

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
HPOG 2.0 National Evaluation descriptive study second round telephone interview protocol	190	63	1	1.25	79
HPOG 2.0 National Evaluation descriptive study program operator interview guide	16	5	1	1.25	6
HPOG 2.0 National Evaluation descriptive study partner interview guide	112	37	1	1	37
HPOG 2.0 National Evaluation descriptive study participant in-depth interview guide	140	47	1	1.33	63
Intermediate follow-up survey for the HPOG 2.0 National Evaluation impact study	4,000	1,333	1	1	1,333
HPOG 2.0 National Evaluation impact study instrument for a Pilot Study of Phone-Based Skills Assessment	300	100	1	.75	75
HPOG 2.0 National Evaluation program cost survey	38	13	1	7	91

Estimated Total Annual Burden Hours: 1,691.

Authority: Section 2008 of the Social Security Act as enacted by Section 5507 of the Affordable Care Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08163 Filed 4–22–19; 8:45 am]

BILLING CODE 4184–72–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; State Access and Visitation Grant Application (OMB #0970–0482)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement is requesting a three-year

extension of the application form titled, *Child Access and Visitation Grant Application Form*, expiration 8/31/2019. There are no changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA.SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained by writing to the

Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The application compiles detailed information regarding program administration, services planned, state priorities, and program safeguards for using grant funds to increase noncustodial parent access to and visitation with their children. This information allows OCSE to review states' Access and Visitation services for the purpose of ensuring compliance with federal regulation and to provide enhanced targeted technical assistance as indicated. The application is submitted one time at the beginning of a three year grant program cycle and only updated during the three years if a grantee proposes substantive programmatic or administrative change.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Child Access and Visitation Grant Application Form	54	1	10	540	180

Estimated Total Annual Burden Hours: 180.

Authority: Sec. 469B. [42 U.S.C.669b].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–08109 Filed 4–22–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) hereby announces the renewal of the Best Pharmaceuticals for Children Act (BPCA) Program. The Best Pharmaceuticals for Children Act (BPCA) seeks to improve the level of

information on the safe and effective use of pharmaceuticals used to treat children. The BPCA requires that the NIH identify the drugs of highest priority for study in pediatric populations, publish a list of drugs/needs in pediatric therapeutics, and fund studies in the prioritized areas. This notice will provide a brief summary of recent changes in the legislation, a brief update on the current progress of the BPCA Program and provide the current Priority List of Needs in Pediatric Therapeutics.

ADDRESSES: The complete Priority List of Needs in Pediatric Therapeutics 2018–2019 can be found on the BPCA website at the following address: <https://www.nichd.nih.gov/research/supported/bpca/activities>.

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata via email at taylorpe@mail.nih.gov; or by phone at 301–496–9584.

SUPPLEMENTARY INFORMATION: The BPCA requires that the NIH, in consultation with the Food and Drug Administration and experts in pediatric research, identify the drugs and therapeutic areas of highest priority for study in pediatric populations. The NIH BPCA Program has been in existence since 2004 and is overseen by the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) of the NICHD. To date, the BPCA Program has prioritized over 150 drugs and therapeutic areas, funded more than 25 clinical studies, and improved the labeling to date of eight drugs and one device in the ongoing effort of advancing the knowledge of dosing, safety and effectiveness of medicines used in children. However, despite these and many other efforts, many gaps in our knowledge still remain regarding the use of therapeutics in children including the correct dosage, appropriate indications, side effects, and safety concerns of pharmaceuticals in the short- and long-term. These gaps result in inadequate labeling and/or wide-spread off-label use of prescription drugs in children. Off-label use of a drug substantially limits the ability to obtain important clinical information for more generalized use of a drug product, such as characterizing changes in drug metabolism and response during growth and development, identifying precision-based responses (*i.e.*, impact of genotype and phenotype of medication responses, the impact of obesity on dosing), and determining short- and long-term effects. The mandate of the NIH BPCA Program is to fill knowledge gaps that exist in pediatric therapeutics and to promote an increase in evidence-based data about medications used in

children. Please see the BPCA website for more information: <https://www.nichd.nih.gov/research/supported/bpca/about>.

