the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. Please cite OMB Control No. 3090–0293, Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements, in all correspondence.

Dated: February 20, 2018.

David A. Shive,

Chief Information Officer.

[FR Doc. 2018–03745 Filed 2–22–18; 8:45 am]

BILLING CODE 6820–WY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Expired Listing for Quality Solutions

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. The listing for Quality Solutions has expired and AHRQ has delisted the PSO accordingly.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on January 6, 2018.

ADDRESSES: Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

Quality Solutions, PSO number P0165, is a component entity of: Chest Medicine Associates, Coastal Women's Healthcare, Eyecare Medical Group, Maine Nephrology Associates, New England Cancer Specialists, Plastic & Hand Surgical Associates, Portland Gastroenterology, and Spectrum Medical Group. The PSO chose to let its listing expire by not seeking continued listing. Accordingly, Quality Solutions was delisted effective at 12:00 Midnight ET (2400) on January 6, 2018.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Karen J. Migdail,

Chief of Staff.

[FR Doc. 2018–03744 Filed 2–22–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Aging

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; State Annual Long-Term Care Ombudsman Report Known as the National Ombudsman Reporting System (NORS) and Instructions (OMB No: 0985–0005)

AGENCY: Administration for Community Living/Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living/Administration on Aging (ACL/AoA) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the Long-Term Care Ombudsman Program (Proposed Extension with Changes of a Currently Approved Collection (ICR Rev)).

DATES: Submit written comments on the collection of information by March 26, 2018.

ADDRESSES: Submit written comments on the collection of information by fax to 202.395.5806, Attn: OMB Desk Officer for ACL; by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL; or by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Louise Ryan, telephone: (206) 615–2514; email: *louise.ryan@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL/AoA has submitted the following proposed collection of information to OMB for review and clearance.

States provide the following data and narrative information in the report:

1. Numbers and descriptions of cases filed and complaints made on behalf of long-term care facility residents to the statewide ombudsman program;
2. Major issues identified that impact the quality of care and life of long-term care facility residents;
3. Statewide program operations; and
4. Ombudsman activities in addition to complaint investigation.

The report form and instructions have been in continuous use, with minor modifications, since they were first approved by OMB for the FY 1995 reporting period. This current request is for a Revision of a Currently Approved Collection (ICR Rev) to acquire new approval for a revised modification of instruction and data collection elements for FFY 2019–2021.

The data collected on complaints filed with ombudsman programs and narrative on long-term care issues provide information to the Centers for Medicare and Medicaid Services and others on patterns of concerns and major long-term care issues affecting residents of long-term care facilities. Both the complaint and program data collected assist the states and local Ombudsman programs in planning strategies and activities, providing training and technical assistance, and developing performance measures.

Comments in Response to the 60 Day Federal Register Notice

A notice was published in the **Federal Register**, Vol. 81, No. 152, Page 52438 on Monday, August 8, 2016 announcing that ACL/AoA was requesting comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL/AoA's functions, including whether the information will have practical utility; (2) the accuracy of ACL/AoA'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. Readers were directed to the ACL/AoA website where the documents were posted and provided an opportunity to comment. ACL received comments from 18 individuals and groups. Comments were received by the following groups and individuals: National Association of State Ombudsman Programs (NASOP); National Association of Local LTC Ombudsman (NALLTCO); one software vendor; the California Association of Local LTC Ombudsmen; the Consumer Voice for Quality LTC Care. Individuals included one researcher with expertise in dementia, abuse and neglect and one local representative of the Office of State Ombudsman. The following State Ombudsman programs provided comment: California; Florida; Maryland; New York; Iowa; Pennsylvania; Arizona; New Hampshire; Texas; Alaska; Virginia. Many of the state Ombudsman comments were identical to NASOP's comments.

In general, there were no significant comments on the proposed data elements. Instead, comments focused on ways to enhance the quality, utility, and clarity of the information to be collected. These comments were very helpful and many of the proposed edits and language suggestions were adopted.

