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Submitted to: dualeligibles@cassidy.senate.gov

The Honorable Bill Cassidy, MD

RE: Discussion Draft of bill on State Integrated Care Programs for Dual Eligible Individuals

Haystack Project appreciates the opportunity to respond to the Senator's discussion draft of legislation designed to create state integrated care programs for dual eligible individuals.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. Our core mission is to evolve health care payment and delivery systems toward spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other stakeholders about the unique circumstances of extremely rare conditions with respect to product development, commercialization, and fair access to care.

Haystack Project is extremely supportive of the draft bill generally and appreciates the Senator's commitment to improve the health and lives of dual eligible individuals. Our comments reiterate specific policy considerations within Haystack Project's response to the Request for Information preceding the draft bill that are critical to individuals with rare and ultra-rare conditions. We also offer feedback on specific elements of the bill for your consideration and are eager to provide your office with additional contextual information on the real-world experience of our patient communities.

Issues Not Addressed in The Draft Legislation

Access to out-of-state and out-of-network providers

While we are appreciative of the elements included in the bill to ensure that plans maintain accurate provider directories and quality measures related to those directories are established, an accurate provider directory does not ensure an adequate network. Patients with extremely rare diseases often find that there are just a handful of disease-specific specialists in the entire country. Lack of local disease-specific specialists, combined with complexities associated with Medicaid patient access to out-of-state experts has been a longstanding barrier to timely diagnosis and appropriate care for individuals with rare diseases. These barriers are particularly daunting for individuals in rural areas and other underserved communities.

Prior to the Covid Public Health Emergency (PHE), states implemented a variety of requirements for out-of-state providers that, in some states, included lengthy and complex applications for full Medicaid enrollment, registration, and fee payment. Many states pay out-of-state providers at a lower rate than in-state providers receive.

The PHE introduced a pragmatic, streamlined approach to out-of-state Medicaid provider eligibility that should be a permanent pathway for Medicaid providers treating individuals with rare and ultra-rare conditions. Providers enrolled in their own state Medicaid program or participating in Medicare have established track records in patient care that should be recognized by all states. The rare and ultra-rare community needed these flexibilities long before Covid and will need them long after the PHE is over.

We strongly recommend that integrated care plans include streamlined, patient-friendly and uniform mechanisms for patients who need to seek a provider out of network or out-of-state. Telehealth could be one of the mechanisms used to ensure cost-effective access to appropriate out-of-state or out-of-network care.

Rare Disease Patients' are Overlooked in Existing Quality Programs

Again, Haystack commends the drafters of the bill for certain advancements that are long overdue and will have considerable impact. One such provision included in the draft is the requirement that the director of the Federal Coordinated Health Care Office develop quality measures specific to the dual eligible population. We support including measures related to patient satisfaction, quality of life, emergency room utilization, institutionalization for long-term care, hospital admission and readmission rates, and medication errors. We agree that the dual eligible population has unique healthcare needs justifying population-specific quality measures.

However, we again note that most incentive frameworks and policies fail to consider the unique challenges rare disease patients face. This is especially true in the Medicare Shared Savings Program and the Quality Payment Program. Mechanisms that incentivize high-quality, cost-effective care in the general population can present strong disincentives to providing the diagnostic workup, treatment planning, and provider oversight required to adequately manage rare and ultra-rare diseases.

We are concerned that reimbursement and incentive mechanisms that do not proactively address the unique needs of rare disease patients, including the lack of disease-specific benchmark costs, will have the unintended effect of penalizing providers for delivering high-quality care to the most vulnerable patients. We appreciate that the bill includes outlier payment mechanisms to reduce disincentives for enrolling high-cost beneficiaries. However, plans may still seek to avoid patients negatively impacting their quality score, particularly in light of the bill's 3-star enrollment requirement.

Haystack Project continues to advocate for specific carve-outs applicable to rare disease patients combined with incentive mechanisms rewarding providers for timely diagnosis, treatment planning, and care coordination. We believe these mechanisms are a pragmatic alternative to either (1) ascertaining a reliable benchmark for each rare and ultra-rare condition

or (2) overlooking the consequences risk arrangements tend to exact on rare disease patients and their providers.

Patient Costs and Premium Assistance Programs

One important element not considered by the legislation is the cost to enrollees. With the exception of PACE enrollees who elect to enroll in a stand alone prescription drug plan, there are no additional guardrails on patient costs in the draft bill. While we appreciate that the intent of this bill is to streamline plan offerings for the dual eligible population, we believe it would be a missed opportunity to not address patient costs.

