On July 20, 2015, the Commission released the part 1 R&O in which it updated many of its part 1 competitive bidding rules (See Updating Part 1 Competitive Bidding Rules; Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions; Petition of DIRECTV Group, Inc. and EchoStar LLC for Expedited Rulemaking to Amend Section 1.2105(a)(2)(xi) and 1.2106(a) of the Commission's Rules and/or for Interim Conditional Waiver; Implementation of the Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures, Report and Order, Order on Reconsideration of the First Report and Order, Third Order on Reconsideration of the Second Report and Order, and Third Report and Order, FCC 15–80, 30 FCC Rcd 7493 (2015), modified by Erratum, 30 FCC Rcd 8518 (2015) (Part 1 R&O)). Of relevance to the information collection at issue here, the Commission: (1) Implemented a new general prohibition on the filing of auction applications by entities controlled by the same individual or set of individuals (but with a limited exception for qualifying rural wireless partnerships); (2) modified the eligibility requirements for small business benefits, and updated the standardized schedule of small business sizes, including the gross revenues thresholds used to determine eligibility; (3) established a new bidding credit for eligible rural service providers; (4) adopted targeted attribution rules to prevent the unjust enrichment of ineligible entities; and (5) adopted rules prohibiting joint bidding arrangements with limited exceptions. The updated Part 1 rules apply to applicants seeking licenses and permits.

Additionally, on June 2, 2014 the Commission released the Mobile Spectrum Holdings R&O, in which the Commission updated its spectrum screen and established rules for its upcoming auctions of low-band spectrum. Of relevance to the information collection at issue here, the Commission stated that it could reserve spectrum in order to ensure against excessive concentration in holdings of below-1–GHz spectrum (In the Matter of Policies Regarding Mobile Spectrum Holdings, Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, FCC 14–63, Report and Order, 29 FCC Rcd 6133, 90) 135 (2014) (Mobile Spectrum Holdings R&O). See also Application Procedures for Broadcast Incentive Auction Scheduled to Begin on March 29, 2016; Technical Formulas for Competitive Bidding, Public Notice, 30 FCC Rcd 11034, Appendix 3 (WTB 2015); Wireless Telecommunications Bureau Releases Updated List of Reserve-Eligible Nationwide Service Providers in each PEA for the Broadcast Incentive Auction, Public Notice, AU No. 14–252 (WTB 2016).

The Commission seeks approval for revisions to its previously approved collection of information under OMB Control Number 3060–0798 to permit the collection of the additional information for Commission licenses and permits, pursuant to the rules and information collection requirements adopted by the Commission in the Part 1 R&O and the Mobile Spectrum Holdings R&O. As part of the collection, the Commission is seeking approval for the information collection and recordkeeping requirements associated with 47 CFR 1.2210(j), 1.2112(b)(2)(iii), 1.2112(b)(2)(v), 1.2112(b)(2)(vii), and 1.2112(b)(2)(viii). Also, in certain circumstances, the Commission requires the applicant to provide copies of their agreements and/or submit exhibits.

In addition, the Commission seeks approval for various other, non-substantive editorial/consistency edits and updates to FCC Form 601 that correct inconsistent capitalization of words and other typographical errors, and better align the text on the form with the text in the Commission rules both generally and in connection with recent non-substantive, organizational amendments to the Commission's rules. The Commission therefore seeks approval for a revision to its currently approved information collection on FCC Form 601 to revise FCC Form 601 accordingly.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–11582 Filed 5–16–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0207]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 18, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0207.

Title: Part 11—Emergency Alert System (EAS), Order, FCC 16–32.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal government.

Number of Respondents and Responses: 63,080 respondents; 3,596,546 responses.

Estimated Time per Response: 1 hour (EAS Participants); 20 hours (SECCs).

Frequency of Response: One-time reporting requirement and recordkeeping requirement.

Obligation to Respond: Obligatory for all entities required to participate in

EAS. Statutory authority for this collection of information is contained in 47 U.S.C. 154(i) and 606 of the Communications Act of 1934, as amended.

Total Annual Burden: 110,476 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: Part 11 contains rules and regulations addressing the nation's Emergency Alert System (EAS). The EAS provides the President with the capability to provide immediate communications and information to the general public at the national, state and local area level during periods of national emergency. The EAS also provides state and local governments and the National Weather Service with the capability to provide immediate communications and information to the general public concerning emergency situations posing a threat to life and property. State and local use of the EAS is required to be described in State EAS Plans that are administered by State Emergency Communications Committees (SECC) and submitted to the FCC for approval.

