grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at § 411.362(c)(7).

IV. Hospital Exception Request

As permitted by section 1877(i)(3) of the Act and our regulations at § 411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Solutions Medical Consulting, LLC d/b/a Serenity Springs Hospital

Location: 1495 Frazier Road, Ruston, Louisiana 71270–1632

Basis for Exception Request: High Medicaid Facility

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS website at: *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html.* We solicit public comments regarding whether the hospital qualifies as a high Medicaid facility. Under § 411.362(c)(3), a high Medicaid facility is a hospital that satisfies all of the following criteria:

- Is not the sole hospital in the county in which the hospital is located.
- With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.
- Does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Individuals and entities wishing to submit comments on the hospital's request should review the ''DATES'' and ''ADDRESSES'' sections above and state whether or not they are in the community in which the hospital is located.

V. 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.*).

VI. Response to 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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 8, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2020–27354 Filed 12–10–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ORR–3 and ORR–4 Report Forms for the Unaccompanied Refugee Minors Program (OMB #0970–0034)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for Public Comment.

SUMMARY: The Office of Refugee Resettlement (ORR) is requesting a 3-year extension of the ORR–3 and ORR–4 Report Forms (OMB #0970–0034, expiration 01/31/2021). ORR proposes revisions to improve clarity, secure outcome-based data, increase compliance with reporting requirements, and reduce burden.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The ORR–3 Report is submitted within 30 days of the minor's initial placement in the state, within 60 days of a change in the minor's status (*e.g.,* change in legal responsibility, change in foster home placement, change in immigration data), and within 60 days of termination from the program. The ORR–4 Report is submitted every 12 months beginning on the first anniversary of the initial placement date, to record outcomes of the minor's progress.

Respondents: Unaccompanied Refugee Minors (URM) State Agencies, URM Provider Agencies, and Youth Participants.

Annual Burden Estimates: URM State Agencies.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ORR–3 Unaccompanied Refugee Minors Placement Report	15	432	0.25	1,620	540
ORR–4 Unaccompanied Refugee Minors Outcomes Report	15	282	0.50	2,115	705

Estimated Total Annual Burden Hours (State Agencies): 1,245.

Annual Burden Estimates: URM Provider Agencies.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ORR–3 Unaccompanied Refugee Minors Placement Report	24	270	0.50	3,240	1,080
ORR–4 Unaccompanied Refugee Minors Outcomes Report	24	162	1.0	3,888	1,296

Estimated Total Annual Burden Hours (Provider Agencies): 2,376.

Annual Burden Estimates: Youth Participants.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ORR–4 Unaccompanied Refugee Minors Outcomes Report	1032	3	0.50	1,548	516

Estimated Total Annual Burden Hours (Youth Participants): 516.

Total Estimated Annual Burden Hours: 4,137.

Authority: 8 U.S.C. 1522(d).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–27194 Filed 12–10–20; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–D–1647, FDA–2019–D–1652, and FDA–2019–D–1650]

Performance Criteria for Safety and Performance Based Pathway; Guidances for Industry and Food and Drug Administration Staff; 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 three device-specific final guidance documents for the Safety and Performance Based Pathway—specifically, ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' and ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidances identified in this notice were developed in accordance with the final guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidances is published in the **Federal Register** on December 11, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2019–D–1647 for ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' Docket No. FDA–2019–D–1652 for ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff,'' and Docket No. FDA–2019–D–1650 for ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' 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