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Brenda Destro
Deputy Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 415F
200 Independence Avenue, S.W.
Washington, DC 20201

Re: REQUEST FOR INFORMATION: IMPACT ACT Research Study: Provider and health plan approaches to improve care for Medicare beneficiaries with social risk factors

Dear Deputy Assistant Secretary Destro:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recently proposed request for information (RFI) regarding the IMPACT ACT Research Study.

ASCO is the national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

In furtherance of ASCO's mission, the Society operates multiple quality assessment improvement initiatives and has taken concerted steps to address the needs of underserved populations. For example:

- ASCO's rapid learning system, CancerLinQ, is a "big data" solution to help practicing physicians distill massive volumes of data into meaningful information that supports the delivery of high-quality, high-value oncology care. This platform provides real-time feedback to oncologists on performance, allows point of care decision support, and provides rapid insight into patient outcomes. Through the Minimum Common Oncology Data Elements (M-CODE) project, ASCO is working to identify the core data elements necessary to populate an oncology EHR.

Making a world of difference in cancer care

- ASCO has invested substantial time and resources over the past 15 years in developing a Qualified Clinical Data Registry (QCDR) called the Quality Oncology Practice Initiative (QOPI). ASCO's QCDR includes 27 cancer-specific measures that have undergone an extremely robust, evidence-based process to ensure their clinical validity and reliability. As part of ASCO's criteria for measure development, the society assesses the degree to which its measures are meaningful and relevant to a wide range of patient populations.
- To ensure oncology practices caring for medically underserved patients can take advantage of, and benefit from, ASCO's growing quality improvement efforts, ASCO offers a grant program to teach practices serving underserved populations to improve their care delivery. A key goal of this program is to utilize QOPI and ASCO's Quality Training Program to coach teams through measurable and sustainable improvements in a clinical setting to improve the capacity and capability of participating practices to provide evidence-based, high-quality care. Another important goal is to understand better the quality improvement needs and challenges that may be unique to and/or exacerbated in low-resource settings, and to devise better strategies to address these needs. Additional information on this program description can be found [here](#).
- ASCO's work has also included evaluation, and analysis of the impact of new payment models, delivery systems and other policies in the Medicare and Medicaid programs and beyond. To that end, we have recommended ways that CMS could consider underserved populations in the Quality Payment Program (QPP). Collection of social risk factors could help in identifying the most appropriate measures to ensure clinical quality improvement through activities that are achievable for underserved populations, including in small practices and rural areas. For example, we recommended:
 - Within the (QPP), CMS create standards that are achievable and do not impose substantial burdens for participants practicing in small practices and rural areas. We also recommended that CMS not establish burdensome requirements for practices that treat underserved and minority populations, so that existing disparities in access and outcomes in oncology care would not be exacerbated. Many of the administrative burdens that are created by new regulatory actions impact the smaller or rural practices most.
 - CMS should seek to compare providers at the subspecialty level in a manner that promotes fairness to ensure that resource use is fairly compared among providers in the QPP. It is imperative that CMS make adjustments that account for the extreme variation that may exist in the cost of treating cancer compared to other diseases, as well as in treating different types and stages of cancer. Risk adjustment is especially crucial in oncology since there is significant variance in resource use among oncologists based on their subspecialties.
 - In addition to assuring appropriate comparisons across subspecialties, CMS should develop a mechanism to adjust for resource-constrained practices or practices that care for historically underserved populations.

In response to specific questions in the RFI regarding the collection and use of data by providers and health plans on Medicare beneficiaries' social risk factors, ASCO offers several points of consideration and input, provided herein.

Which social risk factors are most important to capture?

ASCO believes that race/ethnicity, gender identity, health literacy, family income level, travel distance to cancer centers and social support (marital support or caregiver support) should be captured. Measures of race, ethnicity, sexual orientation and gender identity should be self-reported, not based on observation. In the case of race and ethnicity, questions could address ancestry, and enclave effects. To assess neighborhood and structural effects on health, measures of the built (man-made) environment should be included, or patient address should be collected and geocoded, so that physical and other contextual effects, in addition to individual-level impacts, can be considered. Also, social networks/support, beyond marital/caregiver status including social companions is essential, as well as religious support/communities, psychosocial risk factors, addictive behavior, BMI/Weight/Diet/Physical Activity Food Insecurity are also important.

