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Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Thank you for the opportunity to provide comments on the proposed regulation 958 CMR 11.00: Internal Appeals Process and External Review Process for Risk-Bearing Provider Organizations (RBPOs) and Accountable Care Organizations (ACOs). Children's Medical Center Corporation staff reviewed the proposed regulation in detail and offer the following comments and questions, which we hope will be resolved in the final regulation.

In particular, we direct your attention to four high-level issues of concern:

- The potential for overlap, conflict, or confusion among the standards and processes laid out in these proposed regulations with other established standards and processes governed by MassHealth and the Division of Insurance (DOI).
- The burden on ACOs/RBPOs posed by these proposed regulations, with respect to both the proposed requirements for internal appeals processes and the proposed requirement that ACOs/RBPOs pay for the external review process even in cases in which the appeal is decided in favor of the ACO/RBPO.
- The poorly defined standard proposed for External Review Agencies to use in their adjudication of external appeals.
- The lack of indication that External Review Agencies will have sufficient expertise to adjudicate cases related to complex pediatric subspecialty care and the lack of acknowledgment that pediatric subspecialty expertise may vary across External Review Agencies, making it necessary to direct pediatric appeals to specific agencies.

These issues and others are addressed in detail in our section-by-section comments below.

11.03 Right to an Internal Appeal

This section establishes a right to internal appeal under terms that are so broad as to be unhelpful. In particular, (2)(d) ("other concerns") functions as a catchall for any type of concern a patient may have about their care under an alternative payment contract (APC). We would encourage the HPC to provide a more defined statement of the scope of appeals; striking (2)(d) would be appropriate.

In part (2)(a) of this section, which identifies referral decisions as a topic for appeals, the term "affiliated" is used in the description of internal appeals process scope. We read this phrasing to mean describe referrals to providers who are out of the preferred referral network of the RBPO or ACO. "Affiliated" is never defined, although several specific types of affiliations are referenced in the definitions section. This lack of definition may lead to confusion about the intent of the section. We encourage the HPC to define the term "affiliated" or rephrase (2)(a) to read "Referrals to Providers out of the preferred referral network of the RBPO or ACO."

We are concerned that, in the case of risk-based arrangements that operate in a managed care structure (such as Accountable Care Partnership Plans in the MassHealth ACO program), the appeals process outlined in the proposed regulation may overlap or conflict with managed care rules under the purview of DOI. We would encourage HPC to clarify the ways in which this regulation may intersect with DOI's jurisdiction and to delineate clearly when appeals should be directed to a managed care organization (MCO) internal appeals process, rather than an ACO or RBPO internal appeals process.

11.04 Information on Internal Appeals
The information for patients laid out in 11.04(3) duplicates information about the authorization of a patient representative presented in 11.03(4). The duplicative content should be stricken in one of these sections.

Broadly, the description of information ACOs and RBPOs are required to provide is confusing and seems to lay out a suboptimal policy. With respect to (1), which establishes requirements related to availability of materials on appeals, it was unclear whether (1) is intended to state that ACOs and RBPOs shall make information available through both the mechanisms described in (1)(a) and (1)(b), and whether this information may be posted (for example, on a public facing website) to meet this requirement. We request that the HPC supply boilerplate language for this purpose in subregulatory guidance.

11.05 Form and Manner of Request
The use of 'or' in (1) is ambiguous. It could mean that the ACO/RBPO can meet the standard by making any one of the listed means available, or it could mean that the ACO/RBPO must make it possible for a consumer to register an appeal by any of the listed means. The latter interpretation would be extremely onerous in terms of staff time to receive appeals and administrative processing required to manage appeals from four different streams. Moreover, we are skeptical of the added value of an in-person appeals process, as this seems particularly burdensome on the consumer or their authorized representative. We request that the HPC clarify this requirement here or in subregulatory guidance.

In (2), we ask that the HPC clarify that if an internal appeal is resolvable with medical records held within the organization subject to the appeal, it is unnecessary for the appeal to include a signed release of medical and treatment information.

11.07 Time Limits for Resolution of Internal Appeals
Beginning in this section and continuing throughout the document (11.10 External Review, 11.11 Expedited External Review, 11.16 Requests Ineligible for External Review—Notification, 11.19 Medical Records and Other Information, 11.21 Decisions and Notice), we urge the HPC to adopt the use of business days to define timelines for steps of the appeals process.

