discussion of 2010 amendments); *see also Sara Lee Corp.* v. *Kraft Foods, Inc.,* 273 FRD. 416, 419 (N.D. Ill. 2011); *Fialkowski* v. *Perry,* No. 11–5139, 2012 WL 2527020, at *5 (E.D. Pa. Jun. 29, 2012) (holding that even if the requested documents are considered ''communications'' between a party's attorney and an expert within the meaning of FRCP 26(b)(4)(C), they are discoverable to the extent that they fall within the exceptions listed in FRCP 26(b) (4)(C)(ii) and (iii), for ''facts and data'' that the expert considered and for ''assumptions'' that the expert relied on). The Department believes that the rule adequately addresses the concern raised in the comment, and no change has been made in the final rule.

The Department received a comment stating that some of the commentary in the NPRM relating to limitations on the scope of discovery could lead judges to believe that limiting discovery is more important than providing whistleblower complainants with access to the evidence they need to prove their claims. This commenter pointed out that discovery is critical in whistleblower litigation where ''smoking gun'' evidence of unlawful motivation is rare, and he suggests that it would be helpful if the comments accompanying the final rule are balanced to recognize that while judges have discretion to limit unnecessary discovery, they also have a duty to enforce discovery when it is necessary to prove a relevant point. The commenter did not suggest any change in the proposed rule establishing the scope of discovery and its limits. The Department notes that the discussion of the changes in the disclosure and discovery rules in the NPRM contains several references to limitations on the scope of discovery which were necessitated by recent changes in the FRCP that were incorporated into the new § 18.51. However, the Department believes the new rule, like FRCP 26(b) upon which it is based, appropriately balances competing discovery interests.

Another commenter similarly suggested with respect to whistleblower cases that the rules should encourage early exchange of discoverable information, prompt resolution of discovery disputes and broad discovery of probative information. This commenter also did not advocate any particular change in the proposed rule. The Department believes that the new disclosure and discovery rules, taken as a whole, are designed to accomplish the commenter's recommended objectives in a fair and impartial manner. The Department further believes that adoption of special disclosure and discovery rules for a particular category of cases is neither necessary nor desirable as judges have discretion to resolve discovery disputes in a manner that is consistent with the requirements of the particular governing statute and implementing regulations. The Department therefore has not made any change to the new rules based on this comment.

§ 18.55 Using depositions at hearings. Two commenters suggested that the new rule should be revised to permit wider use of depositions at hearings. One commenter proposed addition of a paragraph that would permit unconditional use of depositions at hearings in the absence of any objection. The commenter submitted that this revision would better align the rule with current practice and procedure. Another commenter urged deletion of the requirement of showing unavailability as a pre-condition to the admission of deposition testimony from a lay or non-expert witness. This commenter asserted that the unavailability requirement is overly burdensome and particularly so for benefits claimants who have fewer

resources to pay witnesses to attend hearings. The Department agrees. Allowing unconditional use of depositions in the absence of an objection comports with current practice and procedure and reduces the potential financial burden of producing live witnesses on all parties. While the proponent of using the deposition of a non-expert witness at hearing would still be required to demonstrate unavailability in the face of an objection, the Department believes that the unavailability provisions of the rule, which track FRCP 32(a)(4), are sufficiently broad to minimize the burden of producing live witnesses. Accordingly, the new rule has been revised and renumbered to add a new paragraph allowing unconditional use of depositions at hearings in the absence of an objection.

§ 18.56 Subpoenas. The Department received two comments regarding the provisions of paragraph (a) relating to issuance of subpoenas. One of the commenters proposed that the rule state that any attorney authorized to practice under the rules may issue subpoenas and that the judge may issue subpoenas on written application of a non-attorney. The other comment urged that paragraph (a)(3), which would permit a judge by order in a specific proceeding to authorize an attorney representative to issue and sign subpoenas, be revised to exempt LHWCA and BLBA proceedings because 33 U.S.C. 927(a) expressly delegates subpoena issuance authority to judges who cannot sub-delegate such authority to persons outside the Department. The Department is persuaded by this latter argument that the authority to issue subpoenas should remain with the judge. The comment cited two cases—*FTC* v. *Gibson,* 460 F.2d 605 (5th Cir. 1972), and *United States* v. *Marshall Durbin & Co. of Haleyville,* 363 F.2d 1 (5th Cir. 1966),—where sub-delegation of statutory subpoena authority to subordinate employees of an agency was upheld based on reorganization plans, authorized by the Reorganization Act of 1949, 5 U.S.C. 901–*912,* that specifically provided for the challenged sub-delegation of subpoena power. *See also Lewis* v. *NLRB,* 357 U.S. 10, 14–15 (1958) (upholding sub-delegation of subpoena authority to the Board's regional directors). Unlike the cited cases, there is no reorganization plan under which the Department's judges have been authorized to sub-delegate statutory subpoena authority. Consequently, a question exists as to whether the sub-delegation authorized by paragraph (a)(3) would withstand legal scrutiny. The Department has therefore deleted paragraph (a)(3) from the new rule. This revision renders moot the concerns raised by the other commenter about the need for additional protective procedures to protect parties from abusive subpoena practices by parties' representatives in the event they were authorized to issue subpoenas.

The Department received a comment that paragraph (b)(1) dealing with service of subpoenas be revised to track a change in FRCP 45(a)(4), upon which the rule is patterned, that was recommended to the U.S. Supreme Court by the Committee on Rules of Practice and Procedure of the Judicial Conference of the United States in its report of September 2012. *See* Federal Rules of Practice & Procedure, Report of the Judicial Conference Committee on Rules of Practice and Procedure to the Chief Justice of the United States and Members of the Judicial Conference of the United States 23 (2012), available at *www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09–2012.pdf.* To maintain harmony with the FRCP, the commenter proposed that paragraph (b)(1) be amended to read as follows:

> *By whom; tendering fees; serving a copy of certain subpoenas.* Any person who is at least 18 years old and not a party may serve a subpoena. Serving a subpoena requires delivering a copy to the named person and, if the subpoena requires that person's attendance, tendering with it the fees for 1 day's attendance and the mileage allowed by law. Service may also be made by certified mail with return receipt. Fees and mileage need not be tendered when the subpoena issues on behalf of the United States or any of its officers or agencies. If the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before the formal hearing, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.

The Department adopts this proposal as consistent with the objective of bringing the OALJ rules of practice and procedure into alignment with the FRCP where appropriate. Paragraph (b)(1) in the final rule has been amended accordingly.

The Department received two additional comments regarding paragraph (b)(1). One commenter raised a concern that the phrase ''allowed by law'' is vague and should be replaced by a reference to the particular controlling law. The language in question is taken verbatim from FRCP 45(a)(4) and is intended to be interpreted in a manner consistent with the federal rule under which witness fees and expenses are currently controlled by 28 U.S.C. 1821. *See Dishman* v. *Cleary,* 279 FRD. 460, 466 (N.D. Ill. 2012); *Fisher* v. *Ford Motor Co.,* 178 FRD. 195, 197 (N.D. Ohio 1998). The Department does not believe that it is prudent to incorporate specific statutory references into the rule as statutory provisions are subject to change which would lead to potential confusion until the rule could be amended. Further, the Department notes that the discovery subcommittee to the Civil Rules Advisory Committee undertook an exhaustive survey of published commentary regarding FRCP 45. *See* Federal Rules of Practice & Procedure, Survey of Issues Regarding Federal Rule of Civil Procedure 45 (2009), available at *www.uscourts.gov/uscourts/RulesAndPolicies/rules/MemoreRule45issues.pdf.* Review of the survey discloses no published concern or comment or other criticism related to the use of ''allowed by law.''

The second commenter proposed a requirement that notice of a subpoena(s) relating to medical or financial information include a statement certifying that the information will not be used or disclosed for any purpose other than the litigation or proceeding for which the information was requested and will be destroyed or returned at the end of the litigation or proceeding. The commenter stated that this additional provision is necessary to protect against inadvertent disclosure of sensitive information. The Department rejects this proposal, noting that the handling of sensitive information obtained during discovery should be addressed in parties' discovery plans under § 18.50(b)(3) and that any unresolved issues relating to sensitive information may more appropriately be addressed by the judge on a case-by-case basis under the protective order procedures in § 18.52.

One commenter proposed that paragraph (c)(1), requiring a judge to impose an appropriate sanction on a party or representative who violates the duty to avoid imposing an undue burden on a person subject to a subpoena, be revised to explicitly state that it does not apply to LHWCA and BLBA proceedings which are subject to the summary contempt procedure established by 33 U.S.C. 927(b). The Department declines to adopt the commenter's suggestion for the reasons detailed above in section II, ''*Conflicts with the LHWCA and BLBA.*''

§ 18.57 Failure to make disclosures or to cooperate in discovery; sanctions. Two comments proposed revising the rule to specifically exempt LHWCA and BLBA cases from the sanction provisions which, the commenters

argued, are preempted by section 927(b) of the LHWCA. One of the commenters additionally argued that these sanction provisions violate the ''separation of powers'' doctrine by usurping contempt powers solely vested in the Article III courts. The Department declines to adopt the commenters' suggestions for the reasons detailed above in section II, ''*Conflicts with the LHWCA and BLBA.*''

§ 18.62 Physical and Mental Examinations. One commenter suggested that § 18.62(a)(1) should be amended to restrict an examination to the mental or physical ''condition in controversy.''

The Department declines to adopt the commenter's suggestion. The suggested text would offer no meaningful limit because the medical examiner does not know how the issues have been framed in litigation. The party who retains an examiner and notices the examination however knows the scope of the report it retains an examiner to prepare. The Department believes it is preferable to rely on the language taken from FRCP 35(a), which requires the party who notices an examination to specify the ''time, place, manner, conditions, and scope of the examination,'' and to disclose the ''person or persons who will perform it.'' The notice must also describe the examination in a way that informs the party to be examined of its scope. That party may object if the conditions or scope of the examination stray into areas that are not in controversy.

Two commenters argued that the final rule should retain the 30-day notice requirement found in previous § 18.19(4)(d). One commenter stated that the new 14-day notice requirement would unreasonably burden the claimant. Specifically, the shorter notice period would make it harder for the claimant to arrange for time off from work, travel plans, and other matters. The commenters also asserted that § 18.62(a)(4) would not give sufficient time to object to the examination notice with particularity. The person to be examined may have to consult with others (such as experts or a treating physician) to frame and serve a specific objection.

The Department agrees with the commenters' suggestions. Therefore, § 18.62(a)(3) is amended to provide a notice period of 30 days in advance of an examination when the parties do not agree to a shorter notice in their proposed discovery plan, by stipulation, or through informal discussion. Section 18.62(a)(4) is amended to extend the time to serve an objection from 7 days to 14 days.

One commenter suggested that the text of the rule on physical and mental examinations should mandate a three-step procedure before an examination can be noticed: (1) The parties must attempt to resolve all issues informally before an examination is noticed; (2) if agreement cannot be reached, the party that intends to notice an examination must request a telephone or other prehearing conference with the judge to discuss whether an examination is needed, and any specific procedure or limitations on the examination that may be appropriate; and (3) before the prehearing conference, the party proposing the examination must state with particularity why the examination is needed, why the deposition of the party to be examined is insufficient to address the issues the examination would address, and describe what will occur at the examination.

The Department declines to adopt the commenter's proposal. First, the parties ordinarily should have discussed whether an examination is appropriate, and its scope, when they frame the proposed discovery plan early in the case, just as happens in the U.S. district courts. Second, the claims at the OALJ frequently involve a physical or mental condition that serves as one of the bases raised for relief—an issue that is litigated less often in U.S. district courts. It makes sense therefore for the default assumption in the rules to be that an examination is appropriate in cases before the OALJ, even though FRCP 35 allows such examinations only upon motion for good cause before the U.S. district courts.

One commenter suggested that § 18.62(c)(1) be amended to require that the examination report (1) be delivered to the examined party within 21 days, (2) be delivered no fewer than 45 days before the hearing, and (3) fulfill the requirements of expert testimony found in proposed § 18.50(c)(2)(ii) [required for witnesses who must provide a written report].

The Department declines to adopt these additional requirements. Section 18.62 establishes a procedure to set an examination. It should not be conflated with the separate disclosures a party must make before final hearing, particularly about the testimony of experts. The examiner may not be a trial witness. The examination report may be only a portion of the data an expert witness who testifies at final hearing rely on to reach an opinion. Section 18.50(c)(2)(ii) has an independent effect. With respect to the timing of reports, the parties should build into the discovery plan an appropriate period for the examiner to write and serve a report, which can be incorporated into a prehearing order. To ensure the party examined has the examination report promptly, however the Department agrees that the party who retained the examiner and receives the examination report must serve a copy of the examination report on the party examined no later than seven days after it receives the report.

§ 18.64 Depositions by oral examination. One commenter asserted that an ALJ cannot impose the sanctions enumerated in § 18.57 in LHWCA and BLBA adjudications for the types of misconduct described in § 18.64(d)(2) and (g). Therefore, the commenter suggested that the Department add an exception to the rules for these cases. The Department declines to amend § 18.64 to provide such an exception for the reasons detailed above in section II, ''*Authority to Regulate the Conduct of Administrative Proceedings; Sanctions*'' and ''*Conflicts with the LHWCA and BLBA.*''

§ 18.64 Depositions by oral examination and *§ 18.65 Depositions by written questions.* One commenter stated that proposed §§ 18.64 and 18.65 refer to an ''officer,'' but do not clarify the ''officer's'' relations to the deposition proceeding. FRCP 30(b)(5) and 31(b) use the term ''officer'' to describe the court reporter who administers the oath, takes and certifies the testimony, states that the deposition is complete when it ends, and reads the written deposition questions. The Department agrees with the commenter that the title to §§ 18.64(b)(5) and 18.65(b) should be altered to clarify that the ''officer'' is the ''deposition officer.''

§ 18.70 Motions for dispositive action. One commenter objected generally to the use of motions to dismiss in proceedings where there are shifting burdens of proof or where the claimant benefits from legal presumptions. The commenter argued specifically that § 18.70(c) should be stricken or made not applicable to cases under the LHWCA because such a rule would require claimants to plead with more specificity than required under the Act, and noted that an injury and timely filing are presumed. The Department declines to strike or modify § 18.70(c). That section states that a party is permitted to move to dismiss part or all of the matter ''for reasons recognized under controlling law.'' The new section is not intended to modify existing law controlling the standard for dispositive motions, including motions challenging the sufficiency of a pleading. Moreover, § 18.10(a) states that ''[t]o the extent that these rules may be inconsistent with a governing statute, regulation, or

executive order, the latter controls.'' Thus, a party's motion to dismiss under § 18.70(c) does not upset any statutory or regulatory presumptions or shifting burdens of proof.

§ 18.72 Summary decision. One commenter argued for the development of a rule that would allow ALJs to enter summary decision in a condensed order that is compliant with the APA, but which does not require a complete recitation of all evidence. The commenter argued that such a summary ruling would minimize judges' workload and allow for quicker adjudications. The commenter suggested that the rules permit such a summary ruling upon agreement of the parties because without such a provision in the rules, parties will have concerns about whether such an order would be deemed deficient by the BRB. Because the APA specifies what must be included in an ALJ's decision and order, the Department declines to modify § 18.72 to provide for a condensed decision on summary decision. Section 18.72(a) provides that the judge should state on the record the reasons for granting or denying a motion for summary decision or partial summary decision.