In our RFI response, we noted that health care for individuals with rare and ultra-rare conditions can be relatively high-cost and often requires highly specialized clinicians to deliver quality care. Because a robust network of providers is essential, rare disease patients are often good candidates for Medicaid premium payment programs (Medicaid pays the premium costs for commercial coverage as well as “wrap-around” coverage to ensure access to the full set of benefits available in Medicaid). The wrap-around benefits and cost-sharing protections are ensure that Medicaid beneficiaries receiving private coverage will maintain access to Medicaid’s full set of benefits without incurring additional out-of-pocket costs.

Unfortunately, implementation of premium payment programs varies from state to state, patients are generally unaware of this alternative coverage mechanism, and available information is confusing for patients and their families. In addition, there are no mechanisms to facilitate coordination between Medicare and Medicaid that would enable use of premium payment programs for dually eligible patients.

We expect that it may be helpful to ask that CMS collect data and other information on state implementation of premium assistance programs to assess the extent to which statutory refinements expanding the program to dual eligible individuals could improve care and its coordination while reducing costs, including:

- Use of this mechanism in both Medicaid expansion and non-expansion states
- How states identify high-cost Medicaid enrollees for premium assistance eligibility
- Written materials (online and print) available to patients that explain:
 - Wrap-around benefits
 - Cost-sharing protections
- Resources for patients enrolled in Medicaid premium assistance programs
- How much the state Medicaid program spends on wrap-around benefits and cost-sharing protections

Comments on the draft legislation

TITLE XXII—State Integrated Care Programs for Dual Eligible Individuals

Sec. 2202. State selection of program models, development, and implementation

Haystack strongly supports the proposed framework for state integrated care programs for dual eligible individuals. We appreciate the provision requiring that the director of the Federal

Coordinated Health Care Office design a range of model options for states to implement. Haystack Project appreciates that this system will ensure that every state is using a model designed and vetted by the Federal Coordinated Health Care Office. We suggest that there be a limit to the number of models so that the provision has its intended effect of reducing complexity and variability among the states and facilitating federal oversight. In addition, a limited set of options would ensure that patients moving from state to state are able to quickly identify the nuances between their new state and old state's programs.

We also support the provision requiring that each state establish an implementation council that includes appropriate stakeholders. We believe patients must be at the table when refinements to the programs impacting their health and well-being are considered.

Sec. 2203. Enrollment in integrated care plans.

Haystack supports the following requirements:

- That states require beneficiaries enroll in an integrated care plan as a condition of receiving medical assistance under title XIX
- That states notify beneficiaries within 60 days (or 90 days for initial enrollment) prior to enrollment with an integrated care plan
- That beneficiaries only be passively enrolled in plans that have a 3-star or higher rating and include the beneficiary's primary care provider in-network
- That fully integrated plan enrollees can change plans monthly

Sec. 2204. Plan requirements and payments.

Haystack generally supports the plan requirements set forth in the bill, including the requirement that issuers offer fully and partially integrated plans utilizing the same network. Patients in both fully and partially integrated plans have equal need for access to a robust provider network. We further support the requirement that plans automatically transfer enrollment of full benefit enrollees to the partial benefit plan when eligibility requires.

We are, however, concerned that limiting plan switches due to network changes to primary care providers will fail to ensure that rare disease patients maintain access to the clinician(s) they rely upon to manage their care. As you know, a specialist is often the most important member of the care team for rare and ultra-rare disease patients. These patients routinely select a plan for the sole reason that their treating physician specialist is in-network. It can be catastrophic for patients when their treating provider leaves their plan network. We believe this draft legislation has the solution – providing 30 additional days of coverage and an opportunity to switch plans – it just needs to be applied to the right providers.

We suggest allowing this provision to apply to PCPs or other "critical providers." This new category of providers could be defined in a number of ways. One option is any providers with whom the patient has routine treatment. For example, a patient undergoing cancer treatment will prioritize ongoing access to their medical oncologist. Although the oncologist is not the patient's primary care physician, she develops the patient's treatment plan and may coordinate care with surgeons, radiation oncologists, and other providers. The key inquiry should be

whether losing access to a provider would disrupt continuity of care. In addition, clinicians without in-network peers of equal disease-specific qualifications or expertise might be critical providers for individuals with rare conditions. Finally, a provision could be crafted to enable patients and/or caregivers to designate a limited number of “critical providers.” This approach would empower patients to prioritize members of their care team and identify which providers they need access to the most.