Do you routinely and systematically collect data about social risk?

Most ASCO members do not routinely and systematically collect data about social risk. Where practices do collect the data, the factors frequently vary and depend on disease-specific/clinical programs or cancer registry requirements. Area-level proxy census data may be good proxies for some social risk measures. However, they are imperfect and may represent a distinct phenomenon from measures collected at the individual level.

Who collects this data? When is it collected? Is it collected only once or multiple times for a beneficiary? Is it collected consistently across populations (i.e., Medicare beneficiaries, Medicaid beneficiaries, patients receiving specific services, etc.)? What are the burdens of this data collection on plans, providers, and beneficiaries?

Cancer registries are required to capture race/ethnicity which should be self-reported by patients. Medicare, however, does not collect this information unless it is provided directly by the providers themselves and when Medicare providers have the data it is invalid and incomplete. Providers have much variability in what they collect and what they report. There may also be inconsistencies due to patient fear and resistance to self-reporting. Additionally, many of the factors mentioned above are not collected in a standardized fashion. Some measures could be collected at a single point in time (e.g., educational attainment), but others, like social support and community resources, may change over time.

Would standardized data elements for EHRs help you to collect social risk data? If so, how could these data elements be standardized?

Unless mandated, social risk data is not typically captured in EHRs. ASCO is concerned that mandated capture could result in additional burden for practices if it were not through standardization of data elements. This would require EHR vendors to standardize the fields captured in a structured field so that they can be abstracted. Currently, many of the fields like race and ethnicity are in unstructured data fields which would need to be manually abstracted. Standardization of data elements and fields would be a positive step toward interoperability. One strategy is identifying key social factors that could be collected once at Medicare enrollment (e.g., educational attainment, nativity), reasonable area-level proxies from

census data (e.g., median income, urban/rural status), and those that might be most important to collect at multiple times (e.g., social support).

The impact of ASCO's initiatives could be significantly enhanced with the availability of data on social risk factors for the Medicare population. Because many social risk factors affect health care use and adherence to treatment, a related question is: what are the burdens of not having social risk information for plans and providers?

In 2017 ASCO issued a [position statement](#) in collaboration with the American Association of Cancer Research (AACR), American Cancer Society (ACS), and the National Cancer Institute (NCI) to foster cooperation across the cancer research community to ensure that all patients — regardless of social demographics, socioeconomic status, or the communities in which they live — benefit from cancer research. The joint statement noted patient data are often incomplete, inaccurate, or overly-simplified and usually do not consider many social and community factors. As a result, cancer disparities research is limited by a lack of comprehensive, consistent data on factors that impact disparities in cancer care and patient outcomes, including a patient's social status and demographics, community and lifestyle factors, and biology and genetics, as well as by widespread variation in data collection methodology.

To address these issues, the 2017 statement called for improved steps to define and improve data measures and tools for cancer disparities research, noting that patient data are often incomplete, inaccurate, or overly-simplified and usually do not consider many social and community factors. In addition to calling for the collection of specific data elements referenced above, the statement recommended providers, patients, and the public should be educated regarding the rationale for and importance of collecting sociodemographic data, some of which may be perceived as potentially sensitive questions (e.g., sexual orientation and gender identity). Standard guidelines to facilitate collection and to mitigate patient or participant concerns should be offered. As well, we recommended that the cancer health disparity community establish reporting standards for measurement variables, similar to CONSORT and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, for journal editors and peer reviewers to facilitate and standardize assessment of the quality of the data collection method when evaluating health disparity research findings for publication.

Thank you for the opportunity to provide input on this RFI. We look forward to the opportunity to work with the Agency as you continue to identify ways to deliver high-quality care to high-risk patients and those living in underserved communities. Please contact Sybil Green at Sybil.Green@asco.org or 571-483-1620 with any questions.

Sincerely,



Clifford A. Hudis, MD, FACP, FASCO

ASCO Chief Executive Officer