Two commenters stated that the use of summary adjudications is inconsistent with the goal of fair administrative proceedings for whistleblowers and should be rarely, if ever, used. The commenters argued that summary decisions based on written submissions favor employers over employees and increase costs. The commenters argued that summary decisions deprive the ALJ of the opportunity to determine the credibility of the witnesses, which is important in cases where motive and intent are critical issues. The commenters recommended that § 18.72 state that summary judgment is generally considered inappropriate in administrative proceedings.

The Department declines to revise § 18.72 to state that summary decision is inappropriate in administrative proceedings, in general, or in whistleblower proceedings, in particular. The utility of a summary decision procedure for agencies having a substantial caseload of formal adjudications has long been recognized. *See* Summary Decision in Agency Adjudication,1 CFR 305.70–3 (1995) (ACUS Recommendation 70–3, available at *www.acus.gov/sites/default/files/documents/70–3.pdf*). Section 18.72 is a procedural rule applicable to the many types of adjudications conducted by the OALJ, and is neutral on the question of whether summary decision as a procedural mechanism is disproportionately adverse to the interests of whistleblower complainants. Any rulemaking proposing a regulation discouraging summary decision in whistleblower cases is within the responsibility and purview of the agency which has programmatic and policy responsibility over whistleblower cases, and not the OALJ, whose role is adjudicatory. Moreover, the ARB has issued several decisions that provide ample guidance to the public and to judges on the standards specific to summary decision motions in whistleblower cases. *See Evans* v. *E.P.A.,* ARB No. 08–059, ALJ No. 2008–CAA–3 (ARB Apr. 30, 2010); *Hasan* v. *Enercon Serv., Inc.,* ARB No. 10–061, ALJ Nos. 2004–ERA–22 and 27 (ARB July 28, 2011); *Lee* v. *Parker-Hannifin Corp., Advanced Prod. Bus. Unit,* ARB No. 10–021, ALJ No. 2009–SWD–3 (ARB Feb. 29, 2012); *Franchini* v. *Argonne Nat'l Lab.,* ARB No. 11–006, ALJ No. 2009–ERA–14 (ARB Sept. 26, 2012); *see also Guillory* v. *Domtar Indus.,* 95 F.3d 1320, 1326 (5th Cir. 1996) (''Though summary judgment is rarely proper when an issue of intent is involved, the presence of an intent issue does not automatically preclude summary judgment; the case must be evaluated like any other to determine whether a genuine issue of material fact exists.'').

Another commenter objected that motions for summary judgment allow cases to be framed by the party that does not have the burden of proof at trial, and that under § 18.72, the moving party gets the last word. The commenter described complainants being ''sandbagged'' by primary briefs that provide abbreviated or unclear statements of facts or arguments, which are tactically written to prevent cogent or complete responses. Then, complainants are faced with reply briefs that clarify or even add arguments and provide additional authorities in support of those arguments. The commenter stated that many circuit courts deal with this problem by allowing surreply briefs, or by expressly limiting reply briefs to the four corners of the arguments made by the non-moving party in opposition to summary judgment. Thus, the commenter suggested a rule that specifically allows for a surreply, makes clear that the reply and surreply may only respond to material in the opposing submission, and states that all ''new'' material be disregarded by the court.

The Department declines to revise § 18.72 to expressly allow surreply briefs, or to expressly limit reply briefs to the four corners of the arguments made by the non-moving party in opposition to summary judgment. OALJ judges have the power necessary to conduct fair and impartial proceedings, and are capable of dealing with a parties' raising of new arguments in reply briefs without a specific rule. For example, in *Du Jardin* v. *Morrison Knudsen Corp.,* 1993–TSC–3 (ALJ Nov. 29, 1993), the ALJ refused to consider new arguments raised by the respondent in a reply brief to the complainant's response to the respondent's motion for summary decision. In *Inman* v. *Fannie Mae,* 2007–SOX–47 (ALJ Mar. 5, 2008), *rev'd and remanded on other grounds, Inman* v. *Fannie Mae,* ARB No. 08–060, ALJ No. 2007–SOX–47 (ARB June 28, 2011), the ALJ permitted the complainant to file a surreply on a motion for summary decision. The Department notes that under FRCP 56, on which § 18.72 is modeled, there is no right to file a surreply. Although the commenter stated that many circuit courts allow surreply briefs, it did not identify those circuits. Our review of federal appellate court rules and circuit court local rules found that the rules generally do not mention surreply briefs, or only allow them upon leave of the court. *See, e.g.,* Dist. N.M. Local R. Civ. P. 7.4(b) (2013); Dist. N.H. Local R. 7.1e(3) (2013).

Two commenters suggested that the timing aspects of § 18.72 will be troublesome for whistleblower complainants, for whom the efficiency and cost of opposing motions for summary judgment is of paramount importance. Motions for summary decision are usually filed by respondents, and consequently, when such motions are filed near to the hearing date, complainants are disadvantaged because they are severely burdened by the need to respond to the motion and prepare for the evidentiary hearing within a short time period. The commenters recommended that: (1) Substantive summary motions aimed at eliminating claims or types of damages should be filed no later than 90 days prior to a hearing date; (2) counsel responding to such motions should have 21 to 30 days to file their responsive pleadings; and (3) all such motions should be resolved at least 30 days prior to a hearing date.

The Department declines to revise § 18.72 to require summary decision motions be filed no later than 90 days prior to a hearing date. Prior § 18.40(a) provided that a party may file a motion for summary decision at least 20 days before the date fixed for any hearing. With the new § 18.72, the Department increased the timeframe for filing motions for summary decision to 30 days before the date fixed for the formal

hearing. In the OALJ's experience, this timeframe would generally afford sufficient time for all parties and the judge to address the motion. As noted in the new § 18.10(a), the OALJ rules of practice and procedure are to be administered to secure the just, speedy, and inexpensive determination of every proceeding. In whistleblower cases, in particular, the regulations direct that hearings are to commence expeditiously. *See, e.g.,* 20 CFR 1979.107(b). Moreover, if necessary, § 18.72 gives the ALJ the discretion to adjust deadlines, as appropriate.

One comment argued that § 18.72(h) should be revised to explicitly state that it does not apply in proceedings under the LHWCA and the BLBA because 33 U.S.C. 927(b) expressly provides a procedure (*i.e.,* certification of facts to a federal district court for summary contempt proceedings) for resistance of a lawful order, misconduct during hearings, and discovery violations. The commenter thus argued that the sanctions listed in the § 18.72(h) are unavailable to ALJs presiding in hearings under the LHWCA or BLBA. The Department declines to adopt the commenters' suggestion for the reasons detailed above in section II, ''*Conflicts with the LHWCA and BLBA*.''

§ 18.80 Prehearing statement. The Department added a requirement that a participating party file a prehearing statement at least 21 days prior to the date set for hearing. Prior § 18.7 did not have a requirement for filing prehearing statements.

A commenter proposed that the time for filing the prehearing statement be extended to 45 days prior to hearing to allow the parties time to ascertain if additional discovery is needed, and to prevent the need for continuances to conduct discovery on witnesses and evidence not timely disclosed. The commenter argued that the additional time will preclude post trial depositions to rectify untimely disclosed information. The Department declines to extend the date for submission of the prehearing statement and notes that the rule allows for the judge to order a different time frame, if appropriate.

A commenter objected to the statement in the NPRM that the Department proposed to add a new regulation at § 18.80(e) requiring a party to file objections to an opposing party's proposed exhibits or use of deposition testimony within 14 days of being served, and that failure to object waives an objection unless the judge finds good cause for failure to object. The NPRM is in error. The new rule does not include such a provision.

§ 18.84 Official notice. The Department clarifies procedures in § 18.84 that a judge may follow when taking judicial notice. The rule provides that official notice may be taken of any adjudicative fact or other matter subject to judicial notice, and the parties must be given an adequate opportunity to show the contrary of the matter noticed.

A commenter objected to a practice by ALJs in BLBA claims of taking official notice of the Dictionary of Occupational Titles (4th ed. Rev. 1991). He contended that such practice invades upon the province of a medical expert who must consider job duties and tasks in assessing whether a pulmonary impairment would or would not prevent the performance of such tasks. Although the Department agrees with the commenter that a matter subject to judicial notice is a matter whose accuracy cannot be reasonably questioned, it declines to identify specific matters for which official notice is not appropriate. The rule states that parties must be given an adequate opportunity to show the contrary of the matter noted. The Department accordingly declines to amend this provision.

§ 18.87 Standards of conduct. The Department relocated the prior § 18.36 to § 18.87 and divided the prior paragraph (b) into two paragraphs: (b) *Exclusion for misconduct,* and (c) *Review of representative's exclusion.* A commenter contended that the rule should be revised to explicitly state that § 18.87 does not apply in proceedings under the LHWCA and BLBA. The commenter reasoned that rules of procedure apply only to the extent that they are consistent with the BLBA or its implementing regulations, and since the LHWCA and BLBA contain a specific statutory provision dealing with the resistance of an order, misconduct during hearings, and discovery violations, 33 U.S.C. 927(b), the sanction provisions under either the Rules of Practice and Procedure before the OALJ or the FRCP do not apply. The commenter also objected to the rule because Congress did not vest the OALJ with contempt powers. The Department declines to adopt the commenters' suggestion for the reasons detailed above in section II, ''*Conflicts with the LHWCA and BLBA*.''

§ 18.88 Transcript of proceedings. Section 18.88(b) of the new rule states that motions to correct the official transcript must be filed within 14 days of the receipt of the transcript unless the judge permits additional time. A commenter suggested that motions to correct be filed seven days after filing of the post-hearing brief. The commenter reasoned that attorneys typically review the transcript as they write the brief, and that counsel can be more helpful in this regard after they have reviewed the transcript in preparation for their brief. The Department declines to extend the date for motions to correct. The Department contemplates that parties would have a corrected transcript at the time they prepare their brief. Also, the rule allows for correction of errors discovered during preparation of a brief, as the rule provides that a judge may correct errors in the transcript at any time before issuing a decision and upon notice to the parties.

§ 18.92 Decision and order. The Department revised the prior § 18.57 into two sections, § 18.91, Post-hearing Briefs; and § 18.92, Decision and Order. The language that the Department deleted stated that the ALJ was to issue a decision within a ''reasonable time'' after receiving the parties' filings or within 30 days after receiving the parties' consent findings. Two commenters submitted concerns about the new § 18.92. They observed that, under the current practice, parties ''have no mechanism or ability to know when decisions will be issued,'' and expressed concern that delays adversely impact both employers and employees. The Department has determined that questions about how long it takes the OALJ's judges to issue their decisions are best handled as matters of policy and resource allocation. The Department therefore declines to adopt the commenters' suggestions that § 18.92 be amended to include a timeframe for issuance of a judge's decision.

§ 18.93 Motion for reconsideration. The prior rule contained no general provision on motions for reconsideration of decisions and orders. The Department added a new provision stating that motions for reconsideration of a decision and order must be filed within 10 days after service of the decision on the moving party.

One commenter suggested that the provision be amended to permit motions for reconsideration to be filed within 30 days, instead of the 10 days in the new rule. The commenter stated that the BLBA regulation permits such motions to be filed within 30 days. 20 CFR 725.479(b). In the commenter's view, its proposal will provide for uniformity among all types of cases. The commenter also indicated that a longer time period for such motions will obviate the need to submit motions for extensions of time to file motions for reconsideration, and will provide practitioners and their clients with sufficient time to make informed

decisions about whether to even file motions for reconsideration. Broad motions aimed at all issues will thus be avoided and the resulting burden on ALJs will be reduced.

As the commenter correctly indicated, and as mentioned in the NPRM, the new rule is modeled after FRCP 59(e), which gives parties 28 days from the date of entry of a judgment to file a motion to alter or amend the judgment. A motion for reconsideration may be filed in BLBA cases within 30 days. 20 CFR 725.479(b). Compensation orders in LHWCA cases similarly are final 30 days after filing unless other proceedings are instituted.

The Department considered other timeframes for motions for reconsideration that were more in line with FRCP 59(e) or 20 CFR 725.479(b). However, some of the Department's regulations pertaining to specific statutes within the OALJ's purview state that the ALJ's decision and order is final, unless a petition for review is filed with the ARB within a specific time, less than 30 days from service of the ALJ's decision and order. *See, e.g.,* 29 CFR 1978.109(e)(specifying 14 days for cases under the Surface Transportation Assistance Act); 29 CFR 1980.110(e) (specifying 10 days for cases under the Sarbanes-Oxley Act); 29 CFR 1992.110(a)(specifying 10 days for cases under the National Transit Systems Security Act/Federal Railroad Safety Act). Permitting a party to move for reconsideration after the date that a petition for review must be filed with the ARB would be inconsistent with the Department's position regarding finality of ALJ decisions in such cases. Additionally, if the deadline for submitting a motion for reconsideration is after the deadline for submitting a petition for review, if a motion for reconsideration is not submitted, a party may thereby inadvertently foreclose its options regarding appeal. The Department therefore declines to adopt the commenter's suggestion regarding the number of days within which motions for reconsideration can be filed.

IV. Cross Referencing Chart

To assist in the transition to the revised Subpart A, the chart below provides cross references between the new section and section title, and the old section and section title of each rule. The chart also provides cross references to the corresponding FRCP rule, where applicable. Finally, the chart lists the sections from the old Subpart A that have been deleted.

Part 18, Subpart A—Cross Referencing Chart

New section	New section title	Old section	Old section title	Federal Rule of Civil Procedure
		General Provisions		
18.10	Scope and purpose	18.1/18.26	Scope of rules and conduct of hearings	Fed. R. Civ. P. 1.
18.11	Definitions	18.2	Definitions.	
18.12	Proceedings before administrative law judge.	18.25/18.29(a)	Proceedings before administrative law judge/authority of the administrative law judge.	
18.13	Settlement judge procedure	18.9	Consent order or settlement; settlement judge procedure.	
18.14	Ex parte communication	18.38	Ex parte communications.	
18.15	Substitution of administrative law judge	18.30	Unavailability of administrative law judge.	Fed. R. Civ. P. 63.
18.16	Disqualification	18.31	Disqualification.	
18.17	Legal assistance	18.35	Legal assistance.	
		Parties and Representatives		
18.20	Parties to a proceeding	18.10	Parties, how designated.	
18.21	Party appearance and participation	18.39/18.34(a)	18.39, Waiver of right to appear and failure to participate or to appear—text was incorporated into proposed "participation" rule.	
18.22	Representatives	18.34	Representatives.	
18.23	Disqualification of representatives.			
18.24	Briefs from amicus curiae	18.12	Amicus curiae.	
		Service, Format and Timing of Filings and Other Papers		
18.30	Service and filing	18.3	Service and filing	Fed. R. Civ. P. 5.
18.31	Privacy protection for filings and exhibits.			Fed. R. Civ. P. 5.2.
18.32	Computing and extending time	18.4	Time computations	Fed. R. Civ. P. 6.
18.33	Motions and other papers	18.6	Motions and requests	Fed. R. Civ. P. 7(b) & 43(c).
18.34	Format of papers filed.			
18.35	Signing motions and other papers; representations to the judge; sanctions.			Fed. R. Civ. P. 11.
18.36	Amendments after referral to the Office of Administrative Law Judges.	18.5	Responsive pleadings—answer and request for hearings.	
		Prehearing Procedure		
18.40	Notice of hearing	18.27	Notice of hearing.	
18.41	Continuances and changes in place of hearing.	18.28	Continuances.	
18.42	Expedited proceedings	18.42	Expedited proceedings.	
18.43	Consolidation; separate hearings	18.11	Consolidation of hearings	Fed. R. Civ. P. 42.

