RRC
Regulatory Relief Coalition
Protecting Patients' Timely Access To Care

October 18, 2023

The Honorable Michael Burgess, Chair
Health Care Task Force
House Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Via: hbcr.health@mail.house.gov

Dear Congressman Burgess:

The Regulatory Relief Coalition is pleased to have the opportunity to respond to the Budget Committee Health Care Task Force's August 25, 2023, Request for Information (RFI), soliciting input on actions Congress could take to improve health care outcomes while reducing spending. The RRC is a coalition of national physician specialty organizations seeking to reduce regulatory burdens that interfere with patient care. Our recent activities focus on ensuring that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve.

In responding to your RFI, we will address the following areas posed:

1) Regulatory, statutory, or implementation barriers that could be addressed to reduce health care spending;
2) Efforts to promote and incorporate innovation into programs like Medicare to reduce health care spending and improve patient outcomes; and
3) Congressional Budget Office's (CBO) modeling capabilities on health care policies, including limitations or improvements to such analyses and processes.

Removing regulatory barriers to improve patient outcomes and lower costs

The RRC strongly supports enacting the *Improving Seniors' Timely Access to Care Act*[1] (*"Seniors Act"*), which unanimously passed the House of Representatives last year. Enactment of this legislation would modernize and streamline the prior authorization (PA) process for the nearly 32 million Americans currently enrolled in Medicare Advantage (MA) plans. Along with the RRC, more than 500 organizations representing patients, health care physicians and other clinicians, the medical technology and biopharmaceutical industry, health plans and other organizations have endorsed this legislation.

[1] H.R. 3173 in the 117th Congress. Most recently, the provisions in the Seniors Act were included in the House Ways and Means Committee-passed Health Care Transparency Act of 2023 (H.R.4822).

Enacting the *Seniors Act* has the potential to significantly improve health care outcomes while saving costs. Research clearly demonstrates that the delays and denials resulting from onerous PA requirements are harming patients. For example, one recent national physician survey[2] found the following:

- 89% of physicians reported that PA has a negative impact on clinical outcomes;
- 80% of respondents reported that PA can at least sometimes lead to treatment abandonment;
- 33% of physicians reported that PA has resulted in serious adverse events;
- 25% of physicians reported that PA has led to a patient's hospitalization;
- 19% of physicians reported that PA has led to a life-threatening event or required intervention to prevent permanent impairment or damage; and
- 9% of physicians reported that PA has led to a patient's disability/permanent bodily damage, congenital anomaly/birth defect or death.

Delays in care not only have a negative impact on patient outcomes but they also increase health care costs. A number of examples illustrating the adverse impact of PA on patient outcomes and health care costs are attached.

Additionally, the most recent (2022) Annual Report issued by the Council for Affordable Quality Health Care (CAQH)[3] indicates that increased use of electronic prior authorization would result in $449 million in cost savings for the medical industry annually, including $139 million/year for health plans and $310 million/ year for providers.

RECOMMENDATION: Since a more judicious and cost-effective use of PA falls squarely within the goals of the Budget Committee's Health Care Task Force, the RRC recommends that Congress swiftly enact the *Seniors Act*.

CBO Modeling

Since CBO modeling of the costs of legislation has the potential to derail legislation that is strongly supported by legislators on both sides of the aisle — or to accelerate its adoption — the RRC very much appreciates the Health Care Task Force's interest in examining potential improvements to CBO modeling processes and analyses.

The RRC believes that CBO cost modeling processes and analyses require significant reform to improve transparency, accuracy, consistency, and timeliness. While the CBO does publish some limited information purporting to explain the basis for its cost estimates, this information is skeletal, providing virtually no insight into the CBO's rationale for its projections. The information CBO analysts currently make available to Congress and the public often fails to

[2] See https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[3] See https://www.caqh.org/sites/default/files/2022-caqh-index-report%20FINAL%20SPREAD%20VERSION.pdf

detail the assumptions upon which its projections are based, the empirical basis or other data supporting these assumptions, or the CBO's basis for dismissing data that does not support its assumptions. Moreover, CBO's failure to provide or update cost estimates on a timely basis may interfere with legislative progress, particularly for bills that may have significant budgetary implications, thus disrupting the legislative process.

The deficiencies in CBO processes and analyses are especially evident in the case of cost estimates related to preventive health services. For example, CBO's June 15, 2020 report, entitled *How CBO Analyzes Approaches to Improve Health Through Disease Prevention*[4] makes it clear that CBO's modeling does not take into account the cost implications of long-term improvements in health status and resulting cost savings. The legislation that you introduced along with Diana DeGette (D-Colo.), which was likewise introduced in the Senate by Senators Ben Cardin (D-Md.), Mike Crapo (R-Idaho), Angus King (I-Maine) and Kevin Cramer (R-N.D.)== the *Preventive Health Savings Act* (H.R. 766 /S. 114)-- seeks to address this deficiency.

