

Supporting Statement A

Be The Match® Patient Support Center Survey OMB Control No. 0906–0004-REVISION

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) currently has approval under the generic clearance, Office of Management and Budget (OMB) Control No. 0915-0212, to conduct customer satisfaction surveys and focus groups. This is a request for Office of Management and Budget (OMB) approval of a voluntary customer satisfaction survey titled, Be The Match® Patient Support Center Survey, under the Health Resources and Services Administration's (HRSA) generic clearance. The C.W. Bill Young Cell Transplantation Program (CWBYCTP) was established by the Stem Cell Therapeutic and Research Act of 2005 (Public Law 109 - 129) and was most recently reauthorized in 2021 (S. 288 (117th): Transplant Act of 2021). The CWBYCTP Office of Patient Advocacy is operated by the National Marrow Donor Program® (NMDP) which operates publicly as Be The Match®. NMDP has explicit requirements to conduct surveys of patient satisfaction. As such, NMDP will elicit feedback from marrow and cord blood transplant patients, caregivers, and family members who had contact with the Be The Match Patient Support Center for navigation services, educational information, and support. The survey also includes demographic questions to determine the representativeness of the findings. The objectives of the survey are to 1) Determine the level of satisfaction with existing services of the Patient Support Center and 2) Determine areas for improvement and opportunities for the development of new programs and services.

This collection of information helps fulfill the requirements of Executive Order 12862, "Setting Customer Service Standards," which requires agencies that provide significant services directly to the public to identify and gather feedback from customers; establish service standards and measure performance against those standards; and benchmark customer service performance against the best customer experience provided in the private sector." Executive Order 12862 also states that "Strengthening the democratic process requires providing direct lines of feedback and mechanisms for engaging the American people in the design and improvement of Federal Government programs, processes, and services." This survey aims to gather that feedback and measure

performance to improve customer experience and performance.

There are revisions to the survey since the prior approval. The revisions are changes to the order that questions are asked in the survey. There are no changes to the instructions, frequency of collection, or use of the information.

2. Purpose and Use of Information Collection

Barriers restricting access to marrow and cord blood transplant-related care and educational information are multi-factorial. The CWBYCTP Office of Patient Advocacy works to help patients overcome barriers by providing access to programs, information, and services related to transplants. Feedback from participants is essential to understand the changing needs for services and information as well as to demonstrate the effectiveness of existing services. The primary use for information gathered through the survey is to determine the helpfulness of participants' initial contact with the Be The Match Patient Support Center and to identify areas for improvement in the delivery of services. Stakeholders (i.e., program managers, NMDP leadership, and HRSA) use this evaluation data to make program improvements and inform resource allocation decisions. Feedback acquired through the survey showed that the services provided by the Patient Support Center benefit patients throughout their treatment. These results have led to greater investment in patient services programs including proactive outreach to support more patients. Survey results have also led to the development of additional post-transplant survivorship services.

3. Use of Improved Information Technology and Burden Reduction

The Be The Match Patient Support Center Survey is a web-based survey designed to reduce respondent burden (508 compliant). All responses (100%) are collected through electronic submission. This technology allows reminders to be sent only to non-responders which reduces the number of contacts during the time of decision-making and treatment.

4. Efforts to Identify Duplication and Use of Similar Information

The Be the Match Patient Support Center Survey does not duplicate any other information collection tool. None of the questions are present on other evaluation instruments. The proposed survey is unique in capturing feedback that will measure the navigation program objectives.

5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this survey.

6. Consequences of Collecting the Information Less Frequently

The survey informs program development and resource allocation but does not significantly impact program delivery as patient satisfaction has remained consistently high through each contract cycle. Providing participants with the ability to provide direct feedback to the program remains important.

To reduce burden, each patient, caregiver, or family member will be administered the survey one time only, even when multiple contacts between the Patient Support Center and the participant occur. If the participant contacts the Patient Support Center and the survey was administered one or more years previously, the participant will receive another survey. Available resources, services, and delivery methods will likely have changed, and new feedback will be important for evaluating the effectiveness of the services. If the information is collected less frequently, program managers will not have accurate data to effectively improve existing programs or develop new programs to meet the needs of the participant population.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day Federal Register Notice published in the *Federal Register* on March 2, 2023, vol. 88, No. 41; pp. 13130-31, and closed on May 1, 2023. There were no public comments.