Update on the BPCA Legislation

First authorized in 2002, the Best Pharmaceuticals for Children Act (BPCA) has been reauthorized as part of larger Food and Drug Administration (FDA) user fee legislation three additional times: 2007, 2012, and now 2017. The overall mandate for the implementation of the research program at NIH has remained the same throughout, but with clarifications each time: To prioritize testing of pediatric therapeutics that do not have labeling for pediatric use, to sponsor clinical trials and other research to provide the necessary data, and to submit those data to the FDA to begin the process of obtaining label changes and provide clinicians with the appropriate information on appropriate pediatric use and dosing. In August of 2017, the BPCA legislation was reauthorized by Congress, which renewed the NIH BPCA Program for five years (the FDA portion of the program is permanently authorized). The new legislation also permits the NIH to prioritize research on the identification of biomarkers for pediatric diseases and conditions. In addition, a new provision specifically allows the NIH to post the data from the pediatric studies it funded on its public website when it submits the report to the FDA, as required for potential label changes.

Update on BPCA Prioritization

The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents identified for further study; it is organized by therapeutic area, which can be a group of conditions, a subgroup of the population, or a setting of care. The first priority list of off-patent drugs needing further study under the 2002 BPCA legislation was published in January 2003 in the **Federal Register** (FR Vol. 68, No. 13; Tuesday, January 21, 2003; 2789–2790). The most recent priority list has been published to the BPCA website; more information on the prioritization process, all BPCA priority lists, and all **Federal Register** Notices can be found on the BPCA website: <https://www.nichd.nih.gov/research/supported/bpca/prioritizing-pediatric-therapies>. The BPCA authorizing legislation requires the NIH to update the priority list every three years. This Notice serves as an update to the BPCA priority list of needs in pediatric therapeutics.

Each year, the NICHD revisits the current list of needs in pediatric therapeutics and seeks input from experts in pediatric research and medicine to determine if previous needs still exist and if new areas of needs have developed.

Below is an updated list of therapeutic areas and drugs that have been prioritized for study since the inception of the BPCA and a summary of the NICHD's plans and progress in all of these areas to date. In 2017, the NIH BPCA Program focused on the following areas: Treatment options in Pediatric Hypertension, Biomarkers in Pediatric Research (various subspecialties), and Treatment strategies in several neonatal conditions (including Neonatal Opioid Withdrawal Syndrome, also known as Neonatal Abstinence Syndrome). Meeting minutes for workshops and lectures on the above topics can be found on the BPCA website <https://www.nichd.nih.gov/research/supported/bpca/research-initiatives-collaborations>.

For 2018, the NIH BPCA Program's priorities have included: Heart failure in children, Kidney diseases, and Lactation (in particular, neonatal and infant medication exposure). The NICHD welcomes input from the pediatric medical community on additional gaps in pediatric therapeutics for future consideration. The most recent BPCA stakeholders meeting was held in Bethesda, Maryland on March 22, 2019. More information will be provided on the BPCA website as it becomes available. All inquiries should be submitted to Dr. Perdita Taylor-Zapata at the contact information above.

Priority List of Needs in Pediatric Therapeutics 2018–2019

In accordance with the BPCA legislation, the list outlines priority needs in pediatric therapeutics for multiple therapeutic areas listed below. The complete list can be found on the BPCA website at the following address: <https://www.nichd.nih.gov/research/supported/bpca/activities>.

- Table 1: Infectious Disease Priorities
- Table 2: Cardiovascular Disease Priorities
- Table 3: Respiratory Disease Priorities
- Table 4: Intensive Care Priorities
- Table 5: Bio-defense Research Priorities
- Table 6: Pediatric Cancer Priorities
- Table 7: Psychiatric Disorder Priorities
- Table 8: Neurological Disease Priorities
- Table 9: Neonatal Research Priorities
- Table 10: Adolescent Research Priorities

- Table 11: Hematologic Disease Priorities
- Table 12: Endocrine Disease Priorities and Diseases with Limited Alternative Therapies
- Table 13: Dermatologic Disease Priorities
- Table 14: Gastrointestinal Disease Priorities
- Table 15: Renal Disease Priorities
- Table 16: Rheumatologic Disease Priorities
- Table 17: Special Considerations.

Dated: April 17, 2019.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2019-08167 Filed 4-22-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6101-N-04]

Notice of Regulatory Waiver Requests Granted for the Fourth Quarter of Calendar Year 2018

AGENCY: Office of the General Counsel, HUD.