We agree with this dynamic scoring approach and believe if CBO had evaluated the costs of the *Seniors Act* through this lens, the score of this bill would have been significantly lower since unwarranted delays in diagnosis and treatment attributable to the misuse of PA likewise result in negative long term health consequences that result in increased health care expenditures over a period that exceeds the 10-year CBO budget window.

The CBO's cost estimate for the *Seniors Act* also illustrates the deficiencies of the current process. The primary provisions of the *Seniors Act* increase the transparency of the PA processes used by MA plans while also requiring MA plans to institute real-time electronic PA for frequently approved items and services. The bill does not preclude or otherwise limit MA plans' ability to utilize PA for any item or service, nor does it mandate coverage of any item or service that is not already required to be covered under existing legal authorities. Yet, on July 26, 2022, the CBO published an estimate indicating that enacting the *Seniors Act* would increase Medicare expenditures by over $16 billion over 10 years. This cost estimate defies common sense and illustrates the pressing need to improve the transparency, accuracy and timeliness of CBO cost estimates. Consider the following:

- Transparency: The CBO's rationale for its cost estimate is cursory and conclusory, leaving Hill sponsors and proponents of the legislation at a loss regarding CBO's reasoning. In explaining its estimate, the CBO states that by placing "additional requirements" on plans that use PA, it expects the legislation to result in "greater use of services" and, therefore, higher bids by MA plans. Since the bill does not restrict MA plans' use of PA, it is difficult to understand how it would result in "greater use of services." Nor is it clear how CBO determined that the projected increase in the use of services would be of sufficient magnitude to impact MA plans' bids or how CBO projected the amount of the projected bid increases. The rationale is not supported by data, nor does it appear to take into account existing and published data on the financial impact of PA for both plans and

[4] https://www.cbo.gov/publication/56345.

providers that suggests that modernization of PA processes would actually result in cost savings for both plans and providers.

- Accuracy: The CBO estimate is inconsistent with a highly detailed analysis of proposed regulatory provisions that essentially mirror the critical provisions of the *Seniors Act.* Specifically, the Centers for Medicare & Medicaid Services determined that regulatory provisions that largely parallel the *Seniors Act* provisions for a broader range of health plans would ***save*** an estimated $16 billion over 10 years and would not appreciably increase health plan costs.[5] Nor does the CBO estimate consider CAQH data indicating that health plans' implementation of electronic PA would actually result in appreciable health plan savings, estimated at $139 million/ year.

- Consistency: The CBO's *Seniors Act* cost estimate is inconsistent with cost estimates produced by CBO for several other PA-related legislation.[6] In other contexts, CBO has also acknowledged considerable uncertainty about whether and to what extent MA plans can be expected to change their bids — upward or downward — in response to legislative or regulatory changes.[7] These issues are not addressed or considered in the CBO *Seniors Act* score.

- Timeliness: Since CBO's initial *Seniors Act* cost estimate, CMS has proposed and/or finalized several regulations that address various aspects of PA. While the RRC has received information suggesting that regulatory action has impacted the budget score, the score has not been formally updated.

RECOMMENDATION: Based on our experience with the CBO's cost estimation process, we urge the Budget Committee's Health Care Task Force to consider reforms that address each of these problem areas:

- Transparency: The CBO should be required to do the following to improve transparency:

    - Provide a written, plain language explanation of the methodology used to produce cost estimates for proposed legislation;

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[5] https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.

[6] For example, the CBO cost estimate for the mental health parity bill which includes a provision relating to PA and step therapy, was less than a million dollars; H.R. 7539 (cbo.gov). The CBO did found no cost for H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018 | Congressional Budget Office (cbo.gov) or for electronic PA for H.R. 5773, Preventing Addiction for Susceptible Seniors Act of 2018 | Congressional Budget Office (cbo.gov).

[7] See Options for Reducing the Deficit, 2023 to 2032--Volume I: Larger Reductions. Reduce Medicare Advantage Benchmarks. https://www.cbo.gov/budget-options/58626.

- Identify the primary economic, behavioral or other assumptions made in the cost model; and
- Identify the data supporting the model's primary assumptions.

In addition, the CBO analysis should identify any available published data relevant to the cost projection and explain why existing data sources were (or were not) considered.

- Accuracy: CBO should be required to consult with knowledgeable sources to obtain the data used in its cost models and should be required to detail in writing the sources consulted. The rationale for all assumptions not supported by data should be explained.