In the *Third Report and Order* in EB Docket No. 04–296, FCC 11–12, the Commission adopted rules establishing a regulatory structure for a national test of the EAS. In order for the Commission to determine the extent to which the test, and by extension the EAS, was successful, the FCC adopted rules requiring EAS Participants, within forty five (45) days of the date of the first national EAS test, to record and submit to the Commission the following test-related diagnostic information for each alert received from each message source monitored at the time of the national test:

- Whether they received the alert message during the designated test;
- whether they retransmitted the alert;
- if they were not able to receive and/or transmit the alert, their 'best effort' diagnostic analysis regarding the cause(s) for such failure;
- a description of their station identification and level of designation (PEP, LP–1, etc.);
- the date/time of receipt of the EAN message by all stations; the date/time of PEP station acknowledgement of receipt of the EAN message to FOC;
- the date/time of initiation of actual broadcast of the Presidential message;
- the date/time of receipt of the EAT message by all stations;
- who they were monitoring at the time of the test, and the make and
- model number of the EAS equipment that they utilized.

The *Third Report and Order* indicates that the national tests of EAS, and related information collections will likely be carried out on an annual basis. On March 10, 2010, OMB approved the collection as indicated by the related Notice of Office of Management and Budget Action notification.

The FCC is submitting this information collection to the Office of Management and Budget (OMB) as a revision of the previously approved information collection that established the mandatory Electronic Test Reporting System (ETRS) that EAS Participants must utilize to file identifying and test result data as part of their participation in nationwide EAS testing. Specifically, the *Order* adopted in EB Docket No. 04–296, FCC 16–32, amends the State EAS Plan filing requirements set forth at Section 11.21 of the Commission's rules to require EAS Participants (*i.e.,* the broadcasters, cable systems, and other service providers subject to the FCC's EAS rules) to provide the following information to their respective SECC, who in turn will include such information in the State EAS Plan submitted to the Commission for approval:

- A description of any actions taken by the EAS Participant (acting individually, in conjunction with other EAS Participants in the geographic area, and/or in consultation with state and local emergency authorities), to make EAS alert content available in languages other than English to its non-English speaking audience(s);
- A description of any future actions planned by the EAS Participant, in consultation with state and local emergency authorities, to provide EAS alert content in languages other than English to its non-English speaking audience(s), along with an explanation for the EAS Participant's decision to plan or not plan such actions; and
- Any other relevant information that the EAS Participant may wish to provide.

In addition, in the event that there is a material change to any of the information that EAS Participants are required to furnish their respective SECCs, EAS Participants must, within 60 days of the occurrence of such material change, submit aa letter to their respective SECCs, copying the Commission's Public Safety and Homeland Security Bureau (Bureau) that describe such change. The SECCs are required to incorporate the information in such letters as amendments to the State EAS Plans on file with the Bureau.

This information will be used by FCC staff to gauge the effectiveness of the EAS's capacity to disseminate in-language EAS emergency alert content to persons who communicate in a language other than English or may have a limited understanding of the English language; to determine whether private and local efforts to disseminate EAS multilingual content might be incorporated into the overall national EAS structure; and to confirm that private and local EAS multilingual operations are consistent with national plans, FCC regulations, and EAS operation.

The Commission expects that the costs to EAS Participants to comply with these reporting requirements will be minimal, and largely limited to internal administrative charges associated with drafting a brief statement, and submitting that statement, and any other relevant information that the EAS Participant may wish to provide to their SECC for inclusion into the State EAS Plan for the state in which the EAS Participant operates. The Commission further expects that the vast majority of EAS Participants are not engaged in multilingual EAS activities and therefore will need to submit nothing more than a very brief statement to their SECC explaining their decision to plan or not plan future actions to provide EAS alert content in languages other than English to their non-English speaking audience(s). For the presumably small percentage of EAS Participants that actually are engaged in multilingual EAS activities, the filing will merely require that they supply a summary of actions they already have taken in this regard. Accordingly, the FCC estimates that complying with the reporting requirement will take EAS Participants, on average, approximately one hour. The FCC estimates that compiling the EAS Participant summaries of multilingual EAS activities and incorporating such information into the State EAS Plan will take SECCs, on average, approximately 20 hours.

The following information collection contained in part 11 may be impacted by these rule amendments: Section 11.21 requires that state and local EAS plans be reviewed and approved by the Chief, Public Safety and Homeland Security, prior to implementation to ensure that they are consistent with national plans, FCC regulations, and EAS operation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–11583 Filed 5–16–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1224]

Use of Electronic Health Record Data in Clinical Investigations; 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 ''Use of Electronic Health Record Data in Clinical Investigations.'' The draft guidance is intended to assist sponsors, clinical investigators, contract research organizations, institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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 deliveryCourier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–1224 for ''Use of Electronic Health Record Data in Clinical Investigations; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments 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.

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; the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3348, Silver Spring, MD 20993–0002, 301–796–2500; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Irfan Khan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3563, Silver Spring, MD 20993–0002, 301–796–7100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Use of Electronic Health Record Data in Clinical Investigations.'' The draft guidance is intended to assist sponsors, clinical investigators, contract research organizations, IRBs, and other interested parties on the use of EHR data in FDA-