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June 5, 2020

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515-4329

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, D. C. 20515-4329

Dear Congresswoman DeGette and Congressman Upton:

I am writing on behalf of GO_2 Foundation for Lung Cancer, which has a mission of transforming survivorship by saving, extending and improving the lives of those vulnerable, at risk and diagnosed with lung cancer; to provide feedback on the modernization effort that you are contemplating to benefit patient communities.

We are pleased that important policies to allow for new technologies, treatments and modern approaches to coverage and reimbursement are included in the 21st Century Cures 2.0 concept paper. We are encouraged by the Title I: Public Health Provision that is both necessary and timely in addressing the current COVID-19 pandemic and includes strategies for future pandemic responses.

We wish to express our gratitude for a number of provisions included in the concept paper, which we supported in our initial comments, submitted in December 2019. Title II: Caregiver Integration, Section on Educational Programs and Training for Caregivers and Title III: Patient Engagement in Health Care Decision Making, Section for Increasing Health Literacy to Promote Better Outcomes for Patients has captured GO_2 Foundation's recommendation for improving health literacy of patients and caregivers to better inform them of treatment options and services, and associated costs to prevent surprise billing.

We are extremely pleased with the inclusion of Title IV: Clinical Trials, Section on Diversity in Clinical Trials, as it captures the hope of the entire health community by recommending diversity in clinical trials of racial and ethnic minorities, women, children, and rural

populations. GO_2 Foundation has recommended the inclusion of the Clinical Treatment Act in order to provide Medicaid coverage of the routine care costs of clinical trials participation for patients with life-threatening conditions. Additionally, we support the recommendations in the concept paper to improve demographic data, increase awareness and understanding of importance of trials, improve user-patient utility of clinicaltrials.gov and enhance coordination between the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS).

Moreover, GO_2 Foundation recommended Digital Health to Improve Patient Care and Cures 2.0 concept paper includes Title V. FDA, Section on Coordinating FDA Approach. This will improve patient lives through digital health technologies by providing access to information, treatment, and participation in clinical trials.

Finally, GO_2 Foundation has recommended policy changes to preventive services, early detection, and treatment for lung cancer, in requesting that Cures 2.0 streamline and expedite the federal structure and process responsible for review and implementation of new preventive services to remove the barriers to patients' immediate access to life-saving breakthroughs and scientific progress. We therefore appreciate the inclusion of Title VI: CMS Modernization, a section that is calling for ideas and input from stakeholders to develop more comprehensive policy solutions. In response to the questions being asked, GO_2 Foundation would like to contribute to the General Coverage Modernization.

In response to the questions, we believe the rules are in need of reform to better serve our community and keep up with the pace of innovation. With new technologies emerging in the early detection space, modernization would pave the way for approval of coverage for new methods of life-saving early detection. We recommend the following areas be considered relevant to Medicare, Medicare Advantage, and Medicaid health programs, as well as, preventive tests recommended under the United States Preventive Task Force Services (USPSTF), preventive services and benefits under the Affordable Care Act, and products and testing approved through the Food and Drug Administration (FDA).

- **Allow a mechanism for screening and early detection tests to go through the CMS National Coverage Determinations (NCD) process independent from the USPSTF process, and therefore, providing Medicare beneficiaries timely access to medically needed screening and preventive services.** Given the need for innovation in cancer testing, treatment, and research, it is clear the current statutory

language [SSA, 1861(ddd)(1)(B)] is dated. The current process requires all screening tests be given a grade A/B rating by the USPSTF before CMS will consider opening an NCD process, which can take years or decades before obtaining coverage for the Medicare population, a population who would receive a high benefit from cancer screening. While some cancers (e.g., breast, prostate, colorectal) have legislative carve-outs to bypass this statutory requirement, a separate bill for each cancer and disease should not be the only pathway to obtain direct screening coverage for the Medicare population. For example, if a new cancer screening test or multi-cancer screening test was developed and approved by the FDA, it would take years to get through a USPSTF grade A/B process and then add on more years to go through the CMS NCD process.

These dated coverage and reimbursement approaches are not in pace with innovation and have become barriers to patient access to timely screening, care, and treatment. We believe that CMS should have the ability to initiate and complete an NCD process for any preventive screening service independent from the USPSTF grade A/B process, especially when a screening test is 1) FDA approved, 2) generalizable to the Medicare population, and/or 3) age 65 and greater are the at-risk or higher-risk cohort.

- **Develop a simultaneous pathway for preventive services (USPSTF) and model after the CMS and FDA parallel review process for National Coverage Determinations (NCD).** Implementing a simultaneous multi-pronged (USPSTF/CMS/FDA and USPSTF/CMS) coverage pathway for both screening and diagnostic tests will help modernize and refine dated coverage and reimbursement rules and approaches that impact the patient community and especially those individuals with cancer. A simultaneous approval process would significantly shorten the required timeframe that can take years upon years per each federal agency (FDA/USPSTF/CMS) process. Time is crucial for sick cancer patients. As you may know, when lung cancer is caught early the 5-year survival rate for lung cancer increases significantly with up to 90% survival at stage 1 diagnosis vs. 1-10% with stage 4.

- **Refine and improve the CMS and FDA NCD parallel review process to help bring new devices to market faster in a more efficient and expedited way that benefits patients more broadly.** The CMS and FDA NCD parallel review process is limited to devices that are subject to pre-market approval or de novo classification.

This is only a small portion of the market today which means the vast majority of devices will not be eligible for Parallel Review. In 2016, CMS in conjunction with the FDA announced the extension of their parallel review process for the NCD pilot program indefinitely. This parallel review process was intended to provide a pathway for timely feedback on data requirements. While we applaud the initial intent, there is room for improvement to make it current and in pace with innovation.