ACTION: Notice.

SUMMARY: Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (the HUD Reform Act) requires HUD to publish quarterly **Federal Register** notices of all regulatory waivers that HUD has approved. Each notice covers the quarterly period since the previous **Federal Register** notice. The purpose of this notice is to comply with the requirements of section 106 of the HUD Reform Act. This notice contains a list of regulatory waivers granted by HUD during the period beginning on October 1, 2018 and ending on December 31, 2018.

FOR FURTHER INFORMATION CONTACT: For general information about this notice, contact Ariel Pereira, Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10282, Washington, DC 20410-0500, telephone 202-708-3055 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

For information concerning a particular waiver that was granted and for which public notice is provided in this document, contact the person whose name and address follow the description of the waiver granted in the

accompanying list of waivers that have been granted in the fourth quarter of calendar year 2018.

SUPPLEMENTARY INFORMATION: Section 106 of the HUD Reform Act added a new section 7(q) to the Department of Housing and Urban Development Act (42 U.S.C. 3535(q)), which provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary or equivalent rank, and the person to whom authority to waive is delegated must also have authority to issue the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that HUD has approved, by publishing a notice in the **Federal Register**. These notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;

b. Describe the nature of the provision waived and the designation of the provision;

c. Indicate the name and title of the person who granted the waiver request;

d. Describe briefly the grounds for approval of the request; and

e. State how additional information about a particular waiver may be obtained.

Section 106 of the HUD Reform Act also contains requirements applicable to waivers of HUD handbook provisions that are not relevant to the purpose of this notice.

This notice follows procedures provided in HUD's Statement of Policy on Waiver of Regulations and Directives issued on April 22, 1991 (56 FR 16337). In accordance with those procedures and with the requirements of section 106 of the HUD Reform Act, waivers of regulations are granted by the Assistant Secretary with jurisdiction over the regulations for which a waiver was requested. In those cases in which a General Deputy Assistant Secretary granted the waiver, the General Deputy Assistant Secretary was serving in the absence of the Assistant Secretary in accordance with the office's Order of Succession.

This notice covers waivers of regulations granted by HUD from October 1, 2018 through December 31, 2018. For ease of reference, the waivers granted by HUD are listed by HUD program office (for example, the Office of Community Planning and

Development, the Office of Fair Housing and Equal Opportunity, the Office of Housing, and the Office of Public and Indian Housing, etc.). Within each program office grouping, the waivers are listed sequentially by the regulatory section of title 24 of the Code of Federal Regulations (CFR) that is being waived. For example, a waiver of a provision in 24 CFR part 58 would be listed before a waiver of a provision in 24 CFR part 570.

Where more than one regulatory provision is involved in the grant of a particular waiver request, the action is listed under the section number of the first regulatory requirement that appears in 24 CFR and that is being waived. For example, a waiver of both § 58.73 and § 58.74 would appear sequentially in the listing under § 58.73.

Waiver of regulations that involve the same initial regulatory citation are in time sequence beginning with the earliest-dated regulatory waiver.

Should HUD receive additional information about waivers granted during the period covered by this report (the fourth quarter of calendar year 2018) before the next report is published (the first quarter of calendar year 2019), HUD will include any additional waivers granted for the fourth quarter in the next report.

Accordingly, information about approved waiver requests pertaining to HUD regulations is provided in the Appendix that follows this notice.

Dated: April 16, 2019.

J. Paul Compton, Jr.,

General Counsel.

Appendix—Listing of Waivers of Regulatory Requirements Granted by Offices of the Department of Housing and Urban Development October 1, 2018 Through December 31, 2018

Note to Reader: More information about the granting of these waivers, including a copy of the waiver request and approval, may be obtained by contacting the person whose name is listed as the contact person directly after each set of regulatory waivers granted. The regulatory waivers granted appear in the following order:

- I. Regulatory waivers granted by the Office of Community Planning and Development.
- II. Regulatory waivers granted by the Office of Housing.
- III. Regulatory waivers granted by the Office of Public and Indian Housing.

I. Regulatory Waivers Granted by the Office of Community Planning and Development

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

- *Regulation:* 24 CFR 92.252(d)(1) Utility Allowance Requirements.