New section	New section title	Old section	Old section title	Federal Rule of Civil Procedure
18.44	Prehearing conference	18.8	Prehearing conferences	Fed. R. Civ. P. 16.
	Disclosure and Discovery			
18.50	General provisions governing disclosure and discovery.			Fed. R. Civ. P. 26 (a), (d), (f), (g).
18.51	Discovery scope and limits	18.14	Scope of discovery	Fed. R. Civ. P. 26 (b).
18.52	Protective orders	18.15	Protective orders	Fed. R. Civ. P. 26 (c).
18.53	Supplementing disclosures and responses.	18.16	Supplementation of responses	Fed. R. Civ. P.26 (e).
18.54	Stipulations about discovery and procedure.	18.17	Stipulations regarding discovery	Fed. R. Civ. P. 29.
18.55	Using depositions at hearings	18.23	Use of depositions at hearings	Fed. R. Civ. P. 32.
18.56	Subpoena	18.24	Subpoenas	Fed. R. Civ. P. 45.
18.57	Failure to make disclosures or to cooperate in discovery; sanctions.	18.21	Motion to compel discovery	Fed. R. Civ. P. 37.
	Types of Discovery			
18.60	Interrogatories to parties	18.18	Written interrogatories to parties/	Fed. R. Civ. P. 33.
18.61	Producing documents, electronically stored information, and tangible things, or entering onto land, for inspection and other purposes.	18.19	Production of documents and other evidence; entry upon land for inspection and other purposes; and physical and mental examination.	Fed. R. Civ. P. 34.
18.62	Physical and mental examinations	18.19	Production of documents and other evidence; entry upon land for inspection and other purposes; and physical and mental examination.	Fed. R. Civ. P. 35.
18.63	Requests for admission	18.20	Admissions	Fed. R. Civ. P. 36.
18.64	Depositions by oral examination	18.22	Depositions by oral examinations	Fed. R. Civ. P. 30.
18.65	Depositions by written questions			Fed. R. Civ. P. 31.
	Disposition Without Hearing			
18.70	Motions for dispositive action.			
18.71	Approval of settlement or consent findings.	18.9.		
18.72	Summary decision	18.40/18.41	18.40, Motion for summary decision *merged with* 18.41, Summary decision.	Fed. R. Civ. P. 56.
	Hearing			
18.80	Prehearing statement	18.7	Prehearing statements.	
18.81	Formal hearing	18.43	Formal hearings	Fed. R. Civ. P. 43(a).
18.82	Exhibits	18.47/18.48 18.49/18.50.	Exhibits/records in other proceedings/ designation of parts of documents/ authenticity.	
18.83	Stipulations	18.51	Stipulations.	
18.84	Official notice	18.45	Official notice.	
18.85	Privileged, sensitive, or classified material.	18.46/18.56	In camera and protective orders/restricted access.	
18.86	Hearing room conduct	18.37	Hearing room conduct.	
18.87	Standards of conduct	18.36	Standards of conduct.	
18.88	Transcript of proceedings	18.52	Record of hearings.	
	Post Hearing			
18.90	Closing the record; subsequent motions.	18.54/18.55	Closing the record /receipt of documents after hearing.	
18.91	Post-hearing brief	18.57	Decision of the administrative law judge and post-hearing briefs.	
18.92	Decision and order	18.57	Decision of the administrative law judge and post-hearing briefs.	
18.93	Motion for reconsideration			Fed. R. Civ. P. 59 (e).
18.94	Indicative ruling on a motion for relief that is barred by a pending petition for review.			Fed. R. Civ. P. 62.1.
18.95	Review of Decision	18.58	Appeals.	
	Deleted Sections			
	Deleted	18.13	Discovery methods.	
	Deleted	18.32	Separation of functions.	

New section	New section title	Old section	Old section title	Federal Rule of Civil Procedure
	Deleted	18.33	Expedition.	
	Deleted	18.53	Closing of hearings.	
	Deleted	18.59	Certification of official record.	

List of Subjects in 29 CFR Part 18

Administrative practice and procedure, Labor.

Signed: At Washington, DC, this 7th of May, 2015.

Thomas E. Perez,

Secretary of Labor.

For the reasons set forth in the preamble, amend part 18 of title 29 of the Code of Federal Regulations as follows:

PART 18—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE THE OFFICE OF ADMINISTRATIVE LAW JUDGES

■ 1. The authority citation for part 18 continues to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. 551–553; 5 U.S.C. 571 note; E.O. 12778; 57 FR 7292.

■ 2. Revise subpart A to read as follows:

Subpart A—General

Sec.

General Provisions

18.10 Scope and purpose.
18.11 Definitions.
18.12 Proceedings before administrative law judge.
18.13 Settlement judge procedure.
18.14 Ex parte communication.
18.15 Substitution of administrative law judge.
18.16 Disqualification.
18.17 Legal assistance.

Parties and Representatives

18.20 Parties to a proceeding.
18.21 Party appearance and participation.
18.22 Representatives.
18.23 Disqualification of representatives.
18.24 Briefs from amicus curiae.

Service, Format, and Timing of Filings and Other Papers

18.30 Service and filing.
18.31 Privacy protection for filings and exhibits.
18.32 Computing and extending time.
18.33 Motions and other papers.
18.34 Format of papers filed.
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18.36 Amendments after referral to the Office of Administrative Law Judges.

Prehearing Procedure

18.40 Notice of hearing.
18.41 Continuances and changes in place of hearing.
18.42 Expedited proceedings.
18.43 Consolidation; separate hearings.
18.44 Prehearing conference.

Disclosure and Discovery

18.50 General provisions governing disclosure and discovery.
18.51 Discovery scope and limits.
18.52 Protective orders.
18.53 Supplementing disclosures and responses.
18.54 Stipulations about discovery procedure.
18.55 Using depositions at hearings.
18.56 Subpoena.
18.57 Failure to make disclosures or to cooperate in discovery; sanctions.

Types of Discovery

18.60 Interrogatories to parties.
18.61 Producing documents, electronically stored information, and tangible things, or entering onto land, for inspection and other purposes.
18.62 Physical and mental examinations.
18.63 Requests for admission.
18.64 Depositions by oral examination.
18.65 Depositions by written questions.

Disposition Without Hearing

18.70 Motions for dispositive action.
18.71 Approval of settlement or consent findings.
18.72 Summary decision.

Hearing

18.80 Prehearing statement.
18.81 Formal hearing.
18.82 Exhibits.
18.83 Stipulations.
18.84 Official notice.
18.85 Privileged, sensitive, or classified material.
18.86 Hearing room conduct.
18.87 Standards of conduct.
18.88 Transcript of proceedings.

Post Hearing

18.90 Closing the record; subsequent motions.
18.91 Post-hearing brief.
18.92 Decision and order.
18.93 Motion for reconsideration.
18.94 Indicative ruling on a motion for relief that is barred by a pending petition for review.
18.95 Review of decision

General Provisions

§ 18.10 Scope and purpose.

(a) *In general.* These rules govern the procedure in proceedings before the United States Department of Labor, Office of Administrative Law Judges. They should be construed and administered to secure the just, speedy, and inexpensive determination of every proceeding. To the extent that these rules may be inconsistent with a governing statute, regulation, or executive order, the latter controls. If a specific Department of Labor regulation governs a proceeding, the provisions of that regulation apply, and these rules apply to situations not addressed in the governing regulation. The Federal Rules of Civil Procedure (FRCP) apply in any situation not provided for or controlled by these rules, or a governing statute, regulation, or executive order.

(b) *Type of proceeding.* Unless the governing statute, regulation, or executive order prescribes a different procedure, proceedings follow the Administrative Procedure Act, 5 U.S.C. 551 through 559.

(c) *Waiver, modification, and suspension.* Upon notice to all parties, the presiding judge may waive, modify, or suspend any rule under this subpart when doing so will not prejudice a party and will serve the ends of justice.

§ 18.11 Definitions.

For purposes of these rules, these definitions supplement the definitions in the Administrative Procedure Act, 5 U.S.C. 551.

Calendar call means a meeting in which the judge calls cases awaiting hearings, determines case status, and assigns a hearing date and time.

Chief Judge means the Chief Administrative Law Judge of the United States Department of Labor Office of Administrative Law Judges and judges to whom the Chief Judge delegates authority.

Docket clerk means the Chief Docket Clerk at the Office of Administrative Law Judges in Washington, DC. But once a case is assigned to a judge in a district office, *docket clerk* means the docket staff in that office.

Hearing means that part of a proceeding consisting of a session to decide issues of fact or law that is recorded and transcribed and provides the opportunity to present evidence or argument.

Judge means an administrative law judge appointed under the provisions of 5 U.S.C. 3105.

Order means the judge's disposition of one or more procedural or substantive issues, or of the entire matter.

Proceeding means an action before the Office of Administrative Law Judges

that creates a record leading to an adjudication or order.

Representative means any person permitted to represent another in a proceeding before the Office of Administrative Law Judges.

§ 18.12 Proceedings before administrative law judge.

(a) *Designation.* The Chief Judge designates the presiding judge for all proceedings.

(b) *Authority.* In all proceedings under this part, the judge has all powers necessary to conduct fair and impartial proceedings, including those described in the Administrative Procedure Act, 5 U.S.C. 556. Among them is the power to:

(1) Regulate the course of proceedings in accordance with applicable statute, regulation or executive order;

(2) Administer oaths and affirmations and examine witnesses;

(3) Compel the production of documents and appearance of witnesses within a party's control;

(4) Issue subpoenas authorized by law;

(5) Rule on offers of proof and receive relevant evidence;

(6) Dispose of procedural requests and similar matters;

(7) Terminate proceedings through dismissal or remand when not inconsistent with statute, regulation, or executive order;

(8) Issue decisions and orders;

(9) Exercise powers vested in the Secretary of Labor that relate to proceedings before the Office of Administrative Law Judges; and

(10) Where applicable take any appropriate action authorized by the FRCP.

§ 18.13 Settlement judge procedure.

(a) *How initiated.* The Office of Administrative Law Judges provides settlement judges to aid the parties in resolving the matter that is the subject of the controversy. Upon a joint request by the parties or upon referral by the judge when no party objects, the Chief Judge may appoint a settlement judge. A settlement judge will not be appointed when settlement proceedings would be inconsistent with a statute, regulation, or executive order.

(b) *Appointment.* The Chief Judge has discretion to appoint a settlement judge, who must be an active or retired judge. The settlement judge will not be appointed to hear and decide the case or approve the settlement without the parties' consent and the approval of the Chief Judge.

(c) *Duration of settlement proceeding.* Unless the Chief Judge directs otherwise, settlement negotiations under this section must be completed within 60 days from the date of the settlement judge's appointment. The settlement judge may request that the Chief Judge extend the appointment. The negotiations will be terminated if a party withdraws from participation, or if the settlement judge determines that further negotiations would be unproductive or inappropriate.

(d) *Powers of the settlement judge.* The settlement judge may convene settlement conferences; require the parties or their representatives to attend with full authority to settle any disputes; and impose other reasonable requirements to expedite an amicable resolution of the case.

(e) *Stay of proceedings before presiding judge.* The appointment of a settlement judge does not stay any aspect of the proceeding before the presiding judge. Any motion to stay must be directed to the presiding judge.

(f) *Settlement conferences.* Settlement conferences may be conducted by telephone, videoconference or in person at the discretion of the settlement judge after considering the nature of the case, location of the participants, availability of technology, and efficiency of administration.

(g) *Confidentiality.* All discussions with the settlement judge are confidential; none may be recorded or transcribed. The settlement judge must not disclose any confidential communications made during settlement proceedings, except as required by statute, executive order, or court order. The settlement judge may not be subpoenaed or called as a witness in any hearing of the case or any subsequent administrative proceedings before the Department to testify to statements made or conduct during the settlement discussions.

(h) *Report.* The parties must promptly inform the presiding judge of the outcome of the settlement negotiations. If a settlement is reached, the parties must submit the required documents to the presiding judge within 14 days of the conclusion of settlement discussions unless the presiding judge orders otherwise.

(i) *Non-reviewable decisions.* Whether a settlement judge should be appointed, the selection of a particular settlement judge, and the termination of proceedings under this section are matters not subject to review by Department officials.

§ 18.14 Ex parte communication.

The parties, their representatives, or other interested persons must not engage in ex parte communications on the merits of a case with the judge.

§ 18.15 Substitution of administrative law judge.

(a) *Substitution during hearing.* If the judge is unable to complete a hearing, a successor judge designated pursuant to § 18.12 may proceed upon certifying familiarity with the record and determining that the case may be completed without prejudice to the parties. The successor judge must, at a party's request, recall any witness whose testimony is material and disputed and who is available to testify again without undue burden. The successor judge may also recall any other witness.

(b) *Substitution following hearing.* If the judge is unable to proceed after the hearing is concluded, the successor judge appointed pursuant to § 18.12 may issue a decision and order based upon the existing record after notifying the parties and giving them an opportunity to respond. Within 14 days of receipt of the judge's notice, a party may file an objection to the judge issuing a decision based on the existing record. If no objection is filed, the objection is considered waived. Upon good cause shown, the judge may order supplemental proceedings.

§ 18.16 Disqualification.

(a) *Disqualification on judge's initiative.* A judge must withdraw from a proceeding whenever he or she considers himself or herself disqualified.

(b) *Request for disqualification.* A party may file a motion to disqualify the judge. The motion must allege grounds for disqualification, and include any appropriate supporting affidavits, declarations or other documents. The presiding judge must rule on the motion in a written order that states the grounds for the ruling.

§ 18.17 Legal assistance.

The Office of Administrative Law Judges does not appoint representatives, refer parties to representatives, or provide legal assistance.

Parties and Representatives

§ 18.20 Parties to a proceeding.

A party seeking original relief or action is designated a complainant, claimant or plaintiff, as appropriate. A party against whom relief or other action is sought is designated a respondent or defendant, as appropriate. When participating in a proceeding, the applicable Department of Labor's agency is a party or party-in-interest.

§ 18.21 Party appearance and participation.

(a) *In general.* A party may appear and participate in the proceeding in person or through a representative.

(b) *Waiver of participation.* By filing notice with the judge, a party may waive the right to participate in the hearing or the entire proceeding. When all parties waive the right to participate in the hearing, the judge may issue a decision and order based on the pleadings, evidence, and briefs.

(c) *Failure to appear.* When a party has not waived the right to participate in a hearing, conference or proceeding but fails to appear at a scheduled hearing or conference, the judge may, after notice and an opportunity to be heard, dismiss the proceeding or enter a decision and order without further proceedings if the party fails to establish good cause for its failure to appear.

§ 18.22 Representatives.

(a) *Notice of appearance.* When first making an appearance, each representative must file a notice of appearance that indicates on whose behalf the appearance is made and the proceeding name and docket number. Any attorney representative must include in the notice of appearance the license registration number(s) assigned to the attorney.

(b) *Categories of representation; admission standards*—(1) *Attorney representative.* Under these rules, ''attorney'' or ''attorney representative'' means an individual who has been admitted to the bar of the highest court of a State, Commonwealth, or Territory of the United States, or the District of Columbia.

(i) *Attorney in good standing.* An attorney who is in good standing in his or her licensing jurisdiction may represent a party or subpoenaed witness before the Office of Administrative Law Judges. The filing of the Notice of Appearance required in paragraph (a) of this section constitutes an attestation that:

(A) The attorney is a member of a bar in good standing of the highest court of a State, Commonwealth, or Territory of the United States, or the District of Columbia where the attorney has been licensed to practice law; and

(B) No disciplinary proceeding is pending against the attorney in any jurisdiction where the attorney is licensed to practice law.

