TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115; IRB records (documentation of IRB activities), including waiver request reviews..	2,520	14.6	36,792	40	1,471,680
Total					1,522,104

There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.24 and 50.27 as recordkeeping burden. We assume each of the 2,520 IRBs meets an average of 14.6 times annually and assume 40 hours of person-time per meeting are required to meet the IRB recordkeeping requirements of § 56.115. We also assume most recordkeeping is completed electronically.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(g); IRB written statement about public disclosures to sponsor of emergency research under § 50.24.	8	2	16	1	16
Total					103,336

There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.25 and 56.109(d) and (e) as disclosure burden. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under § 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19849 Filed 9–28–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Marrow Donor Program Patient Support Center Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than October 29, 2026.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Marrow Donor Program Patient Support Center Survey, OMB No. 0906–0004—Revision.

Abstract: The C.W. Bill Young Cell Transplantation Program (CWBYCTP) was established by the Stem Cell Therapeutic and Research Act of 2005 (Public Law [Pub. L.] 109–129) and was reauthorized in 2010 (Pub. L. 111–264), 2015 (Pub. L. 114–104), and again in 2021 (Pub. L. 117–15). The CWBYCTP's

Office of Patient Advocacy (OPA) is operated by the National Marrow Donor Program, d.b.a. NMDP℠. Through the OPA, NMDP℠ provides navigation services, educational resources, and support to people in need of or who have received an allogeneic hematopoietic cell transplant (HCT). As the contractor for the OPA, NMDP℠ is required to conduct surveys to evaluate patient satisfaction with the services provided. Accordingly, NMDP℠ will solicit feedback from HCT patients, caregivers, and family members who have contacted the NMDP℠ Patient Support Center (PSC). The survey is administered through a web-based system. In addition to questions that measure satisfaction, the survey also includes demographic questions to assess the representativeness of the findings.

A 60-day Notice was published in the **Federal Register** on July 1, 2026, vol. 91, No. 125, pp. 40004–40005. There were two public comments. The first commenter suggested that, for surveys administered repeatedly over time, previously submitted information be pre-populated to reduce respondent burden and improve the user experience. HRSA reviewed the comment and did not adopt this change, because this survey is not designed to collect longitudinal data. Although pre-populated information may reduce burden in some post-transplant follow-up contexts, this survey is specific to respondents who contact the NMDP℠ PSC immediately before and after transplant, generally within a 12-month period. Respondents generally receive the survey only once within that 12-month period after the first interaction. A subsequent survey is sent only if they have another contact with the NMDP℠ PSC after a 12-month period. Pre-populating the survey with prior responses would not be relevant to a subsequent survey because each survey measures satisfaction with a specific interaction. The second commenter recommended administering the survey in alternate formats (such as Short Message Service) and also suggested that survey response data should be presented in a way that clearly delineates the proportion of individuals served by the NMDP℠ PSC who received the survey, those that did not receive the survey because no email address was provided, those that responded to the survey, and those that received the survey but did not respond. HRSA reviewed this comment and determined that suggestions related to the presentation and interpretation of survey data are consistent with existing analysis and evaluation methodologies for this survey including delineation of surveyed and non-surveyed groups within the total population. HRSA also determined that the use of Short Message Service or other technologies for survey administration must be reviewed further for cost and implementation considerations. HRSA will complete this review and implement changes, if appropriate, by December 31, 2028. Therefore, no changes were made to the information collection in response to the two comments received.

Need and Proposed Use of the Information: HCT is a complex medical procedure that requires significant support before, during, and after the procedure. Many patients experience barriers that impede access to HCT. Barriers to HCT-related care and educational information are multifactorial. The NMDP℠ PSC offers programs and services to support patients, caregivers, and family members throughout their HCT journey. Feedback from recipients of NMDP℠ services is essential to understand the changing needs for services and information, as well as to assess the effectiveness of existing services. The primary use of information gathered through the survey is to assess the helpfulness of participants' initial contact with PSC patient navigators and to identify areas for improvement in service delivery. Patient navigators are nurses or oncology certified navigators, who respond to requests for information and support. Program managers and NMDP℠ leadership use this evaluation data to understand patient experiences and inform program and resource allocation decisions.

Web-based surveys will be administered to all participants (patients, caregivers, and family members) who have contact with the PSC. All participants for whom an email address is known will be invited to complete the survey online. Survey respondents will be notified via email invitation and in the survey instructions that participation is voluntary and that responses will be kept confidential. A follow-up invitation will be sent to non-respondents within 2 weeks.

The survey will include these items to measure: (1) their experience; (2) if the contact helped the participant feel more confident in coping with treatment; (3) if the contact helped the participant feel more hopeful; (4) if the contact helped the participant feel less alone; (5) increased awareness of available resources; (6) if the contact helped the participant feel more informed about treatment options; (7) if their questions were answered; and (8) types of challenges faced by participant. The survey data will be analyzed quarterly and annually, and results will be shared with program managers. Feedback indicating a need for improvement will be reviewed by program managers semiannually and implementation of resulting program changes or additions will be documented.