- Consistency: CBO should be required to establish a binding internal process to ensure that the assumptions and methodologies used in producing budget scores are consistent across all legislation for which budget scores are made. In addition, CBO should be encouraged to publish reports — such as the report published on the methods used to analyze the cost implications of preventive services legislation — for other economic modeling issues commonly raised by proposed health care legislation (e.g., how to account for the costs of commonly accepted practices, how to estimate the impact of increased administrative costs in MA plans, how to estimate utilization changes attributable to cost reductions for a particular service, etc.).

- Timeliness: Guidelines for completing (and updating) preliminary and final scores for proposed legislation should be established.

We appreciate the opportunity to comment on these critical issues and look forward to working with the Budget Committee Health Care Task Force on this and future initiatives.

Respectfully,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Association of Orthopaedic Surgeons
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Cardiology
American College of Surgeons
American Gastroenterological Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
Medical Group Management Association
National Association of Spine Specialists (NASS)

Illustrations of the Adverse Impact of PA on Health Care Outcomes and Costs

- The patient is a 51-year-old AA male who presented in the fall of 2021 with SOB (shortness of breath) and cough. He was treated with abx (antibiotics) and steroids and improved but after the holidays noted increasing SOB especially when lying flat. He was admitted with a large mediastinal mass and after several biopsies was dx (diagnosed) with Hodgkin's Lymphoma. Because of the policy that PET (scan) cannot be done in the hospital, he received steroids with some relief and was seen by me the next week. At the time, consent for chemotherapy was obtained and orders written to begin urgently. PA (prior authorization) was required prior to the PET and treatment. Ten days after the orders were written, he developed increasing SOB and went to the ED and was re-admitted to the hospital. His PET had been scheduled the morning of admission, but his treatment was still not yet scheduled awaiting PA. His breathing deteriorated and he was intubated and taken to the MICU. The physician visited him in the ICU the morning after admission and helped orchestrate emergent chemotherapy with AVD Br (arterial vascular disease/bronchitis?). His course was complicated by bacterial hospital acquired pneumonia, and he remained in the ICU for 10 days when he was weaned from the vent and transferred to the Hem/Onc service. He was discharged to receive his treatment in the outpatient setting. Brentuximab was denied by his insurance until "peer to peer," which took several days to arrange. None of this needed to happen had he received timely therapy.

- The patient is a 32-year-old AA female who presented to the ED with SOB, chest pain and a large anterior chest mass growing into the anterior soft tissues. A bx (biopsy) was done in interventional radiology (IR) and the physician was called about the patient while she was in radiology. The physician added her to the next clinic, and because of her sx (symptoms), she was admitted to receive her first dose of ABVD (chemotherapy combination used to treat Hodgkin lymphoma). A randomized trial has shown that AVD-Br is superior, but the Br requires approval and her situation required urgent treatment. After receiving her C1D1 treatment, she was to receive C1D15 in the clinic. The orders were written but the infusion center refused to schedule her because they had yet to receive PA. After multiple communications including texts, phone calls, and "peer to peer" the patient was scheduled for treatment 5 days late. For her second cycle, her payor finally approved brentuximab after more back and forth with insurance.

- Following cataract surgery, an ophthalmology patient travels to have an exam and needs a YAG laser capsulotomy. This procedure addresses post-cataract surgery vision issues by using a laser to rupture a membrane holding the lens implant in place that can become cloudy and reduce vision. The ophthalmologist cannot do the procedure immediately because of PA requirements by the patient's insurance company. This requires the patient to again travel to the ophthalmologist's office for a common procedure on a later date. It also requires the practice to make adjustments to their already overbooked schedule to accommodate the patient's additional visit. This practice is a regional referral center for many rural areas in northwest Georgia and northeast Alabama. In this case, PA results in increased cost an inconvenience for the patient for a procedure that could have been provided during a previously scheduled visit.

- In Florida, a third-party administrator manages Aetna Medicare Advantage beneficiaries' ophthalmology services. The administrator is now asking for Manifest Refractions to be within 90

days of cataract surgery scheduled for the patient's second eye. Although a Manifest Refraction was done for both eyes prior to the first eye surgery that clearly showed the patient's vision could not be improved, the administrator is requiring the practice to repeat the patient's Manifest Refraction if more than 90 days have passed since the patient's first eye surgery. The passage of 90 or more days sometimes occurs with the elderly population, as other health issues arise between the procedures for the first and second eye. Repetition of the Manifes Refraction results in a waste or time and resources. This ophthalmology practice has also had PA denied for not specifically indicating that "The patient would like to have cataract surgery". This has unnecessarily delayed patients' timely access to needed eye care and added additional administrative burden for the practice's staff.