program enables CMS to compare its data to SSA data to confirm an applicant's or other relevant individual's identity, citizenship, status as deceased or imprisoned, and Title II disability benefit quarters of coverage (QC) and monthly and annual income. The data is used by CMS to authenticate identity, determine eligibility, and determine the amount of an advance payment of the premium tax credit (APTC) or cost sharing reduction (CSR).

CATEGORIES OF INDIVIDUALS:

The categories of individuals whose information is involved in the matching program are consumers who apply for any of the following eligibility determinations, and other relevant individuals (*e.g.,* an applicant's household members) who have eligibility to enroll in a qualified health plan through an exchange established under the ACA, eligibility for insurance affordability programs and certificates of exemption, and subsequent eligibility redeterminations and renewals, including appeal determinations.

CATEGORIES OF RECORDS:

The categories of records used in the matching program are identity, citizenship, birth, death, disability coverage and income, and imprisonment status records. The data elements are as follows:

1. For each applicant and for relevant individuals, CMS will submit a request file to SSA that contains the following mandatory specified data elements in a fixed record format: Last name, first name, date of birth, social security number (SSN), and citizenship indicator.

2. For each applicant, SSA will provide CMS with a response file in a fixed record format. Depending on CMS' request, SSA's response may include the following data elements: Last name, first name, date of birth, death indicator, disability indicator, prisoner information, Title II (annual and monthly) income information, and confirmation of attestations of citizenship status and SSN. SSA may also provide QC data when CMS requests it.

3. For relevant individuals, CMS will request a limited amount of SSA information. Based on CMS' request, SSA will verify a relevant individual's SSN with a death indicator and may provide a relevant individual's QC data or Title II (annual and monthly) income information. CMS will not request citizenship or immigration status data for a relevant individual.

4. For renewals and redeterminations, CMS will request and SSA will verify SSN with a death indicator, disclose Title II income information, and provide the disability indicator.

5. For self-reported redeterminations, CMS will provide SSA with the following: Updated or new information reported by the enrollee or enrolled individual, last name, first name, date of birth, and SSN. Depending on CMS' request, SSA's response will include each of the following data elements that are relevant and responsive to CMS' request: Last name, first name, date of birth, death indicator, disability indicator, prisoner information, Title II (annual and monthly) income information, and confirmation of new attestations of citizenship status, verification of SSN, and QC data.

6. For individuals seeking an exemption, CMS will provide last name, first name, date of birth, citizenship indicator, and SSN to SSA. SSA will provide CMS with a response including: Last name, first name, date of birth, confirmation of attestations of citizenship status, verification of SSN, death indicator, disability indicator, prisoner information, and Title II (annual and monthly) income information.

SYSTEM(S) OF RECORDS:

The records used in this matching program are disclosed from the following systems of records, as authorized by routine uses published in the System of Records Notices (SORNs) cited below:

CMS System of Records:

☐ The CMS SOR that supports this matching program is the ''CMS Health Insurance Exchanges System (HIX)'', CMS System No. 09–70–0560, last published in full at 78 FR 63211 (October 23, 2013), as amended at 83 FR 6591 (February 14, 2018).

SSA Systems of Records:

☐ Master Files of SSN Holders and SSN Applications, 60–0058, 75 FR 82121 (Dec. 29, 2010), as amended at 78 FR 40542 (July 5, 2013), and 79 FR 8780 (Feb. 13, 2014);

☐ Prisoner Update Processing System (PUPS), 60–0269, 64 FR 11076 (Mar. 8, 1999), as amended at 72 FR 69723 (Dec. 10, 2007) and 78 FR 40542 (July 5, 2013);

☐ Master Beneficiary Record, 60–0090, 71 FR 1826 (Jan. 1, 2006), as amended at 72 FR 69723 (Dec. 10, 2007) and 78 FR 40542 (July 5, 2013); and

☐ Earnings Recording and Self-Employment Income System, 60–0059, 71 FR 1819 (Jan. 11, 2006), as amended at 78 FR 40542 (July 5, 2013).

[FR Doc. 2018–16821 Filed 8–6–18; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3366–PN]

Medicare and Medicaid Programs: National Dialysis Accreditation Commission (NDAC) for Approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the National Dialysis Accreditation Commission (NDAC) for recognition as a national accrediting organization (AO) for End Stage Renal Disease (ESRD) Facilities that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2018.

ADDRESSES: In commenting, refer to file code CMS–3366–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3366–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3366–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Tara Lemons, (410) 786–3030, Monda Shaver, (410) 786–3410, or Marie Vasbinder, (410) 786–8665.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an end-stage renal disease (ESRD) facility provided the facility meets the requirements established by the Secretary of the Department of Health and Human Services (Secretary). Section 1881(b) of the Social Security Act (the Act) establishes distinct requirements for facilities seeking designation as an ESRD facility under Medicare. Regulations concerning provider agreements and supplier approval are at 42 CFR part 489 and those pertaining to activities relating to the survey, certification, and enforcement procedures of suppliers which include ESRD facilities are at 42 CFR part 488. The regulations at 42 CFR part 494 subparts A through D implement section 1881(b) of the Act, which specify the conditions that an ESRD facility must meet in order to participate in the Medicare program and the conditions for Medicare payment for ESRD facilities.

Generally, to enter into a Medicare agreement, an ESRD facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 494 subparts A through D of our Medicare regulations. Thereafter, the ESRD facility is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Section 1865(a)(1) of the Act had historically prohibited dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 of the Bipartisan Budget Act of 2018 amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

II. Provisions of the Proposed Notice

A. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of National Dialysis Accreditation Commission's (NDAC) request for CMS-approval of its ESRD facility accreditation program. This notice also solicits public comment on whether NDAC's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ESRD facilities.

This is the first application from a national accreditation body seeking approval of an accreditation program for ESRD facilities.

B. Evaluation of Deeming Authority Request

NDAC submitted all the necessary materials to enable us to make a determination concerning its request for CMS-approval of its ESRD facility accreditation program. This application was determined to be complete on June 8, 2018. Under section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of NDAC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of NDAC's standards for ESRD facilities as compared with Medicare's CfCs for ESRD facilities.
- NDAC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of NDAC's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ NDAC's processes and procedures for monitoring an ESRD facility found out of compliance with NDAC's program requirements. These monitoring procedures are used only when NDAC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ NDAC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ NDAC's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of NDAC's staff and other resources, and its financial viability.

++ NDAC's capacity to adequately fund required surveys.

++ NDAC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ NDAC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: July 27, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–16871 Filed 8–6–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2382]

Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment.'' This guidance addresses the clinical endpoints acceptable to demonstrate effectiveness of drugs for medication-assisted treatment of opioid use disorder. FDA is also requesting comments on when the use of placebo or active controls is most appropriate in clinical trials for such drugs.

DATES: Submit either electronic or written comments on the draft guidance by October 9, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2382 for ''Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Silvana Borges, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3200,