HRSA is revising some of the survey questions and phrasing to improve clarity, without changing the intent of the question. One response option has been added to the question about the respondent's education level. There are no changes to the instructions, frequency of collection, or use of the information.

Likely Respondents: Respondents will include patients, caregivers, and family members who have contact with the PSC via phone or email for HCT navigation services and support (advocacy). The decision to survey all participants was made based on the historically low response rate to this survey due to patients' frequent transitions in health status as well as transfers between home and the hospital for initial treatment and care for complications. Participants will receive the survey once in a 1-year cycle. If a participant contacts the PSC 1 or more years after the initial contact, the participants will receive a second survey. This is because participants' needs may change over time.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total respondent burden for the customer satisfaction survey is estimated to be 75 hours. HRSA expects a total of 1,000 respondents to complete the NMDP℠ PSC Survey with an estimated 4.5 minutes to complete each survey.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
National Marrow Donor Program Patient Support Center Survey	1,000	1	1,000	0.075	75
Total	1,000	1	1,000	0.075	75

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the burden of the information collection.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–19883 Filed 9–28–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response To Honor Our Living Donors Act

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of final Living Organ Donation Reimbursement Program guidelines.

SUMMARY: On July 1, 2026, HRSA published a notice in the **Federal Register** to solicit comments on proposed modifications to the Living Organ Donation Reimbursement Program (LODRP or Program) eligibility guidelines in response to the Honor Our Living Donors (HOLD) Act. The HOLD Act, enacted in February 2026, prohibits consideration of an organ recipient's household income in determining a living organ donor's eligibility for reimbursement. This notice responds to the comments received and finalizes the Program Eligibility Guidelines.

FOR FURTHER INFORMATION CONTACT: Allison Hutchings, Division of Transplantation, Health Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; 240–290–2179 or *livingdonorsupport@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview of the Living Organ Donation Reimbursement Program (LODRP)

Under section 377 of the PHS Act, as amended,[1] Congress gives the Secretary of Health and Human Services specific authority to reimburse eligible living donors and donor candidates for qualifying expenses incurred toward living organ donation, with a preference for individuals who the Secretary determines are more likely to be otherwise unable to meet such expenses. Since 2007, HRSA's LODRP has fulfilled this function, reimbursing eligible living organ donor candidates and donors for qualifying non-medical expenses, including travel, meals, lost wages, and child and elder care. Eligible donors may receive reimbursement of up to $6,000 per organ donated for qualifying travel, lost wage, child-care, and elder-care expenses associated with donor evaluation, the donation surgery, and follow-up care occurring within two years of the procedure, or beyond that period in exceptional circumstances. Since the program's inception, LODRP (currently operated by Mayo Clinic Arizona and the National Living Donor Assistance Center, also known as NLDAC, via a cooperative agreement) has received more than 21,000 applications, approving nearly 89 percent of them. During this timeframe, LODRP facilitated over 12,000 living organ donations.

II. Summary of Comments Received

On July 1, 2026, HRSA published a notice[2] in the **Federal Register** requesting comments on proposed modifications to the LODRP eligibility guidelines to implement the HOLD Act, which prohibits consideration of an organ recipient's household income in determining a living organ donor's eligibility for reimbursement.[3]

The proposed guidelines established a donor-centered eligibility framework consisting of a first priority category for donors with household incomes (HHI) at or below 350 percent of the HHS Poverty Guidelines, a second priority category for donors with HHIs above 350 but no more than 500 percent of the HHS Poverty Guidelines (which would open mid-project period, subject to available funding), and a capped financial hardship waiver for donors with HHIs above 500 but no more than 750 percent of the HHS Poverty Guidelines.

2026 ANNUAL HOUSEHOLD INCOME THRESHOLDS[4]

Household size	48 Contiguous states and Washington, DC	Alaska	Hawaii
500% HHS Poverty Guidelines			
1	$79,800	$99,750	$91,800
2	108,200	135,250	124,450

[1] 42 U.S.C. 274f.

[2] HHS, HRSA. ''Modification of Living Organ Donation Reimbursement Program Eligibility Guidelines in Response to Honor Our Living Donors Act.'' **Federal Register**, vol. 91, no. 125, 1 July 2026, pp. 40005–40009, FR Doc. No. 2026–13250, *www.federalregister.gov/documents/2026/07/01/2026-13250/modification-of-living-organ-donation-reimbursement-program-eligibility-guidelines-in-response-to.*

[3] United States Congress, House. *Consolidated Appropriations Act, 2026.* H.R. 7148, 119th Congress, 2nd Session. Signed into law 3 Feb. 2026. Public Law 119–75. Congress.gov, *www.congress.gov/bill/119th-congress/house-bill/7148/text.*