Haystack Project further supports provisions related to:

- Requiring plans administer a health risk assessment, develop a comprehensive care plan, and assign each beneficiary a care coordinator,
- Requiring all plans cover clinical health services, behavioral health services and long-term services and supports.

Sec. 102. Conforming amendments relating to Federal Coordinated Health Care Office responsibilities.

Haystack Project supports the provisions in this section including requiring the director to:

- Develop a range of program models
- Create standardized appeals processes
- Develop a standardized health risk assessment
- Establish standards for reporting supplemental benefits
- Establish maximum staffing ratios for care coordinators and standardized training, and
- Develop new quality measure specific to the dual eligible population.

Title II - Improving Eligibility Determinations, Enrollment Processes, And Quality of Care for Dual Eligible Individuals

Haystack Project appreciates the draft bill’s inclusion of provisions designed to improve the patient experience from eligibility and enrollment through care delivery. We offer the following comments on specific sections:

Sec. 209. Requiring regular updates of provider directories.

As previously mentioned, Haystack Project appreciates the importance of an accurate, current provider directory. We note that CMS recently issued a proposed rule (CMS–2439–P) to ensure that provider directories are accurate and reflect an adequate provider network. The proposed rule would implement a secret shopper enforcement mechanism to test the accuracy of provider information listed in a directory, including their willingness to accept new patients. The proposed rule, however, falls short of the comprehensive requirement within the draft bill in that it would only apply to outpatient mental health and substance use disorder (SUD) treatment, primary care, obstetrics and gynecology (OB/GYN), and an additional type of service determined by the state.

Our comments to CMS expressed our concern that limiting secret shopper reviews and other requirements to a specified subset of services could have the unintended impact of reducing network breadth and provider capacity in other service types, including specialist care. will only

apply to certain categories, plans will have no incentive to ensure other categories of provider types are accurate. We encourage the drafters of this bill to consider combining the network adequacy provisions of the proposed rule with the provider directory provisions in the draft bill and applying those requirements broadly enough to ensure adequate networks for rare disease patients.

Sec. 210. Additional responsibilities for the Federal Coordinated Health Care Office with respect to integrated care plans under Medicaid and Medicare.

The draft bill requires the director to develop outreach plans for providers treating dual eligible beneficiaries that provide information and education on the new state integrated care programs. We welcome this requirement and note that even with the bill's requirement that each beneficiary be assigned a care coordinator, most patients rely on their providers to navigate the complexities of healthcare. It is therefore critically important that providers are able to assist patients, are not forced to spend undue time trying to understand the new program and, most importantly are not dissuaded from treating these patients because of the complexity of the program. We note that the difficulties in claims processing and billing related to dual eligible individuals can be an immense burden for providers. Often providers must submit a claim for payment to one plan (or the Medicare Administrative Contractor) and another claim for the copayment to another plan or state Medicaid office.

We appreciate that this draft bill's provisions on integrated plans will provide considerable relief from the administrative burden these provider face. However, providers will likely continue to find that the billing rules associated with the various permutations and combinations of plans covering dual eligible individuals increase their fears of running afoul of federal law. For example, providers who mistakenly bill the patient could be subject to sanctions (see Sections 1902(n)(3)(C), 1905(p)(3), 1866(a)(1)(A), and 1848(g)(3)(A) of the Act). While Haystack Project supports the draft bill's patient protections, we also believe that providers need clear guidance on how to treat these patients and get paid for their work without worrying that they may have legal and financial implications. We strongly recommend that the bill's provision on education for providers specifically include clear billing instructions.

Title IV -PACE

Haystack Project supports the draft bill's mandate that all states implement a PACE program, including the related provisions on enrollment timing, eligibility, and outlier payments.

Finally, we applaud the draft bill's inclusion of a provision allowing Medicare-only beneficiaries to enroll in a stand alone Part D plan that includes protections on cost-sharing, data collection and data sharing. This provision could make a tremendous difference for Medicare beneficiaries with significant medical needs (and their caregivers) wishing to continue to live in and receive their health care in the community, as opposed to within a nursing home. Although this is precisely what PACE was designed to do, it is simply not an option for many Medicare beneficiaries due to the high costs of prescription drugs within PACE programs.

Conclusion

Haystack Project appreciates the opportunity to submit feedback on the draft legislation and welcomes the opportunity for a continuing dialogue toward meaningful access to quality care for dually eligible patients.

Once again, we thank you for your consideration of our comments. If you have any questions, please contact our policy consultant M Kay Scanlan, JD at 410.504.2324.