Concerns regarding burden included: Disagreement about the burden hours because of changes in data collection requirements and additional structured requirements of narrative complaint examples, systems issues and conflicts of interest reporting. The new reporting system will streamline these current reporting activities, allowing for flexibility and the ability to import data from the previous year for use in the next year, where appropriate, and will reduce overall reporting burden for State LTC Ombudsmen. Several commenters expressed concern about undue burden of a name change from ''board and care'' to ''residential care community'', but did not provide a specific estimate of burden hours. In response to their concerns the definition of residential care was revised to eliminate any confusion about the jurisdiction of the program with regards to the types of settings the program serves. ACL does not believe that a change in definition and title will cause confusion at the state and local level because there will not be a change in state level practice. These concerns are addressed in detail in the response to comments tables posted on the ACL website. Some responders expressed concern about burden with a data collection item to indicate if a complaint was a complaint on behalf of more than one complainant, *i.e.,* a ''group complaint'' (Table 1, code C5 on the 60 day submission). ACL removed this data element. Some commenters expressed concerns about the cost to update and revise their reporting systems, but the estimates of impact on data collection burden varied. One State that has developed their own software utilizing in-house IT services, estimates a range from 9–52 days of work for software changes and 5–55 days to update training materials, update their in-house reference guide, provide training, etc. Another state estimates that the changes required will cost around $10,000. One vendor commented that they see ''no issue'' with the proposed changes and that they are committed to keeping all of their customers using their Ombudsman product up to date with any NORS reporting changes. Since the comments were not consistent in this area no changes have been made. Additional concerns about the wording in proposed definitions and requests to add additional data collection elements are addressed in the response to comments tables.

Some commenters expressed concerns about training needs and time required to adapt their software. ACL is working with the contractor developing the reporting software to develop training modules on how to use the new software. ACL anticipates that states will not need to develop training materials or host training to meet the federal reporting requirements. Training will be offered as webinars and in person at national conferences, when possible. User support materials and recorded webinars will also be available on the submission website. The National Ombudsman Resource Center will develop modules on how to interpret the new definitions and codes similar to past training. This includes hosting webinars and providing in-person training at their annual spring training for state LTC Ombudsmen. In addition, they will host all tools and modules on their website. The contractor is holding meetings with vendors and state information technology staff on the technical requirements of the new system and will provide data templates in various formats; and detailed crosswalks of the current data collection to the new data collection. Despite the concerns addressed, there was an overall positive tone to the comments. State Ombudsman programs largely support the changes made by ACL to NORS. They indicated they appreciate ACL's efforts to incorporate many of the revisions previously recommended. Further, they indicated these changes will result in more accurate and consistent reporting as well as more precise identification of trends and the systems advocacy needed to address common complaints.

Estimated Program Burden

In consideration of the comments, additional burden time has been factored in to accommodate changes in data collection at the case level resulting in an average increase of 75.6 hours per state for a total 223.6 hours annually. Despite the decrease in the number of data elements we believe this more adequately reflects the overall burden. This increase in burden hours also recognizes that this revision is the most significant change to NORS data collection since its implementation in 1995.

The reporting form tables and a crosswalk from the old data collection to the new may be viewed at the ACL website: *https://www.acl.gov/about-acl/public-input.*

AoA estimates the burden of this collection and entering the additional report information as follows:

Instrument	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Annual State Ombudsman Report	52	1	223.6	11,628.6

Dated: February 16, 2018.

Mary Lazare,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2018–03767 Filed 2–22–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–2602; FDA–2015–E–2615]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZYDELIG—New Drug Application 206545

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZYDELIG based on new drug application (NDA) 206545 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 24, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 22, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 24, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Nos. FDA–2015–E–2602 and FDA–2015–E–2615 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZYDELIG–NDA 206545.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the dockets 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 § 10.20 (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