(ii) *Attorney not in good standing.* An attorney who is not in good standing in his or her licensing jurisdiction may not represent a party or subpoenaed witness before the Office of Administrative Law Judges, unless he or she obtains the judge's approval. Such an attorney must file a written statement that establishes why the failure to maintain good standing is not disqualifying. The judge may deny approval for the appearance of such an attorney after providing notice and an opportunity to be heard.

(iii) *Disclosure of discipline.* An attorney representative must promptly disclose to the judge any action suspending, enjoining, restraining, disbarring, or otherwise currently restricting the attorney in the practice of law in any jurisdiction where the attorney is licensed to practice law.

(2) *Non-attorney representative.* An individual who is not an attorney as defined by paragraph (b)(1) of this section may represent a party or subpoenaed witness upon the judge's approval. The individual must file a written request to serve as a non-attorney representative that sets forth the name of the party or subpoenaed witness represented and certifies that the party or subpoenaed witness desires the representation. The judge may require that the representative establish that he or she is subject to the laws of the United States and possesses communication skills, knowledge, character, thoroughness and preparation reasonably necessary to render appropriate assistance. The judge may inquire as to the qualification or ability of a non-attorney representative to render assistance at any time. The judge may deny the request to serve as non-attorney representative after providing the party or subpoenaed witness with notice and an opportunity to be heard.

(c) *Duties.* A representative must be diligent, prompt, and forthright when dealing with parties, representatives and the judge, and act in a manner that furthers the efficient, fair and orderly conduct of the proceeding. An attorney representative must adhere to the applicable rules of conduct for the jurisdiction(s) in which the attorney is admitted to practice.

(d) *Prohibited actions.* A representative must not:

(1) Threaten, coerce, intimidate, deceive or knowingly mislead a party, representative, witness, potential witness, judge, or anyone participating in the proceeding regarding any matter related to the proceeding;

(2) Knowingly make or present false or misleading statements, assertions or representations about a material fact or law related to the proceeding;

(3) Unreasonably delay, or cause to be delayed without good cause, any proceeding; or

(4) Engage in any other action or behavior prejudicial to the fair and orderly conduct of the proceeding.

(e) *Withdrawal of appearance.* A representative who desires to withdraw after filing a notice of appearance or a party desiring to withdraw the appearance of a representative must file a motion with the judge. The motion must state that notice of the withdrawal has been given to the party, client or representative. The judge may deny a representative's motion to withdraw when necessary to avoid undue delay or prejudice to the rights of a party.

§ 18.23 Disqualification of representatives.

(a) *Disqualification*—(1) *Grounds for disqualification.* Representatives qualified under § 18.22 may be disqualified for:

(i) Suspension of a license to practice law or disbarment from the practice of law by any court or agency of the United States, highest court of a State, Commonwealth, or Territory of the United States, or the District of Columbia;

(ii) Disbarment from the practice of law on consent or resignation from the bar of a court or agency while an investigation into an allegation of misconduct is pending; or

(iii) Committing an act, omission, or contumacious conduct that violates these rules, an applicable statute, an applicable regulation, or the judge's order(s).

(2) *Disqualification procedure.* The Chief Judge must provide notice and an opportunity to be heard as to why the representative should not be disqualified from practice before the Office of Administrative Law Judges. The notice will include a copy of the document that provides the grounds for the disqualification. Unless otherwise directed, any response must be filed within 21 days of service of the notice. The Chief Judge's determination must be based on the reliable, probative and substantial evidence of record, including the notice and response.

(b) *Notification of disqualification action.* When an attorney representative is disqualified, the Chief Judge will notify the jurisdiction(s) in which the attorney is licensed to practice and the National Lawyer Regulatory Data Bank maintained by the American Bar Association Standing Committee on Professional Discipline, by providing a copy of the decision and order.

(c) *Application for reinstatement.* A representative disqualified under this section may be reinstated by the Chief Judge upon application. At the discretion of the Chief Judge, consideration of an application for reinstatement may be limited to written submissions or may be referred for

further proceedings before the Chief Judge.

§ 18.24 Briefs from amicus curiae.

The United States or an officer or agency thereof, or a State, Territory, Commonwealth, or the District of Columbia may file an amicus brief without the consent of the parties or leave of the judge. Any other amicus curiae may file a brief only by leave of the judge, upon the judge's request, or if the brief states that all parties have consented to its filing. A request for leave to file an amicus brief must be made by written motion that states the interest of the movant in the proceeding. The deadline for submission of an amicus brief will be set by the presiding judge.

Service, Format, and Timing of Filings and Other Papers

§ 18.30 Service and filing.

(a) *Service on parties*—(1) *In general.* Unless these rules provide otherwise, all papers filed with OALJ or with the judge must be served on every party.

(2) *Service: how made*—(i) *Serving a party's representative.* If a party is represented, service under this section must be made on the representative. The judge also may order service on the party.

(ii) *Service in general.* A paper is served under this section by:

(A) Handing it to the person;

(B) Leaving it;

(*1*) At the person's office with a clerk or other person in charge or, if no one is in charge, in a conspicuous place in the office; or

(*2*) If the person has no office or the office is closed, at the person's dwelling or usual place of abode with someone of suitable age and discretion who resides there.

(C) Mailing it to the person's last known address—in which event service is complete upon mailing;

(D) Leaving it with the docket clerk if the person has no known address;

(E) Sending it by electronic means if the person consented in writing—in which event service is complete upon transmission, but is not effective if the serving party learns that it did not reach the person to be served; or

(F) Delivering it by any other means that the person consented to in writing—in which event service is complete when the person making service delivers it to the agency designated to make delivery.

(3) *Certificate of service.* A certificate of service is a signed written statement that the paper was served on all parties. The statement must include:

(i) The title of the document;

(ii) The name and address of each person or representative being served;

(iii) The name of the party filing the paper and the party's representative, if any;

(iv) The date of service; and

(v) How the paper was served.

(b) *Filing with Office of Administrative Law Judges*—(1) *Required filings.* Any paper that is required to be served must be filed within a reasonable time after service with a certificate of service. But disclosures under § 18.50(c) and the following discovery requests and responses must not be filed until they are used in the proceeding or the judge orders filing:

(i) Notices of deposition,

(ii) Depositions,

(iii) Interrogatories,

(iv) Requests for documents or tangible things or to permit entry onto land;

(v) Requests for admission, and

(vi) The notice (and the related copy of the subpoena) that must be served on the parties under rule 18.56(b)(1) before a ''documents only'' subpoena may be served on the person commended to produce the material.

(2) *Filing: when made—in general.* A paper is filed when received by the docket clerk or the judge during a hearing.

(3) *Filing how made.* A paper may be filed by mail, courier service, hand delivery, facsimile or electronic delivery.

(i) *Filing by facsimile*—(A) *When permitted.* A party may file by facsimile only as directed or permitted by the judge. If a party cannot obtain prior permission because the judge is unavailable, a party may file by facsimile up to 12 pages, including a statement of the circumstances precluding filing by delivery or mail. Based on the statement, the judge may later accept the document as properly filed at the time transmitted.

(B) *Cover sheet.* Filings by facsimile must include a cover sheet that identifies the sender, the total number of pages transmitted, and the matter's docket number and the document's title.

(C) *Retention of the original document.* The original signed document will not be substituted into the record unless required by law or the judge.

(ii) Any party filing a facsimile of a document must maintain the original document and transmission record until the case is final. A transmission record is a paper printed by the transmitting facsimile machine that states the telephone number of the receiving machine, the number of pages sent, the transmission time and an indication that no error in transmission occurred.

(iii) Upon a party's request or judge's order, the filing party must provide for review the original transmitted document from which the facsimile was produced.

(4) *Electronic filing, signing, or verification.* A judge may allow papers to be filed, signed, or verified by electronic means.

§ 18.31 Privacy protection for filings and exhibits.

(a) *Redacted filings and exhibits.* Unless the judge orders otherwise, in an electronic or paper filing or exhibit that contains an individual's social-security number, taxpayer-identification number, or birth date, the name of an individual known to be a minor, or a financial-account number, the party or nonparty making the filing must redact all such information, except:

(1) The last four digits of the social-security number and taxpayer-identification number;

(2) The year of the individual's birth;

(3) The minor's initials; and

(4) The last four digits of the financial-account number.

(b) *Exemptions from the redaction requirement.* The redaction requirement does not apply to the following:

(1) The record of an administrative or agency proceeding;

(2) The official record of a state-court proceeding;

(3) The record of a court or tribunal, if that record was not subject to the redaction requirement when originally filed; and

(4) A filing or exhibit covered by paragraph (c) of this section.

(c) *Option for filing a reference list.* A filing that contains redacted information may be filed together with a reference list that identifies each item of redacted information and specifies an appropriate identifier that uniquely corresponds to each item listed. The reference list must be filed under seal and may be amended as of right. Any reference in the case to a listed identifier will be construed to refer to the corresponding item of information.

(d) *Waiver of protection of identifiers.* A person waives the protection of paragraph (a) of this section as to the person's own information by filing or offering it without redaction and not under seal.

(e) *Protection of material.* For good cause, the judge may order protection of material pursuant to §§ 18.85 and 18.52.

§ 18.32 Computing and extending time.

(a) *Computing time.* The following rules apply in computing any time

period specified in these rules, a judge's order, or in any statute, regulation, or executive order that does not specify a method of computing time.

(1) When the period is stated in days or a longer unit of time:

(i) Exclude the day of the event that triggers the period;

(ii) Count every day, including intermediate Saturdays, Sundays, and legal holidays; and

(iii) Include the last day of the period, but if the last day is a Saturday, Sunday, or legal holiday, the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday.

(2) *''Last day'' defined.* Unless a different time is set by a statute, regulation, executive order, or judge's order, the ''last day'' ends at 4:30 p.m. local time where the event is to occur.

(3) *''Next day'' defined.* The ''next day'' is determined by continuing to count forward when the period is measured after an event and backward when measured before an event.

(4) *''Legal holiday'' defined.* ''Legal holiday'' means the day set aside by statute for observing New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, or Christmas Day; and any day on which the district office in which the document is to be filed is closed or otherwise inaccessible.

(b) *Extending time.* When an act may or must be done within a specified time, the judge may, for good cause, extend the time:

(1) With or without motion or notice if the judge acts, or if a request is made, before the original time or its extension expires; or

(2) On motion made after the time has expired if the party failed to act because of excusable neglect.

(c) *Additional time after certain kinds of service.* When a party may or must act within a specified time after service and service is made under § 18.30(a)(2)(B)(iii) or (iv), 3 days are added after the period would otherwise expire under paragraph (a) of this section.

§ 18.33 Motions and other papers.

(a) *In general.* A request for an order must be made by motion. The motion must:

(1) Be in writing, unless made during a hearing;

(2) State with particularity the grounds for seeking the order;

(3) State the relief sought;

(4) Unless the relief sought has been agreed to by all parties, be accompanied by affidavits, declarations, or other evidence; and

(5) If required by paragraph (c)(4) of this section, include a memorandum of points and authority supporting the movant's position.

(b) *Form.* The rules governing captions and other matters of form apply to motions and other requests.

(c) *Written motion before hearing.* (1) A written motion before a hearing must be served with supporting papers, at least 21 days before the time specified for the hearing, with the following exceptions:

(i) When the motion may be heard ex parte;

(ii) When these rules or an appropriate statute, regulation, or executive order set a different time; or

(iii) When an order sets a different time.

(2) A written motion served within 21 days before the hearing must state why the motion was not made earlier.

(3) A written motion before hearing must state that counsel conferred, or attempted to confer, with opposing counsel in a good faith effort to resolve the motion's subject matter, and whether the motion is opposed or unopposed. A statement of consultation is not required with pro se litigants or with the following motions:

(i) To dismiss;

(ii) For summary decision; and

(iii) Any motion filed as ''joint,'' ''agreed,'' or ''unopposed.''

(4) Unless the motion is unopposed, the supporting papers must include affidavits, declarations or other proof to establish the factual basis for the relief. For a dispositive motion and a motion relating to discovery, a memorandum of points and authority must also be submitted. A judge may direct the parties file additional documents in support of any motion.

(d) *Opposition or other response to a motion filed prior to hearing.* A party to the proceeding may file an opposition or other response to the motion within 14 days after the motion is served. The opposition or response may be accompanied by affidavits, declarations, or other evidence, and a memorandum of the points and authorities supporting the party's position. Failure to file an opposition or response within 14 days after the motion is served may result in the requested relief being granted. Unless the judge directs otherwise, no further reply is permitted and no oral argument will be heard prior to hearing.

(e) A *motions made at hearing.* A motion made at a hearing may be stated orally unless the judge determines that a written motion or response would best serve the ends of justice.

(f) *Renewed or repeated motions.* A motion seeking the same or substantially similar relief previously denied, in whole or in part, must include the following information:

(1) The earlier motion(s),

(2) When the respective motion was made,

(3) The judge to whom the motion was made,

(4) The earlier ruling(s), and

(5) The basis for the current motion.

(g) *Motion hearing.* The judge may order a hearing to take evidence or oral argument on a motion.

§ 18.34 Format of papers filed.

Every paper filed must be printed in black ink on 8.5 x 11-inch opaque white paper and begin with a caption that includes:

(a) The parties' names,

(b) A title that describes the paper's purpose, and

(c) The docket number assigned by the Office of Administrative Law Judges. If the Office has not assigned a docket number, the paper must bear the case number assigned by the Department of Labor agency where the matter originated. If the case number is an individual's Social Security number then only the last four digits may be used. *See* § 18.31(a)(1).

§ 18.35 Signing motions and other papers; representations to the judge; sanctions.

(a) *Date and signature.* Every written motion and other paper filed with OALJ must be dated and signed by at least one representative of record in the representative's name—or by a party personally if the party is unrepresented. The paper must state the signer's address, telephone number, facsimile number and email address, if any. The judge must strike an unsigned paper unless the omission is promptly corrected after being called to the representative's or party's attention.

(b) *Representations to the judge.* By presenting to the judge a written motion or other paper—whether by signing, filing, submitting, or later advocating it—the representative or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:

(1) It is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of the proceedings;

(2) The claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law;

(3) The factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and

(4) The denials of factual contentions are warranted on the evidence or, if specifically so identified, are reasonably based on belief or a lack of information.

(c) *Sanctions*—(1) *In general.* If, after notice and a reasonable opportunity to respond, the judge determines that paragraph (b) of this section has been violated, the judge may impose an appropriate sanction on any representative, law firm, or party that violated the rule or is responsible for the violation. Absent exceptional circumstances, a law firm must be held jointly responsible for a violation committed by its partner, associate, or employee.

(2) *Motion for sanctions.* A motion for sanctions must be made separately from any other motion and must describe the specific conduct that allegedly violates paragraph (b) of this section. The motion must be served under § 18.30(a), but it must not be filed or be presented to the judge if the challenged paper, claim, defense, contention, or denial is withdrawn or appropriately corrected within 21 days after service or within another time the judge sets.

(3) *On the judge's initiative.* On his or her own, the judge may order a representative, law firm, or party to show cause why conduct specifically described in the order has not violated paragraph (b) of this section.

(4) *Nature of a sanction.* A sanction imposed under this section may include, but is not limited to, striking part or all of the offending document, forbidding the filing of any further documents, excluding related evidence, admonishment, referral of counsel misconduct to the appropriate licensing authority, and including the sanctioned activity in assessing the quality of representation when determining an appropriate hourly rate and billable hours when adjudicating attorney fees.