- **Improve and streamline the current CMS NCD process and utilize a patient-centered survey to help identify and prioritize needed change and refinements. We recommend that CMS:**
    - **Create an expedited NCD review process (less than 9 months for externally requested NCDs and less than 6 months for internally generated NCDs);**
    - **Develop an easier and consistent pathway to revisit and reopen existing NCDs;**
    - **Implement a recurrent review cycle for all NCDs to account for advances in technology and medicine;**
    - **Develop a more transparent NCD process and publish an annual public report on all NCDs that provides ratings on the overall process and generated coverage decisions.** For example, such ratings could include measures, crosswalks, and comparisons of coverage decisions with a standard scoring system and benchmark applied to the evidence deemed as *sufficient* and *insufficient.* This would help ensure consistency and transparency for NCDs reviewed in addition to those that were denied opening/reopening; **and**
    - **Identify NCD downstream implementation barriers and issues and develop a mechanism to prevent and/or address potential NCD implementation delays (e.g., CPT and ICD10 coding, billing, MAC instructions) that may result in unpaid/held claims for many months.** Rural hospitals and physician groups cannot stay afloat when claims are held for months on end which worsens the administrative and financial burdens and negatively impacts patient access**.**

A streamlined and patient-centered approach to include the above areas will help address patient access issues to timely care and create a more efficient and reformed NCD process for coverage and reimbursement. This would help alleviate a laborious process that can be burdensome, rigid, and further exacerbate disparities among the patient community.

Implementing a fast-tracked NCD review process for promising and advancing new therapies and tests helps our patients and the lung cancer community for whom early cancer detection, timely testing, and treatment are critical.

In addition, we believe there is an opportunity for modernization around telehealth policies and coverage. Working closely with our Centers of Excellence, we have seen the power of telehealth care for our lung cancer community during the COVID-19 pandemic. Specifically, we recommend that CMS:

- **Adopt National Licensure Standards for Federal Health Programs.** Congress should allow for reimbursement in Medicare plans for telehealth services given by a provider with appropriate licensing in any one state. The Departments of Defense (DoD) and Veterans Affairs (VA) have already removed licensing barriers to telehealth services through changes made in the service-member's Telemedicine and E-Health Portability Act of 2011. Home telehealth services changes have reduced inpatient stays by 59 percent and hospital admissions by 35 percent. If the VA experience can be replicated in Medicare, seniors and the disabled would see increased access to care, and taxpayers would see increased solvency of the Medicare Trust Fund.

- **Make permanent several telehealth policies adopted for COVID-19 response.** Congress created additional flexibilities to access care via telehealth in Medicare and other public programs. However, these flexibilities are temporary and are time-limited or only apply as long as there is an official public health emergency declaration in place. We strongly recommend these temporary changes be made permanent. In addition, we advocate for incentives for states to expand patient's access to telehealth and for higher reimbursements levels.

    - During the public health emergency, Medicare has been authorized to reimburse telehealth visits at the same rate as in-person visits. We believe this should continue as a standard reimbursement rate for telehealth services regardless of whether the service was provided by a smartphone or an audio-only device.
    - Make permanent the language in CARES Act Section 3701 allowing first dollar coverage for telehealth under high deductible health plans with a health savings account. This change expires on December 31, 2021.

- Make permanent the flexibilities adopted in CARES Act Section 3703 allowing qualified providers to establish relationships with patients via telehealth.
- Make permanent the changes made by CARES Act section 3704 allowing reimbursement to FQHCs and Rural health clinics for telehealth services during an emergency.
- Make permanent the changes made by CARES Act section 3705 allowing the remote authorization of dialysis care through telehealth technologies instead of requiring an in-person visit.
- Make permanent the changes adopted in CARES Act section 3706 allowing for the remote recertification of eligibility for hospice treatment through telehealth services rather than an in-person visit.
- Make permanent the changes adopted in CARES Act section 3707 that encourage the use of telehealth technologies for home health services, including remote patient monitoring.

We have some observations from both our patient community and our healthcare colleagues in response to the question "What barriers and issues exist for patients who transition from private insurance to Medicare?" We would like to suggest:

- **Increase health literacy, provide transparency, and increase patient navigation at the point of Medicare enrollment.** We applaud the general efforts in Cures 2.0 to increase health literacy but find Medicare enrollment to be an exceptional pain point for patients. They often do not understand the complicated enrollment structure and are unable to choose the plan or plan parts that would best fit their needs. Upon starting Medicare, they are often hit with unexpected co-pays and patient-facing costs – some of which could have been avoided by choosing different, more appropriate plans. Of particularly note, we have seen patients who, upon enrolling in Medicare, are required to lose co-pay assistance they are receiving from a pharmaceutical company and are then unable to afford their medications. This can be a life-threatening issue in our community and we need to ensure appropriate coverage. Additional transparency, education, and navigation could greatly help the patient community.

The recommendations provided are based on our experience advocating for the coverage of lung cancer screening and our close work with 700+ Screening Centers of Excellence nationwide both before and after coverage approval for the specific high risk population.

Thank you for continuing to demonstrate an understanding of a patient-centered healthcare system that brings choice and greater access to high-quality care in an affordable and equitable way to all communities.

As we are most excited about the process ahead, we hope you will consider holding Congressional Hearings on CMS Modernization to hear patient and community real-life testimonies. GO_2 Foundation looks forward to participating in any potential committee hearings and collaborating with you on the next steps to bring forth a legislative bill. Your staff may contact Elridge Proctor, Senior Director of Government Affairs at 202-742-1427 (eproctor@go2foundation.org) with any questions or updates.

With Sincere Regards,

Laurie Fenton Ambrose
Co-Founder, President & CEO
GO_2 Foundation for Lung Cancer