A 60-day Federal Register Notice published in the *Federal Register* on June 14, 2023, vol. 88, No. 114; pp. 38872-73.

Section 8B:

This survey was not developed with outside consultation from any agency. It was developed internally by NMDP Health Services Research staff and Patient Support Center managers.

Opportunities for public comment have been posted in the Federal Register every three years (most recently in 2017 and 2020). There have been no public comments received in previous years.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

This collection of information will involve names and email addresses to administer the survey only and will fully comply with the Privacy Act. Separate databases are used for participant names and addresses and survey responses. Demographic information will be available in both databases but not used to link survey responses. A unique identifier is assigned to each participant for survey response tracking only. Participation is fully voluntary, and responses are kept confidential to the extent allowed by law. Survey responses are not linked to personally identifying information, such as name and email address. Participants will be assured that their decision whether or not to participate or their responses will not have any effect on their medical care. Completed

surveys are stored electronically on a secure server at NMDP for up to 3 years for trend analyses and are then destroyed.

The Patient Satisfaction Survey does not meet the regulatory definition of research, because the intent is to improve/evaluate an internal program. Therefore, there is no IRB determination or records for this survey. This is based on this definition of research from OHRP: §46.102 **“Definitions for purposes of this policy. (l) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102>.”**

There is no official waiver letter to provide as the NMDP IRB does not issue official determination letters for activities they do not have jurisdiction over (in this case, non-research activities). However, this response was reviewed by NMDP IRB staff and the regulatory language was provided by them both at the time of the OMB submission as well as confirmed in response to this question. Additionally, NMDP’s IRB Administrator and Organizational Official for the IRB has determined this survey does not require IRB oversight based on the regulatory definition of research.

11. Justification for Sensitive Questions

The survey does not include sensitive questions related to sexual behavior and attitudes, alcohol or drug use, religious preferences, or other matters that are considered private. The survey does not request the respondent’s social security number (SSN). The survey does ask for demographic information including race, ethnicity, gender, age group, and education level. These data are important for characterizing responses to understand if support needs vary by segment. Demographic questions are optional and include a “Prefer not to answer” response option. Respondents are informed that answers to these questions are confidential.

12. Estimates of Annualized Hour and Cost Burden

Respondents will include all patients, caregivers, and family members who have contact with the Patient Support Center via phone or email for bone marrow or cord blood transplant navigation services and support.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Patient/ Caregiver/ Family Member	Form A	900	1	0.17	153
Total		900	1	0.17	153

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

Patient Support Center staff will administer the surveys. The estimated annual cost to the government is \$6,903, which includes effort from: Surveys will be administered by the NMDP Patient Support Center staff which includes effort from a Patient Services Coordinator (.06 FTE, \$2,311), Program Analyst (.01 FTE, \$951) and Patient Services leadership (.04 FTE, \$3,641).

(Based on May 2021 National Occupation and Wage Statistics
https://www.bls.gov/oes/current/oes_nat.htm#43-0000)

The contract task that supports this collection is for approximately \$ 6,903 per year.

15. Explanation for Program Changes or Adjustments

Prior estimates for the number of respondents were too high. The estimated number of survey responses has been adjusted based on response rates over the past two years and the number of responses during the first quarter of FY23. Changes in the process have been made and created efficiencies in the distribution of the survey thereby reducing the cost to implement the survey.

16. Plans for Tabulation, Publication, and Project Time Schedule

Surveys will be administered on an ongoing basis to all individuals who receive

services from the Patient Support Center; there is no statistical sampling to select survey respondents. NMDP Patient Services staff will administer, collect, analyze and report survey results to stakeholders. Ongoing data collection will utilize web-based survey software which will be entered and stored in a secure Excel database. Responses will be analyzed using Excel, SPSS, and/or SAS. Narrative information from the surveys will be summarized and examined using descriptive analysis and/or modeling of survey data. The survey data will be analyzed quarterly and annually, and results will be shared with program managers and HRSA. Feedback indicating a need for improvement will be reviewed by program managers biannually and implementation of resulting program changes or additions will be documented. Findings will only be used for internal program improvement and will not be generalized to the public. There are no plans to publish the survey results. We request a 3-year clearance for this survey.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.