(5) *Requirements for an order.* An order imposing a sanction must describe the sanctioned conduct and explain the basis for the sanction.

(d) *Inapplicability to discovery.* This section does not apply to disclosures and discovery requests, responses, objections, and motions under §§ 18.50 through 18.65.

§ 18.36 Amendments after referral to the Office of Administrative Law Judges.

The judge may allow parties to amend and supplement their filings.

Prehearing Procedure

§ 18.40 Notice of hearing.

(a) *In general.* Except when the hearing is scheduled by calendar call, the judge must notify the parties of the hearing's date, time, and place at least 14 days before the hearing. The notice is sent by regular, first-class mail, unless the judge determines that circumstances require service by certified mail or other means. The parties may agree to waive the 14-day notice for the hearing.

(b) *Date, time, and place.* The judge must consider the convenience and necessity of the parties and the witnesses in selecting the date, time, and place of the hearing.

§ 18.41 Continuances and changes in place of hearing.

(a) *By the judge.* Upon reasonable notice to the parties, the judge may change the time, date, and place of the hearing.

(b) *By a party's motion.* A request by a party to continue a hearing or to change the place of the hearing must be made by motion.

(1) *Continuances.* A motion for continuance must be filed promptly after the party becomes aware of the circumstances supporting the continuance. In exceptional circumstances, a party may orally request a continuance and must immediately notify the other parties of the continuance request.

(2) *Change in place of hearing.* A motion to change the place of a hearing must be filed promptly.

§ 18.42 Expedited proceedings.

A party may move to expedite the proceeding. The motion must demonstrate the specific harm that would result if the proceeding is not expedited. If the motion is granted, the formal hearing ordinarily will not be scheduled with less than 7 days notice to the parties, unless all parties consent to an earlier hearing.

§ 18.43 Consolidation; separate hearings.

(a) *Consolidation.* If separate proceedings before the Office of the Administrative Law Judges involve a common question of law or fact, a judge may:

(1) Join for hearing any or all matters at issue in the proceedings;

(2) Consolidate the proceedings; or

(3) Issue any other orders to avoid unnecessary cost or delay.

(b) *Separate hearings.* For convenience, to avoid prejudice, or to expedite and economize, the judge may order a separate hearing of one or more issues.

§ 18.44 Prehearing conference.

(a) *In general.* The judge, with or without a motion, may order one or more prehearing conferences for such purposes as:

(1) Expediting disposition of the proceeding;

(2) Establishing early and continuing control so that the case will not be protracted because of lack of management;

(3) Discouraging wasteful prehearing activities;

(4) Improving the quality of the hearing through more thorough preparation; and

(5) Facilitating settlement.

(b) *Scheduling.* Prehearing conferences may be conducted in person, by telephone, or other means after reasonable notice of time, place and manner of conference has been given.

(c) *Participation.* All parties must participate in prehearing conferences as directed by the judge. A represented party must authorize at least one of its attorneys or representatives to make stipulations and admissions about all matters that can reasonably be anticipated for discussion at the prehearing conference, including possible settlement.

(d) *Matters for consideration.* At the conference, the judge may consider and take appropriate actions on the following matters:

(1) Formulating and simplifying the issues, and eliminating frivolous claims or defenses;

(2) Amending the papers that had framed the issues before the matter was referred for hearing;

(3) Obtaining admissions and stipulations about facts and documents to avoid unnecessary proof, and ruling in advance on the admissibility of evidence;

(4) Avoiding unnecessary proof and cumulative evidence, and limiting the number of expert or other witnesses;

(5) Determining the appropriateness and timing of dispositive motions under §§ 18.70 and 18.72;

(6) Controlling and scheduling discovery, including orders affecting disclosures and discovery under §§ 18.50 through 18.65;

(7) Identifying witnesses and documents, scheduling the filing and exchange of any exhibits and prehearing submissions, and setting dates for further conferences and for the hearing;

(8) Referring matters to a special master;

(9) Settling the case and using special procedures to assist in resolving the dispute such as the settlement judge procedure under § 18.13, private

mediation, and other means authorized by statute or regulation;

(10) Determining the form and content of prehearing orders;

(11) Disposing of pending motions;

(12) Adopting special procedures for managing potentially difficult or protracted proceedings that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems;

(13) Consolidating or ordering separate hearings under § 18.43;

(14) Ordering the presentation of evidence early in the proceeding on a manageable issue that might, on the evidence, be the basis for disposing of the proceeding;

(15) Establishing a reasonable limit on the time allowed to present evidence; and

(16) Facilitating in other ways the just, speedy, and inexpensive disposition of the proceeding.

(e) *Reporting.* The judge may direct that the prehearing conference be recorded and transcribed. If the conference is not recorded, the judge should summarize the conference proceedings on the record at the hearing or by separate prehearing notice or order.

Disclosure and Discovery

§ 18.50 General provisions governing disclosure and discovery.

(a) *Timing and sequence of discovery*—(1) *Timing.* A party may seek discovery at any time after a judge issues an initial notice or order. But if the judge orders the parties to confer under paragraph (b) of this section:

(i) The time to respond to any pending discovery requests is extended until the time agreed in the discovery plan, or that the judge sets in resolving disputes about the discovery plan, and

(ii) No party may seek additional discovery from any source before the parties have conferred as required by paragraph (b) of this section, except by stipulation.

(2) *Sequence.* Unless, on motion, the judge orders otherwise for the parties' and witnesses' convenience and in the interests of justice:

(i) Methods of discovery may be used in any sequence; and

(ii) Discovery by one party does not require any other party to delay its discovery.

(b) *Conference of the parties; planning for discovery*—(1) *In general.* The judge may order the parties to confer on the matters described in paragraphs (b)(2) and (3) of this section.

(2) *Conference content; parties' responsibilities.* In conferring, the parties must consider the nature and basis of their claims and defenses and the possibilities for promptly settling or resolving the case; make or arrange for the disclosures required by paragraph (c) of this section; discuss any issues about preserving discoverable information; and develop a proposed discovery plan. The representatives of record and all unrepresented parties that have appeared in the case are jointly responsible for arranging the conference, for attempting in good faith to agree on the proposed discovery plan, and for submitting to the judge within 14 days after the conference a written report outlining the plan. The judge may order the parties or representatives to attend the conference in person.

(3) *Discovery plan.* A discovery plan must state the parties' views and proposals on:

(i) What changes should be made in the timing, form, or requirement for disclosures under paragraph (c) of this section, including a statement of when initial disclosures were made or will be made;

(ii) The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused on particular issues;

(iii) Any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced;

(iv) Any issues about claims of privilege or of protection as hearing-preparation materials, including—if the parties agree on a procedure to assert these claims after production—whether to ask the judge to include their agreement in an order;

(v) What changes should be made in the limitations on discovery imposed under these rules and what other limitations should be imposed; and

(vi) Any other orders that the judge should issue under § 18.52 or § 18.44.

(c) *Required disclosures*—(1) *Initial disclosure*—(i) *In general.* Except as exempted by paragraph (c)(1)(ii) of this section or otherwise ordered by the judge, a party must, without awaiting a discovery request, provide to the other parties:

(A) The name and, if known, the address and telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment;

(B) A copy—or a description by category and location—of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses, unless the use would be solely for impeachment; and

(C) A computation of each category of damages claimed by the disclosing party—who must also make available for inspection and copying as under § 18.61 the documents or other evidentiary material, unless privileged or protected from disclosure, on which each computation is based, including materials bearing on the nature and extent of injuries suffered.

(ii) *Proceedings exempt from initial disclosure.* The following proceedings are exempt from initial disclosure:

(A) A proceeding under 29 CFR part 20 for review of an agency determination regarding the existence or amount of a debt, or the repayment schedule proposed by the agency;

(B) A proceeding before the Board of Alien Labor Certification Appeals under the Immigration and Nationality Act; and

(C) A proceeding under the regulations governing certification of H–2 non-immigrant temporary agricultural employment at 20 CFR part 655, subpart B;

(D) A rulemaking proceeding under the Occupational Safety and Health Act of 1970; and

(E) A proceeding for civil penalty assessments under Employee Retirement Income Security Act of 1974, 29 U.S.C. 1132.

(iii) *Parties exempt from initial disclosure.* The following parties are exempt from initial disclosure:

(A) In a Black Lung benefits proceeding under 30 U.S.C. 901 *et seq.,* the representative of the Office of Workers' Compensation Programs of the Department of Labor, if an employer has been identified as the Responsible Operator and is a party to the proceeding, *see* 20 CFR 725.418(d); and

(B) In a proceeding under the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 901–950, or an associated statute such as the Defense Base Act, 42 U.S.C. 1651–1654, the representative of the Office of Workers' Compensation Programs of the Department of Labor, unless the Solicitor of Labor or the Solicitor's designee has elected to participate in the proceeding under 20 CFR 702.333(b), or unless an employer or carrier has applied for relief under the special fund, as defined in 33 U.S.C. 908(f).

(iv) *Time for initial disclosures—in general.* A party must make the initial disclosures required by paragraph

(c)(1)(i) of this section within 21 days after an initial notice or order is entered acknowledging that the proceeding has been docketed at the OALJ unless a different time is set by stipulation or a judge's order, or a party objects during the conference that initial disclosures are not appropriate in the proceeding and states the objection in the proposed discovery plan. In ruling on the objection, the judge must determine what disclosures, if any, are to be made and must set the time for disclosure.

(v) *Time for initial disclosures—for parties served or joined later.* A party that is first served or otherwise joined later in the proceeding must make the initial disclosures within 21 days after being served or joined, unless a different time is set by stipulation or the judge's order. Copies of all prior disclosures must be served on a newly served or joined party within 21 days of the service or joinder.

(vi) *Basis for initial disclosure; unacceptable excuses.* A party must make its initial disclosures based on the information then reasonably available to it. A party is not excused from making its disclosures because it has not fully investigated the case or because it challenges the sufficiency of another party's disclosures or because another party has not made its disclosures.

(2) *Disclosure of expert testimony*—(i) *In general.* A party must disclose to the other parties the identity of any witness who may testify at hearing, either live or by deposition. The judge should set the time for the disclosure by prehearing order.

(ii) *Witnesses who must provide a written report.* Unless otherwise stipulated or ordered by the judge, this disclosure must be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain:

(A) A complete statement of all opinions the witness will express and the basis and reasons for them;

(B) The facts or data considered by the witness in forming them;

(C) Any exhibits that will be used to summarize or support them;

(D) The witness's qualifications, including a list of all publications authored in the previous 10 years;

(E) A list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial, a hearing, or by deposition; and

(F) A statement of the compensation to be paid for the study and testimony in the case.

(iii) *Witnesses who do not provide a written report.* Unless otherwise stipulated or ordered by the judge that the witness is not required to provide a written report, this disclosure must state:

(A) The subject matter on which the witness is expected to present expert opinion evidence; and

(B) A summary of the facts and opinions to which the witness is expected to testify.

(iv) *Supplementing the disclosure.* The parties must supplement these disclosures when required under § 18.53.

(3) *Prehearing disclosures.* In addition to the disclosures required by paragraphs (c)(1) and (2) of this section, a party must provide to the other parties and promptly file the prehearing disclosures described in § 18.80.

(4) *Form of disclosures.* Unless the judge orders otherwise, all disclosures under this paragraph (c) must be in writing, signed, and served.

(d) *Signing disclosures and discovery requests, responses, and objections*—(1) *Signature required; effect of signature.* Every disclosure under paragraph (c) of this section and every discovery request, response, or objection must be signed by at least one of the party's representatives in the representative's own name, or by the party personally if unrepresented, and must state the signer's address, telephone number, facsimile number, and email address, if any. By signing, a representative or party certifies that to the best of the person's knowledge, information, and belief formed after a reasonable inquiry:

(i) With respect to a disclosure, it is complete and correct as of the time it is made; and

(ii) With respect to a discovery request, response, or objection, it is:

(A) Consistent with these rules and warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law, or for establishing new law;

(B) Not interposed for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; and

(C) Neither unreasonable nor unduly burdensome or expensive, considering the needs of the case, prior discovery in the case, the amount in controversy, and the importance of the issues at stake in the action.

(2) *Failure to sign.* Other parties have no duty to act on an unsigned disclosure, request, response, or objection until it is signed, and the judge must strike it unless a signature is promptly supplied after the omission is called to the representative's or party's attention.

(3) *Sanction for improper certification.* If a certification violates this section without substantial justification, the judge, on motion or on his or her own, must impose an appropriate sanction, as provided in § 18.57, on the signer, the party on whose behalf the signer was acting, or both.

§ 18.51 Discovery scope and limits.

(a) *Scope in general.* Unless otherwise limited by a judge's order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the judge may order discovery of any matter relevant to the subject matter involved in the proceeding. Relevant information need not be admissible at the hearing if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by paragraph (b)(4) of this section.

(b) *Limitations on frequency and extent*—(1) *When permitted.* By order, the judge may alter the limits in these rules on the number of depositions and interrogatories or on the length of depositions under § 18.64. The judge's order may also limit the number of requests under § 18.63.

(2) *Specific limitations on electronically stored information.* A party need not provide discovery of electronically stored information from sources that the party identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the party from whom discovery is sought must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the judge may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of paragraph (b)(4) of this section. The judge may specify conditions for the discovery.

(3) *Inadvertently disclosed privileged or protected information.* By requesting electronically stored information, a party consents to the application of Federal Rule of Evidence 502 with regard to inadvertently disclosed privileged or protected information.

(4) *When required.* On motion or on his or her own, the judge must limit the frequency or extent of discovery otherwise allowed by these rules when:

(i) The discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;

(ii) The party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or

(iii) The burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

(c) *Hearing preparation: Materials*—(1) *Documents and tangible things.* Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for hearing by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent). But, subject to paragraph (d) of this section, those materials may be discovered if:

(i) They are otherwise discoverable under paragraph (a) of this section; and

(ii) The party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means.

(2) *Protection against disclosure.* A judge who orders discovery of those materials must protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of a party's representative concerning the litigation.

(3) *Previous statement.* Any party or other person may, on request and without the required showing, obtain the person's own previous statement about the action or its subject matter. If the request is refused, the person may move for a judge's order. A previous statement is either:

(i) A written statement that the person has signed or otherwise adopted or approved; or

(ii) A contemporaneous stenographic, mechanical, electrical, or other recording—or a transcription of it—that recites substantially verbatim the person's oral statement.

(d) *Hearing preparation: experts*—(1) *Deposition of an expert who may testify.* A party may depose any person who has been identified as an expert whose opinions may be presented at trial. If § 18.50(c)(2)(B) requires a report from the expert the deposition may be conducted only after the report is provided, unless the parties stipulate otherwise.

(2) *Hearing-preparation protection for draft reports or disclosures.* Paragraphs (c)(1) and (2) of this section protect drafts of any report or disclosure required under § 18.50(c)(2), regardless of the form in which the draft is recorded.

(3) *Hearing-preparation protection for communications between a party's representative and expert witnesses.* Paragraphs (c)(1) and (2) under this section protect communications between the party's representative and any witness required to provide a report under § 18.50(c)(2)(B), regardless of the form of the communications, except to the extent that the communications:

(i) Relate to compensation for the expert's study or testimony;

(ii) Identify facts or data that the party's representative provided and that the expert considered in forming the opinions to be expressed; or

(iii) Identify assumptions that the party's representative provided and that the expert relied on in forming the opinions to be expressed.