Further, given that many of the ACOs/RBPOs operating in Massachusetts are part of the MassHealth ACO program, we observe that the standards for response and resolution times differ from the standards imposed by MassHealth. We encourage the HPC to coordinate with MassHealth to ensure a consistent standard is applied across types of coverage.

11.11 Expedited External Review
The drafting of this section is confusing, and we recommend clarification. Part (1) states that the consumer may apply to the External Review Agency to seek an expedited external review; however, (4) indicates that the consumer may request expedited review from OPP, which can convey the request for expedited review to the External Review Agency. These sections are contradictory, and we recommend

that the HPC clarify this section to state that the OPP is the agency to which consumers make a request for expedited external appeal, if this is the intent. We further request that the HPC clarify that requests for expedited external review proceed through the OPP adjudication process laid out in Section 11.15 Screening of Requests for External Review.

11.12 Fees

We support the principle that the consumer requesting an external review should not bear the cost of that process. However, we are significantly concerned about the open-ended expectation that ACOs/RBPOs that are the subject of external review requests bear the cost of all external reviews. This policy makes ACOs/RBPOs vulnerable to the costs of these reviews even in cases where the finding supports the ACO/RBPO decision. Moreover, nothing in the proposed regulation suggests that ACOs/RBPOs will be able to participate in the External Review Agency contracting process, leaving ACOs/RBPOs to pay costs over which they have no control or input. We encourage the HPC to consider an adjustment to this proposed policy, such that ACOs/RBPOs are not responsible for the costs of external reviews that are decided in their favor.

11.15 Screening of Requests for External Review

As noted in our comments on Section 11.03 Right to an Internal Appeal, we are concerned about ways this appeals process could conflict or overlap with the processes established by DOI for customers of managed care organizations (MCOs). In Section 11.15 (1)(b), the HPC specifies that appeals will only be deemed acceptable for external review if they do not involve an issue within the purview of the Carrier. We recommend that HPC work with DOI to clarify the order of operations that a consumer should use to file an appeal in cases that may involve both an ACO/RBPO and an MCO.

11.17 Assignment of External Reviews

Given the lack of transparency available at this time about the procurement of External Review Agencies, we have significant concerns about the ability of these agencies to adjudicate appeals involving complex pediatric subspecialty care. On this basis, we are further concerned about the proposed process for assigning an appeal to one of the External Review Agencies on a random basis. In the event that expertise varies across contracted External Review Agencies, we argue that the agencies with extensive pediatric competency should be favored over other agencies in the assignment of pediatric cases. Section 15(h) of Chapter 141 of the Acts of 2000 provides for the "coverage of pediatric specialty care, including mental health care, by persons with recognized expertise in specialty pediatrics;" it follows that if pediatric specialty expertise is necessary in the provision of care it would also be necessary in the adjudication of decisions about pediatric specialty care.

11.19 Medical Records and Other Information

While we appreciate the need to provide relevant medical record information to external reviewers in a timely manner, especially in cases of expedited reviews, the timelines laid out in this section are not realistic, and it is unlikely that Boston Children's Hospital would be able to comply. Our standard processes for storage and retrieval of electronic records require more time than two business days. We encourage the HPC to seek input from ACOs/RBPOs about viable timelines for submitted medical records to External Review Agencies and to update this section based on that input.

11.21 Decisions and Notice

The standard of review set out in this section—"whether the requested referral, treatment, or service that is the subject of the review is likely to produce a more clinically beneficial outcome"—is vague, and there does not appear to be any consideration of the degree of likelihood of greater clinical benefit. We

encourage the HPC to establish a more specific standard and explanation of how this determination would be reached. It may also be worth considering whether a differential clinical outcome is the only factor that should be considered. For example, in the case of a child with a complex medical or behavioral health history, the choice of provider for a relatively routine service may have significant implications for the coordination of the patient's care. Moreover, the choice of a specific provider may have implications for the functional outcome of a pediatric patient, such as days of school missed, that are separate from clinical outcomes but nevertheless have an impact on the patient's wellbeing.

11.23 Reporting requirements

We ask that the HPC please clarify whether the general contact described in (e) should be an administrative contact or a patient-facing contact.