(4) *Expert employed only for hearing preparation.* Ordinarily, a party may not, by interrogatories or deposition, discover facts known or opinions held by an expert who has been retained or specially employed by another party in anticipation of litigation or to prepare for hearing and whose testimony is not anticipated to be used at the hearing. But a party may do so only:

(i) As provided in § 18.62(c); or

(ii) On showing exceptional circumstances under which it is impracticable for the party to obtain facts or opinions on the same subject by other means.

(e) *Claiming privilege or protecting hearing-preparation materials*—(1) *Information withheld.* When a party withholds information otherwise discoverable by claiming that the information is privileged or subject to protection as hearing-preparation material, the party must:

(i) Expressly make the claim; and

(ii) Describe the nature of the documents, communications, or tangible things not produced or disclosed—and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim.

(2) *Information produced.* If information produced in discovery is subject to a claim of privilege or of protection as hearing-preparation material, the party making the claim must notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the judge for an *in camera* determination of the claim. The producing party must preserve the information until the claim is resolved.

§ 18.52 Protective orders.

(a) *In general.* A party or any person from whom discovery is sought may file a written motion for a protective order. The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without the judge's action. The judge may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) Forbidding the disclosure or discovery;

(2) Specifying terms, including time and place, for the disclosure or discovery;

(3) Prescribing a discovery method other than the one selected by the party seeking discovery;

(4) Forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matters;

(5) Designating the persons who may be present while the discovery is conducted;

(6) Requiring that a deposition be sealed and opened only on the judge's order;

(7) Requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way;

and

(8) Requiring that the parties simultaneously file specified documents or information in sealed envelopes, to be opened as the judge directs.

(b) *Ordering discovery.* If a motion for a protective order is wholly or partly denied, the judge may, on just terms, order that any party or person provide or permit discovery.

§ 18.53 Supplementing disclosures and responses.

(a) *In general.* A party who has made a disclosure under § 18.50(c)—or who has responded to an interrogatory, request for production, or request for

admission—must supplement or correct its disclosure or response:

(1) In a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing; or

(2) As ordered by the judge.

(b) *Expert witness.* For an expert whose report must be disclosed under § 18.50(c)(2)(B), the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition. Any additions or changes to this information must be disclosed by the time the party's prehearing disclosures under § 18.50(c)(3) are due.

§ 18.54 Stipulations about discovery procedure.

Unless the judge orders otherwise, the parties may stipulate that:

(a) A deposition may be taken before any person, at any time or place, on any notice, and in the manner specified—in which event it may be used in the same way as any other deposition; and

(b) Other procedures governing or limiting discovery be modified— but a stipulation extending the time for any form of discovery must have the judge's approval if it would interfere with the time set for completing discovery, for hearing a motion, or for hearing.

§ 18.55 Using depositions at hearings.

(a) *Using depositions*—(1) *In general.* If there is no objection, all or part of a deposition may be used at a hearing to the extent it would be admissible under the applicable rules of evidence as if the deponent were present and testifying.

(2) *Over objection.* Notwithstanding any objection, all or part of a deposition may be used at a hearing against a party on these conditions:

(i) The party was present or represented at the taking of the deposition or had reasonable notice of it;

(ii) It is used to the extent it would be admissible under the applicable rules of evidence if the deponent were present and testifying; and

(iii) The use is allowed by paragraphs (a)(3) through (9) of this section.

(3) *Impeachment and other uses.* Any party may use a deposition to contradict or impeach the testimony given by the deponent as a witness, or for any other purpose allowed by the applicable rules of evidence.

(4) *Deposition of party, agent, or designee.* An adverse party may use for any purpose the deposition of a party or anyone who, when deposed, was the party's officer, director, managing agent, or designee under § 18.64(b)(6) or § 18.65(a)(4).

(5) *Deposition of expert, treating physician, or examining physician.* A party may use for any purpose the deposition of an expert witness, treating physician or examining physician.

(6) *Unavailable witness.* A party may use for any purpose the deposition of a witness, whether or not a party, if the judge finds:

(i) That the witness is dead;

(ii) That the witness is more than 100 miles from the place of hearing or is outside the United States, unless it appears that the witness's absence was procured by the party offering the deposition;

(iii) That the witness cannot attend or testify because of age, illness, infirmity, or imprisonment;

(iv) That the party offering the deposition could not procure the witness's attendance by subpoena; or

(v) on motion and notice, that exceptional circumstances make it desirable—in the interests of justice and with due regard to the importance of live testimony in an open hearing—to permit the deposition to be used.

(7) *Limitations on use*—(i) *Deposition taken on short notice.* A deposition must not be used against a party who, having received less than 14 days' notice of the deposition, promptly moved for a protective order under § 18.52(a)(2) requesting that it not be taken or be taken at a different time or place—and this motion was still pending when the deposition was taken.

(ii) *Unavailable deponent; party could not obtain a representative.* A deposition taken without leave of the judge under the unavailability provision of § 18.64(a)(2)(i)(C) must not be used against a party who shows that, when served with the notice, it could not, despite diligent efforts, obtain a representative to represent it at the deposition.

(8) *Using part of a deposition.* If a party offers in evidence only part of a deposition, an adverse party may require the offeror to introduce other parts that in fairness should be considered with the part introduced, and any party may itself introduce any other parts.

(9) *Deposition taken in an earlier action.* A deposition lawfully taken may be used in a later action involving the same subject matter between the same parties, or their representatives or successors in interest, to the same extent as if taken in the later action. A deposition previously taken may also be used as allowed by the applicable rules of evidence.

(b) *Objections to admissibility.* Subject to paragraph (d)(3) of this section, an objection may be made at a hearing to the admission of any deposition testimony that would be inadmissible if the witness were present and testifying.

(c) *Form of presentation.* Unless the judge orders otherwise, a party must provide a transcript of any deposition testimony the party offers, but the judge may receive the testimony in nontranscript form as well.

(d) *Waiver of objections*—(1) *To the notice.* An objection to an error or irregularity in a deposition notice is waived unless promptly served in writing on the party giving the notice.

(2) *To the officer's qualification.* An objection based on disqualification of the officer before whom a deposition is to be taken is waived if not made:

(i) Before the deposition begins; or

(ii) Promptly after the basis for disqualification becomes known or, with reasonable diligence, could have been known.

(3) *To the taking of the deposition*—(i) *Objection to competence, relevance, or materiality.* An objection to a deponent's competence—or to the competence, relevance, or materiality of testimony—is not waived by a failure to make the objection before or during the deposition, unless the ground for it might have been corrected at that time.

(ii) *Objection to an error or irregularity.* An objection to an error or irregularity at an oral examination is waived if:

(A) It relates to the manner of taking the deposition, the form of a question or answer, the oath or affirmation, a party's conduct, or other matters that might have been corrected at that time; and

(B) It is not timely made during the deposition.

(iii) *Objection to a written question.* An objection to the form of a written question under § 18.65 is waived if not served in writing on the party submitting the question within the time for serving responsive questions or, if the question is a recross-question, within 7 days after being served with it.

(4) *To completing and returning the deposition.* An objection to how the officer transcribed the testimony—or prepared, signed, certified, sealed, endorsed, sent, or otherwise dealt with the deposition—is waived unless a motion to suppress is made promptly after the error or irregularity becomes known or, with reasonable diligence, could have been known.

§ 18.56 Subpoena.

(a) *In general.* (1) Upon written application of a party the judge may

issue a subpoena authorized by statute or law that requires a witness to attend and to produce relevant papers, books, documents, or tangible things in the witness' possession or under the witness' control.

(2) *Form and contents*—(i) *Requirements—in general.* Every subpoena must:

(A) State the title of the matter and show the case number assigned by the Office of Administrative Law Judges or the Office of Worker's Compensation Programs. In the event that the case number is an individual's Social Security number only the last four numbers may be used. *See* § 18.31(a)(1);

(B) Bear the signature of the issuing judge;

(C) Command each person to whom it is directed to do the following at a specified time and place: attend and testify; produce designated documents, electronically stored information, or tangible things in that person's possession, custody, or control; or permit the inspection of premises; and

(D) Set out the text of paragraphs (c) and (d) of this section.

(ii) *Command to attend a deposition—notice of the recording method.* A subpoena commanding attendance at a deposition must state the method for recording the testimony.

(iii) *Combining or separating a command to produce or to permit inspection; specifying the form for electronically stored information.* A command to produce documents, electronically stored information, or tangible things or to permit the inspection of premises may be included in a subpoena commanding attendance at a deposition or hearing, or may be set out in a separate subpoena. A subpoena may specify the form or forms in which electronically stored information is to be produced.

(iv) *Command to produce; included obligations.* A command in a subpoena to produce documents, electronically stored information, or tangible things requires the responding party to permit inspection, copying, testing, or sampling of the materials.

(b) *Service*—(1) *By whom; tendering fees; serving a copy of certain subpoenas.* Any person who is at least 18 years old and not a party may serve a subpoena. Serving a subpoena requires delivering a copy to the named person and, if the subpoena requires that person's attendance, tendering with it the fees for 1 day's attendance and the mileage allowed by law. Service may also be made by certified mail with return receipt. Fees and mileage need not be tendered when the subpoena issues on behalf of the United States or any of its officers or agencies. If the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before the formal hearing, then before it is served on the person to whom it is directed, a notice and copy of the subpoena must be served on each party.

(2) *Service in the United States.* Subject to paragraph (c)(3)(i)(B) of this section, a subpoena may be served at any place within a State, Commonwealth, or Territory of the United States, or the District of Columbia.

(3) *Service in a foreign country.* 28 U.S.C. 1783 governs issuing and serving a subpoena directed to a United States national or resident who is in a foreign country.

(4) *Proof of service.* Proving service, when necessary, requires filing with the judge a statement showing the date and manner of service and the names of the persons served. The statement must be certified by the server.

(c) *Protecting a person subject to a subpoena*—(1) *Avoiding undue burden; sanctions.* A party or representative responsible for requesting, issuing, or serving a subpoena must take reasonable steps to avoid imposing undue burden on a person subject to the subpoena. The judge must enforce this duty and impose an appropriate sanction.

(2) *Command to produce materials or permit inspection*—(i) *Appearance not required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition or hearing.

(ii) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or representative designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(A) At any time, on notice to the commanded person, the serving party may move the judge for an order compelling production or inspection.

(B) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or modifying a subpoena*—(i) *When required.* On timely motion, the judge must quash or modify a subpoena that:

(A) Fails to allow a reasonable time to comply;

(B) Requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person—except that, subject to paragraph (c)(3)(ii)(C) of this section, the person may be commanded to attend the formal hearing;

(C) Requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(D) Subjects a person to undue burden.

(ii) *When permitted.* To protect a person subject to or otherwise affected by a subpoena, the judge may, on motion, quash or modify the subpoena if it requires:

(A) Disclosing a trade secret or other confidential research, development, or commercial information;

(B) Disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(C) A person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend the formal hearing.

(iii) *Specifying conditions as an alternative.* In the circumstances described in paragraph (c)(3)(ii) of this section, the judge may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(A) Shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(B) Ensures that the subpoenaed person will be reasonably compensated.

(d) *Duties in responding to a subpoena*—(1) *Producing documents or electronically stored information.* These procedures apply to producing documents or electronically stored information:

(i) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(ii) *Form for producing electronically stored information not specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding

must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(iii) *Electronically stored information produced in only one form.* The person responding need not produce the same electronically stored information in more than one form.

(iv) *Inaccessible electronically stored information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the judge may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of § 18.51(b)(4)(iii). The judge may specify conditions for the discovery.

(2) *Claiming privilege or protection*—(i) *Information withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as hearing-preparation material must:

(A) Expressly make the claim; and

(B) Describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(ii) *Information produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as hearing-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the judge *in camera* for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) *Failure to obey.* When a person fails to obey a subpoena, the party adversely affected by the failure may, when authorized by statute or by law, apply to the appropriate district court to enforce the subpoena.

§ 18.57 Failure to make disclosures or to cooperate in discovery; sanctions.

(a) *Motion for an order compelling disclosure or discovery*—(1) *In general.* On notice to other parties and all affected persons, a party may move for an order compelling disclosure or discovery. The motion must include a certification that the movant has in good faith conferred or attempted to confer with the person or party failing to make disclosure or discovery in an effort to obtain it without the judge's action.

(2) *Specific motions*—(i) *To compel disclosure.* If a party fails to make a disclosure required by § 18.50(c), any other party may move to compel disclosure and for appropriate sanctions.

(ii) *To compel a discovery response.* A party seeking discovery may move for an order compelling an answer, designation, production, or inspection. This motion may be made if:

(A) A deponent fails to answer a question asked under §§ 18.64 and 18.65;

(B) A corporation or other entity fails to make a designation under §§ 18.64(b)(6) and 18.65(a)(4);

(C) A party fails to answer an interrogatory submitted under § 18.60; or

(D) A party fails to respond that inspection will be permitted—or fails to permit inspection—as requested under § 18.61.

(iii) *Related to a deposition.* When taking an oral deposition, the party asking a question may complete or adjourn the examination before moving for an order.

(3) *Evasive or incomplete disclosure, answer, or response.* For purposes of paragraph (a) of this section, an evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.

(b) *Failure to comply with a judge's order*—(1) *For not obeying a discovery order.* If a party or a party's officer, director, or managing agent—or a witness designated under §§ 18.64(b)(6) and 18.65(a)(4)—fails to obey an order to provide or permit discovery, including an order under § 18.50(b) or paragraph (a) of this section, the judge may issue further just orders. They may include the following:

(i) Directing that the matters embraced in the order or other designated facts be taken as established for purposes of the proceeding, as the prevailing party claims;

(ii) Prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;

(iii) Striking claims or defenses in whole or in part;

(iv) Staying further proceedings until the order is obeyed;

(v) Dismissing the proceeding in whole or in part; or

(vi) Rendering a default decision and order against the disobedient party;

(2) *For not producing a person for examination.* If a party fails to comply with an order under § 18.62 requiring it to produce another person for examination, the judge may issue any of the orders listed in paragraph (b)(1) of this section, unless the disobedient party shows that it cannot produce the other person.

(c) *Failure to disclose, to supplement an earlier response, or to admit.* If a party fails to provide information or identify a witness as required by §§ 18.50(c) and 18.53, or if a party fails to admit what is requested under § 18.63(a) and the requesting party later proves a document to be genuine or the matter true, the party is not allowed to use that information or witness to supply evidence on a motion or at a hearing, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the judge, on motion and after giving an opportunity to be heard may impose other appropriate sanctions, including any of the orders listed in paragraph (b)(1) of this section.

(d) *Party's failure to attend its own deposition, serve answers to interrogatories, or respond to a request for inspection*—(1) *In general*—(i) *Motion; grounds for sanctions.* The judge may, on motion, order sanctions if:

(A) A party or a party's officer, director, or managing agent—or a person designated under §§ 18.64(b)(6) and 18.65(a)(4)—fails, after being served with proper notice, to appear for that person's deposition; or

(B) A party, after being properly served with interrogatories under § 18.60 or a request for inspection under § 18.61, fails to serve its answers, objections, or written response.

(ii) *Certification.* A motion for sanctions for failing to answer or respond must include a certification that the movant has in good faith conferred or attempted to confer with the party failing to act in an effort to obtain the answer or response without the judge's action.

(2) *Unacceptable excuse for failing to act.* A failure described in paragraph (d)(1)(i) of this section is not excused on the ground that the discovery sought was objectionable, unless the party failing to act has a pending motion for a protective order under § 18.52(a).

(3) *Types of sanctions.* Sanctions may include any of the orders listed in paragraph (b)(1) of this section.

(e) *Failure to provide electronically stored information.* Absent exceptional circumstances, a judge may not impose sanctions under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system.

(f) *Procedure.* A judge may impose sanctions under this section upon:

(1) A separately filed motion; or

(2) Notice from the judge followed by a reasonable opportunity to be heard.

Types of Discovery

§ 18.60 Interrogatories to parties.

(a) *In general*—(1) *Number.* Unless otherwise stipulated or ordered by the judge, a party may serve on any other party no more than 25 written interrogatories, including all discrete subparts. Leave to serve additional interrogatories may be granted to the extent consistent with § 18.51.

(2) *Scope.* An interrogatory may relate to any matter that may be inquired into under § 18.51. An interrogatory is not objectionable merely because it asks for an opinion or contention that relates to fact or the application of law to fact, but the judge may order that the interrogatory need not be answered until designated discovery is complete, or until a prehearing conference or some other time.

(b) *Answers and objections*—(1) *Responding party.* The interrogatories must be answered:

(i) By the party to whom they are directed; or

(ii) If that party is a public or private corporation, a partnership, an association, or a governmental agency, by any officer or agent, who must furnish the information available to the party.

(2) *Time to respond.* The responding party must serve its answers and any objections within 30 days after being served with the interrogatories. A shorter or longer time may be stipulated to under § 18.54 or be ordered by the judge.

(3) *Answering each interrogatory.* Each interrogatory must, to the extent it is not objected to, be answered separately and fully in writing under oath.

(4) *Objections.* The grounds for objecting to an interrogatory must be stated with specificity. Any ground not stated in a timely objection is waived unless the judge, for good cause, excuses the failure.

(5) *Signature.* The person who makes the answers must sign them, and the attorney or non-attorney representative who objects must sign any objections.

(c) *Use.* An answer to an interrogatory may be used to the extent allowed by the applicable rules of evidence.

(d) *Option to produce business records.* If the answer to an interrogatory may be determined by examining, auditing, compiling, abstracting, or summarizing a party's business records (including electronically stored information), and if the burden of deriving or ascertaining the answer will be substantially the same for either party, the responding party may answer by:

(1) Specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could; and

(2) Giving the interrogating party a reasonable opportunity to examine and audit the records and to make copies, compilations, abstracts, or summaries.

§ 18.61 Producing documents, electronically stored information, and tangible things, or entering onto land, for inspection and other purposes.

(a) *In general.* A party may serve on any other party a request within the scope of § 18.51:

(1) To produce and permit the requesting party or its representative to inspect, copy, test, or sample the following items in the responding party's possession, custody, or control:

(i) Any designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form; or

(ii) Any designated tangible things; or

(2) To permit entry onto designated land or other property possessed or controlled by the responding party, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

(b) *Procedure*—(1) *Contents of the request.* The request:

(i) Must describe with reasonable particularity each item or category of items to be inspected;

(ii) Must specify a reasonable time, place, and manner for the inspection and for performing the related acts; and

(iii) May specify the form or forms in which electronically stored information is to be produced.

(2) *Responses and objections*—(i) *Time to respond.* The party to whom the request is directed must respond in writing within 30 days after being served. A shorter or longer time may be stipulated to under § 18.54 or be ordered by the judge.

(ii) *Responding to each item.* For each item or category, the response must either state that inspection and related activities will be permitted as requested or state an objection to the request, including the reasons.

(iii) *Objections.* An objection to part of a request must specify the part and permit inspection of the rest.

(iv) *Responding to a request for production of electronically stored information.* The response may state an objection to a requested form for producing electronically stored information. If the responding party objects to a requested form—or if no form was specified in the request—the party must state the form or forms it intends to use.

(v) *Producing the documents or electronically stored information.* Unless otherwise stipulated or ordered by the judge, these procedures apply to producing documents or electronically stored information:

(A) A party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request;

(B) If a request does not specify a form for producing electronically stored information, a party must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms; and

(C) A party need not produce the same electronically stored information in more than one form.

(c) *Nonparties.* As provided in § 18.56, a nonparty may be compelled to produce documents and tangible things or to permit an inspection.

§ 18.62 Physical and mental examinations.

(a) *Examination by notice*—(1) *In general.* A party may serve upon another party whose mental or physical condition is in controversy a notice to attend and submit to an examination by a suitably licensed or certified examiner.

(2) *Contents of the notice.* The notice must specify:

(i) The legal basis for the examination;

(ii) The time, place, manner, conditions, and scope of the examination, as well as the person or persons who will perform it; and

(iii) How the reasonable transportation expenses were calculated.

(3) *Service of notice.* Unless otherwise agreed by the parties, the notice must be

served no fewer than 30 days before the examination date.

(4) *Objection.* The person to be examined must serve any objection to the notice no later than 14 days after the notice is served. The objection must be stated with particularity.

(b) *Examination by motion.* Upon objection by the person to be examined the requesting party may file a motion to compel a physical or mental examination. The motion must include the elements required by paragraph (a)(2) of this section.

(c) *Examiner's report*—(1) *Delivery of the report.* The party who initiated the examination must deliver a complete copy of the examination report to the party examined no later than seven days after it receives the report, together with like reports of all earlier examinations of the same condition.

(2) *Contents.* The examiner's report must be in writing and must set out in detail the examiner's findings, including diagnoses, conclusions, and the results of any tests.

§ 18.63 Requests for admission.

(a) *Scope and procedure*—(1) *Scope.* A party may serve on any other party a written request to admit, for purposes of the pending action only, the truth of any matters within the scope of § 18.51 relating to:

(i) Facts, the application of law to fact, or opinions about either; and

(ii) The genuineness of any described documents.

(2) *Form; copy of a document.* Each matter must be separately stated. A request to admit the genuineness of a document must be accompanied by a copy of the document unless it is, or has been, otherwise furnished or made available for inspection and copying.

(3) *Time to respond; effect of not responding.* A matter is admitted unless, within 30 days after being served, the party to whom the request is directed serves on the requesting party a written answer or objection addressed to the matter and signed by the party or its attorney. A shorter or longer time for responding may be stipulated to under § 18.54 or be ordered by the judge.

(4) *Answer.* If a matter is not admitted, the answer must specifically deny it or state in detail why the answering party cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter; and when good faith requires that a party qualify an answer or deny only a part of a matter, the answer must specify the part admitted and qualify or deny the rest. The answering party may assert lack of knowledge or information as a reason for failing to admit or deny only if the party states that it has made reasonable inquiry and that the information it knows or can readily obtain is insufficient to enable it to admit or deny.

(5) *Objections.* The grounds for objecting to a request must be stated. A party must not object solely on the ground that the request presents a genuine issue for hearing.

(6) *Motion regarding the sufficiency of an answer or objection.* The requesting party may move to determine the sufficiency of an answer or objection. Unless the judge finds an objection justified, the judge must order that an answer be served. On finding that an answer does not comply with this section, the judge may order either that the matter is admitted or that an amended answer be served. The judge may defer final decision until a prehearing conference or a specified time before the hearing.

(b) *Effect of an admission; withdrawing or amending it.* A matter admitted under this section is conclusively established unless the judge, on motion, permits the admission to be withdrawn or amended. The judge may permit withdrawal or amendment if it would promote the presentation of the merits of the action and if the judge is not persuaded that it would prejudice the requesting party in maintaining or defending the action on the merits. An admission under this section is not an admission for any other purpose and cannot be used against the party in any other proceeding.

§ 18.64 Depositions by oral examination.

(a) *When a deposition may be taken*—(1) *Without leave.* A party may, by oral questions, depose any person, including a party, without leave of the judge except as provided in paragraph (a)(2) of this section. The deponent's attendance may be compelled by subpoena under § 18.56.

(2) *With leave.* A party must obtain leave of the judge, and the judge must grant leave to the extent consistent with § 18.51(b):

(i) If the parties have not stipulated to the deposition and:

(A) The deposition would result in more than 10 depositions being taken under this section or § 18.65 by one of the parties;

(B) The deponent has already been deposed in the case; or

(C) The party seeks to take the deposition before the time specified in § 18.50(a), unless the party certifies in the notice, with supporting facts, that the deponent is expected to leave the United States and be unavailable for examination in this country after that time; or

(ii) If the deponent is confined in prison.

(b) *Notice of the deposition; other formal requirements*—(1) *Notice in general.* Except as stipulated or otherwise ordered by the judge, a party who wants to depose a person by oral questions must give reasonable written notice to every other party of no fewer than 14 days. The notice must state the time and place of the deposition and, if known, the deponent's name and address. If the name is unknown, the notice must provide a general description sufficient to identify the person or the particular class or group to which the person belongs.

(2) *Producing documents.* If a subpoena duces tecum is to be served on the deponent, the materials designated for production, as set out in the subpoena, must be listed in the notice or in an attachment. If the notice to a party deponent is accompanied by a request for production under § 18.61, the notice must comply with the requirements of § 18.61(b).

(3) *Method of recording*—(i) *Method stated in the notice.* The party who notices the deposition must state in the notice the method for recording the testimony. Unless the judge orders otherwise, testimony may be recorded by audio, audiovisual, or stenographic means. The noticing party bears the recording costs. Any party may arrange to transcribe a deposition.

(ii) *Additional method.* With prior notice to the deponent and other parties, any party may designate another method for recording the testimony in addition to that specified in the original notice. That party bears the expense of the additional record or transcript unless the judge orders otherwise.

(4) *By remote means.* The parties may stipulate—or the judge may on motion order—that a deposition be taken by telephone or other remote means. For the purpose of this section, the deposition takes place where the deponent answers the questions.

(5) *Deposition officer's duties*—(i) *Before the deposition.* Unless the parties stipulate otherwise, a deposition must be conducted before a person having power to administer oaths. The officer must begin the deposition with an on-the-record statement that includes:

(A) The officer's name and business address;

(B) The date, time, and place of the deposition;

(C) The deponent's name;

(D) The officer's administration of the oath or affirmation to the deponent;

(E) The identity of all persons present; and

(F) The date and method of service of the notice of deposition.

(ii) *Conducting the deposition; avoiding distortion.* If the deposition is recorded nonstenographically, the officer must repeat the items in paragraphs (b)(5)(i)(A) and (B) of this section at the beginning of each unit of the recording medium. The deponent's and attorneys' appearance or demeanor must not be distorted through recording techniques.

(iii) *After the deposition.* At the end of a deposition, the officer must state on the record that the deposition is complete and must set out any stipulations made by the attorneys about custody of the transcript or recording and of the exhibits, or about any other pertinent matters.

(6) *Notice or subpoena directed to an organization.* In its notice or subpoena, a party may name as the deponent a public or private corporation, a partnership, an association, a governmental agency, or other entity and must describe with reasonable particularity the matters for examination. The named organization must then designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on its behalf; and it may set out the matters on which each person designated will testify. A subpoena must advise a nonparty organization of its duty to make this designation. The persons designated must testify about information known or reasonably available to the organization. This paragraph (b)(6) does not preclude a deposition by any other procedure allowed by these rules.

(c) *Examination and cross-examination; record of the examination; objections; written questions*—(1) *Examination and cross-examination.* The examination and cross-examination of a deponent proceed as they would at the hearing under the applicable rules of evidence. After putting the deponent under oath or affirmation, the officer must record the testimony by the method designated under paragraph (b)(3)(i) of this section. The testimony must be recorded by the officer personally or by a person acting in the presence and under the direction of the officer.

(2) *Objections.* An objection at the time of the examination—whether to evidence, to a party's conduct, to the officer's qualifications, to the manner of taking the deposition, or to any other aspect of the deposition—must be noted on the record, but the examination still proceeds; the testimony is taken subject to any objection. An objection must be stated concisely in a nonargumentative and nonsuggestive manner. A person may instruct a deponent not to answer only when necessary to preserve a privilege, to enforce a limitation ordered by the judge, or to present a motion under paragraph (d)(3) of this section.

(3) *Participating through written questions.* Instead of participating in the oral examination, a party may serve written questions in a sealed envelope on the party noticing the deposition, who must deliver them to the officer. The officer must ask the deponent those questions and record the answers verbatim.

(d) *Duration; sanction; motion to terminate or limit*—(1) *Duration.* Unless otherwise stipulated or ordered by the judge, a deposition is limited to 1 day of 7 hours. The judge must allow additional time consistent with § 18.51(b) if needed to fairly examine the deponent or if the deponent, another person, or any other circumstance impedes or delays the examination.

(2) *Sanction.* The judge may impose an appropriate sanction, in accordance with § 18.57, on a person who impedes, delays, or frustrates the fair examination of the deponent.

(3) *Motion to terminate or limit*—(i) *Grounds.* At any time during a deposition, the deponent or a party may move to terminate or limit it on the ground that it is being conducted in bad faith or in a manner that unreasonably annoys, embarrasses, or oppresses the deponent or party. If the objecting deponent or party so demands, the deposition must be suspended for the time necessary to obtain an order.

(ii) *Order.* The judge may order that the deposition be terminated or may limit its scope and manner as provided in § 18.52. If terminated, the deposition may be resumed only by the judge's order.

(e) *Review by the witness; changes*—(1) *Review; statement of changes.* On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(i) To review the transcript or recording; and

(ii) If there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) *Changes indicated in the officer's certificate.* The officer must note in the certificate prescribed by paragraph (f)(1) of this section whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

(f) *Certification and delivery; exhibits; copies of the transcript or recording; filing*—(1) *Certification and delivery.* The officer must certify in writing that the witness was duly sworn and that the deposition accurately records the witness's testimony. The certificate must accompany the record of the deposition. Unless the judge orders otherwise, the officer must seal the deposition in an envelope or package bearing the title of the action and marked ''Deposition of [witness's name]'' and must promptly send it to the party or the party's representative who arranged for the transcript or recording. The party or the party's representative must store it under conditions that will protect it against loss, destruction, tampering, or deterioration.

(2) *Documents and tangible things*—(i) *Originals and copies.* Documents and tangible things produced for inspection during a deposition must, on a party's request, be marked for identification and attached to the deposition. Any party may inspect and copy them. But if the person who produced them wants to keep the originals, the person may:

(A) Offer copies to be marked, attached to the deposition, and then used as originals—after giving all parties a fair opportunity to verify the copies by comparing them with the originals; or

(B) Give all parties a fair opportunity to inspect and copy the originals after they are marked—in which event the originals may be used as if attached to the deposition.

(ii) *Order regarding the originals.* Any party may move for an order that the originals be attached to the deposition pending final disposition of the proceeding.

(3) *Copies of the transcript or recording.* Unless otherwise stipulated or ordered by the judge, the officer must retain the stenographic notes of a deposition taken stenographically or a copy of the recording of a deposition taken by another method. When paid reasonable charges, the officer must furnish a copy of the transcript or recording to any party or the deponent.

(4) *Notice of filing.* A party who files the deposition must promptly notify all other parties of the filing.

(g) *Failure to attend a deposition or serve a subpoena.* A judge may order sanctions, in accordance with § 18.57, if a party who, expecting a deposition to be taken, attends in person or by an attorney, and the noticing party failed to:

(1) Attend and proceed with the deposition; or

(2) Serve a subpoena on a nonparty deponent, who consequently did not attend.

§ 18.65 Depositions by written questions.

(a) *When a deposition may be taken*—(1) *Without leave.* A party may, by written questions, depose any person, including a party, without leave of the judge except as provided in paragraph (a)(2) of this section. The deponent's attendance may be compelled by subpoena under § 18.56.

(2) *With leave.* A party must obtain leave of the judge, and the judge must grant leave to the extent consistent with § 18.51(b):

(i) If the parties have not stipulated to the deposition and:

(A) The deposition would result in more than 10 depositions being taken under this section or § 18.64 by a party;

(B) The deponent has already been deposed in the case; or

(C) The party seeks to take a deposition before the time specified in § 18.50(a); or

(ii) If the deponent is confined in prison.

(3) *Service; required notice.* A party who wants to depose a person by written questions must serve them on every other party, with a notice stating, if known, the deponent's name and address. If the name is unknown, the notice must provide a general description sufficient to identify the person or the particular class or group to which the person belongs. The notice must also state the name or descriptive title and the address of the officer before whom the deposition will be taken.

(4) *Questions directed to an organization.* A public or private corporation, a partnership, an association, or a governmental agency may be deposed by written questions in accordance with § 18.64(b)(6).

(5) *Questions from other parties.* Any questions to the deponent from other parties must be served on all parties as follows: cross-questions, within 14 days after being served with the notice and direct questions; redirect questions, within 7 days after being served with cross-questions; and recross-questions, within 7 days after being served with redirect questions. The judge may, for good cause, extend or shorten these times.

(b) *Delivery to the deposition officer; officer's duties.* Unless a different procedure is ordered by the judge, the party who noticed the deposition must deliver to the officer a copy of all the questions served and of the notice. The officer must promptly proceed in the manner provided in § 18.64(c), (e), and (f) to:

(1) Take the deponent's testimony in response to the questions;

(2) Prepare and certify the deposition; and

(3) Send it to the party, attaching a copy of the questions and of the notice.

(c) *Notice of completion or filing*—(1) *Completion.* The party who noticed the deposition must notify all other parties when it is completed.

(2) *Filing.* A party who files the deposition must promptly notify all other parties of the filing.

Disposition Without Hearing

§ 18.70 Motions for dispositive action.

(a) *In general.* When consistent with statute, regulation or executive order, any party may move under § 18.33 for disposition of the pending proceeding. If the judge determines at any time that subject matter jurisdiction is lacking, the judge must dismiss the matter.

(b) *Motion to remand.* A party may move to remand the matter to the referring agency. A remand order must include any terms or conditions and should state the reason for the remand.

(c) *Motion to dismiss.* A party may move to dismiss part or all of the matter for reasons recognized under controlling law, such as lack of subject matter jurisdiction, failure to state a claim upon which relief can be granted, or untimeliness. If the opposing party fails to respond, the judge may consider the motion unopposed.

(d) *Motion for decision on the record.* When the parties agree that an evidentiary hearing is not needed, they may move for a decision based on stipulations of fact or a stipulated record.

§ 18.71 Approval of settlement or consent findings.

(a) *Motion for approval of settlement agreement.* When the applicable statute or regulation requires it, the parties must submit a settlement agreement for the judge's review and approval.

(b) *Motion for consent findings and order.* Parties may file a motion to accept and adopt consent findings. Any agreement that contains consent findings and an order that disposes of all or part of a matter must include:

(1) A statement that the order has the same effect as one made after a full hearing;

(2) A statement that the order is based on a record that consists of the paper that began the proceeding (such as a complaint, order of reference, or notice of administrative determination), as it may have been amended, and the agreement;

(3) A waiver of any further procedural steps before the judge; and

(4) A waiver of any right to challenge or contest the validity of the order entered into in accordance with the agreement.

§ 18.72 Summary decision.

(a) *Motion for summary decision or partial summary decision.* A party may move for summary decision, identifying each claim or defense—or the part of each claim or defense—on which summary decision is sought. The judge shall grant summary decision if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to decision as a matter of law. The judge should state on the record the reasons for granting or denying the motion.

(b) *Time to file a motion.* Unless the judge orders otherwise, a party may file a motion for summary decision at any time until 30 days before the date fixed for the formal hearing.

(c) *Procedures*—(1) *Supporting factual positions.* A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:

(i) Citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or

(ii) Showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

(2) *Objection that a fact is not supported by admissible evidence.* A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.

(3) *Materials not cited.* The judge need consider only the cited materials, but the judge may consider other materials in the record.

(4) *Affidavits or declarations.* An affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated.

(d) *When facts are unavailable to the nonmovant.* If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the judge may:

(1) Defer considering the motion or deny it;

(2) Allow time to obtain affidavits or declarations or to take discovery; or

(3) Issue any other appropriate order.

(e) *Failing to properly support or address a fact.* If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by paragraph (c) of this section, the judge may:

(1) Give an opportunity to properly support or address the fact;

(2) Consider the fact undisputed for purposes of the motion;

(3) Grant summary decision if the motion and supporting materials—including the facts considered undisputed—show that the movant is entitled to it; or

(4) Issue any other appropriate order.

(f) *Decision independent of the motion.* After giving notice and a reasonable time to respond, the judge may:

(1) Grant summary decision for a nonmovant;

(2) Grant the motion on grounds not raised by a party; or

(3) Consider summary decision on the judge's own after identifying for the parties material facts that may not be genuinely in dispute.

(g) *Failing to grant all the requested relief.* If the judge does not grant all the relief requested by the motion, the judge may enter an order stating any material fact—including an item of damages or other relief—that is not genuinely in dispute and treating the fact as established in the case.

(h) *Affidavit or declaration submitted in bad faith.* If satisfied that an affidavit or declaration under this section is submitted in bad faith or solely for delay, the judge—after notice and a reasonable time to respond—may order sanctions or other relief as authorized by law.

Hearing

§ 18.80 Prehearing statement.

(a) *Time for filing.* Unless the judge orders otherwise, at least 21 days before the hearing, each participating party must file a prehearing statement.

(b) *Required conference.* Before filing a prehearing statement, the party must confer with all other parties in good faith to:

(1) Stipulate to the facts to the fullest extent possible; and

(2) Revise exhibit lists, eliminate duplicative exhibits, prepare joint exhibits, and attempt to resolve any objections to exhibits.

(c) *Contents.* Unless ordered otherwise, the prehearing statement must state:

(1) The party's name;

(2) The issues of law to be determined with reference to the appropriate statute, regulation, or case law;

(3) A precise statement of the relief sought;

(4) The stipulated facts that require no proof;

(5) The facts disputed by the parties;

(6) A list of witnesses the party expects to call;

(7) A list of the joint exhibits;

(8) A list of the party's exhibits;

(9) An estimate of the time required for the party to present its case-in-chief; and

(10) Any additional information that may aid the parties' preparation for the hearing or the disposition of the proceeding, such as the need for specialized equipment at the hearing.

(d) *Joint prehearing statement.* The judge may require the parties to file a joint prehearing statement rather than individual prehearing statements.

(e) *Signature.* The prehearing statement must be in writing and signed. By signing, an attorney, representative, or party makes the certifications described in § 18.50(d).

§ 18.81 Formal hearing.

(a) *Public.* Hearings are open to the public. But, when authorized by law and only to the minimum extent necessary, the judge may order a hearing or any part of a hearing closed to the public, including anticipated witnesses. The order closing all or part of the hearing must state findings and explain why the reasons for closure outweigh the presumption of public access. The order and any objection must be part of the record.

(b) *Taking testimony.* Unless a closure order is issued under paragraph (a) of this section, the witnesses' testimony must be taken in an open hearing. For good cause and with appropriate safeguards, the judge may permit testimony in an open hearing by contemporaneous transmission from a different location.

(c) *Party participation.* For good cause and with appropriate safeguards, the judge may permit a party to participate in an open hearing by contemporaneous transmission from a different location.

§ 18.82 Exhibits.

(a) *Identification.* All exhibits offered in evidence must be marked with a designation identifying the party offering the exhibit and must be numbered and paginated as the judge orders.

(b) *Electronic data.* By order the judge may prescribe the format for the submission of data that is in electronic form.

(c) *Exchange of exhibits.* When written exhibits are offered in evidence, one copy must be furnished to the judge and to each of the parties at the hearing, unless copies were previously furnished with the list of proposed exhibits or the judge directs otherwise. If the judge does not fix a date for the exchange of exhibits, the parties must exchange copies of exhibits at the earliest practicable time before the hearing begins.

(d) *Authenticity.* The authenticity of a document identified in a pre-hearing exhibit list is admitted unless a party files a written objection to authenticity at least 7 days before the hearing. The judge may permit a party to challenge a document's authenticity if the party establishes good cause for its failure to file a timely written objection.

(e) *Substitution of copies for original exhibits.* The judge may permit a party to withdraw original documents offered in evidence and substitute accurate copies of the originals.

(f) *Designation of parts of documents.* When only a portion of a document contains relevant matter, the offering party must exclude the irrelevant parts to the greatest extent practicable.

(g) *Records in other proceedings.* Portions of the record of other administrative proceedings, civil actions or criminal prosecutions may be received in evidence, when the offering party shows the copies are accurate.

§ 18.83 Stipulations.

(a) The parties may stipulate to any facts in writing at any stage of the proceeding or orally on the record at a deposition or at a hearing. These stipulations bind the parties unless the judge disapproves them.

(b) Every stipulation that requests or requires a judge's action must be written and signed by all affected parties or their representatives. Any stipulation to extend time must state the reason for the date change.

(c) A proposed form of order may be submitted with the stipulation; it may consist of an endorsement on the stipulation of the words, ''Pursuant to stipulation, it is so ordered,'' with spaces designated for the date and the signature of the judge.

§ 18.84 Official notice.

On motion of a party or on the judge's own, official notice may be taken of any adjudicative fact or other matter subject to judicial notice. The parties must be given an adequate opportunity to show the contrary of the matter noticed.

§ 18.85 Privileged, sensitive, or classified material.

(a) *Exclusion.* On motion of any interested person or the judge's own, the judge may limit the introduction of material into the record or issue orders to protect against undue disclosure of privileged communications, or sensitive or classified matters. The judge may admit into the record a summary or extract that omits the privileged, sensitive or classified material.

(b) *Sealing the record.* (1) On motion of any interested person or the judge's own, the judge may order any material that is in the record to be sealed from public access. The motion must propose the fewest redactions possible that will protect the interest offered as the basis for the motion. A redacted copy or summary of any material sealed must be made part of the public record unless the necessary redactions would be so extensive that the public version would be meaningless, or making even a redacted version or summary available would defeat the reason the original is sealed.

(2) An order that seals material must state findings and explain why the reasons to seal adjudicatory records outweigh the presumption of public access. Sealed materials must be placed in a clearly marked, separate part of the record. Notwithstanding the judge's order, all parts of the record remain subject to statutes and regulations pertaining to public access to agency records.

§ 18.86 Hearing room conduct.

Participants must conduct themselves in an orderly manner. The consumption of food or beverage, and rearranging courtroom furniture are prohibited, unless specifically authorized by the judge. Electronic devices must be silenced and must not disrupt the proceedings. Parties, witnesses and spectators are prohibited from using video or audio recording devices to record hearings.

§ 18.87 Standards of conduct.

(a) *In general.* All persons appearing in proceedings must act with integrity and in an ethical manner.

(b) *Exclusion for misconduct.* During the course of a proceeding, the judge may exclude any person—including a party or a party's attorney or non-attorney representative—for contumacious conduct such as refusal to comply with directions, continued use of dilatory tactics, refusal to adhere to reasonable standards of orderly or ethical conduct, failure to act in good faith, or violation of the prohibition against ex parte communications. The judge must state the basis for the exclusion.

(c) *Review of representative's exclusion.* Any representative excluded from a proceeding may appeal to the Chief Judge for reinstatement within 7 days of the exclusion. The exclusion order is reviewed for abuse of discretion. The proceeding from which the representative was excluded will not be delayed or suspended pending review by the Chief Judge, except for a reasonable delay to enable the party to obtain another representative.

§ 18.88 Transcript of proceedings.

(a) *Hearing transcript.* All hearings must be recorded and transcribed. The parties and the public may obtain copies of the transcript from the official reporter at rates not to exceed the applicable rates fixed by the contract with the reporter.

(b) *Corrections to the transcript.* A party may file a motion to correct the official transcript. Motions for correction must be filed within 14 days of the receipt of the transcript unless the judge permits additional time. The judge may grant the motion in whole or part if the corrections involve substantive errors. At any time before issuing a decision and upon notice to the parties, the judge may correct errors in the transcript.

Post Hearing

§ 18.90 Closing the record; subsequent motions.

(a) *In general.* The record of a hearing closes when the hearing concludes, unless the judge directs otherwise. If any party waives a hearing, the record closes on the date the judge sets for the filing of the parties' submissions.

(b) *Motion to reopen the record.* (1) A motion to reopen the record must be made promptly after the additional evidence is discovered. No additional evidence may be admitted unless the offering party shows that new and material evidence has become available that could not have been discovered with reasonable diligence before the record closed. Each new item must be designated as an exhibit under § 18.82(a) and accompanied by proof that copies have been served on all parties.

(2) If the record is reopened, the other parties must have an opportunity to offer responsive evidence, and a new evidentiary hearing may be set.

(c) *Motions after the decision.* After the decision and order is issued, the judge retains jurisdiction to dispose of appropriate motions, such as a motion to award attorney's fees and expenses, a motion to correct the transcript, or a motion for reconsideration.

§ 18.91 Post-hearing brief.

The judge may grant a party time to file a post-hearing brief with proposed findings of fact, conclusions of law, and the specific relief sought. The brief must refer to all portions of the record and authorities relied upon in support of each assertion.

§ 18.92 Decision and order.

At the conclusion of the proceeding, the judge must issue a written decision and order.

§ 18.93 Motion for reconsideration.

A motion for reconsideration of a decision and order must be filed no later than 10 days after service of the decision on the moving party.

§ 18.94 Indicative ruling on a motion for relief that is barred by a pending petition for review.

(a) *Relief pending review.* If a timely motion is made for relief that the judge lacks authority to grant because a petition for review has been docketed and is pending, the judge may:

(1) Defer considering the motion;

(2) Deny the motion; or

(3) State either that the judge would grant the motion if the reviewing body remands for that purpose or that the motion raises a substantial issue.

(b) *Notice to reviewing body.* The movant must promptly notify the clerk of the reviewing body if the judge states that he or she would grant the motion or that the motion raises a substantial issue.

(c) *Remand.* The judge may decide the motion if the reviewing body remands for that purpose.

§ 18.95 Review of decision.

The statute or regulation that conferred hearing jurisdiction provides the procedure for review of a judge's decision. If the statute or regulation does not provide a procedure, the judge's decision becomes the Secretary's final administrative decision.

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FEDERAL REGISTER

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No. 96 May 19, 2015

Part III

The President

Notice of May 15, 2015—Continuation of the National Emergency With Respect to Burma

Federal Register
Vol. 80, No. 96
Tuesday, May 19, 2015

Presidential Documents

Title 3—

The President

Notice of May 15, 2015

Continuation of the National Emergency With Respect to Burma

On May 20, 1997, the President issued Executive Order 13047, certifying to the Congress under section 570(b) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1997 (Public Law 104–208), that the Government of Burma had committed large-scale repression of the democratic opposition in Burma after September 30, 1996, thereby invoking the prohibition on new investment in Burma by United States persons contained in that section. The President also declared a national emergency pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of the Government of Burma.

The actions and policies of the Government of Burma continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on May 20, 1997, and the measures adopted to deal with that emergency in Executive Orders 13047 of May 20, 1997; 13310 of July 28, 2003; 13448 of October 18, 2007; 13464 of April 30, 2008; 13619 of July 11, 2012; and 13651 of August 6, 2013, must continue in effect beyond May 20, 2015. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Burma declared in Executive Order 13047. This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
May 15, 2015.

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