May 25, 2018

Lois Johnson
General Counsel
Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Re: Comments on draft regulation 958 CMR 11.00 – Internal Appeals Process and External Review Process for Risk-bearing Provider Organizations and Accountable Care Organizations

Dear General Counsel Johnson:

Thank you for the opportunity to submit comments regarding the proposed regulations that implement appeals and grievances procedures for patients participating in Risk-Bearing Provider Organizations and/or Accountable Care Organizations (ACOs)[1] as required under M.G.L. c. 176O, § 24.

Health Law Advocates (HLA) is a non-profit public interest law firm that serves some of the Commonwealth's most vulnerable populations. HLA provides pro bono legal representation to low-income Massachusetts residents who have been unjustly denied health care access and those who are burdened with unaffordable medical debt.

Health Care For All (HCFA) is a statewide consumer health advocacy organization that promotes health justice by working to reduce disparities and ensure coverage and access for all. We leverage direct service, policy development, coalition building, community organizing, public education and outreach to achieve our mission.

Mental Health Legal Advisors Committee (MHLAC) is an agency within the Supreme Judicial Court that represents low-income persons with psychiatric challenges on, among other issues, health care matters and that provides information on mental health legal matters to health care providers, family members, the general public, the judiciary, and the legislature. MHLAC has closely monitored many of the changes that have occurred in the provision of health services in the Commonwealth, and their effect on both the physical and mental health care of persons with psychiatric diagnoses.

As consumer-focused health care access organizations, we understand the importance of integrated care and welcome the opportunities afforded to patients participating in RBPOs to

[1] For brevity's sake, these comments refer to both types of organizations simply as "ACOs".

access coordinated, high-quality care. However, we also understand that there can be dangers for patients when providers take on increased financial risk, such as the under-utilization of necessary services and restriction of patient choice of providers.

In this context – with doctors and other providers taking on broader influence and decision-making authority over patient care, while patients are simultaneously facing more constraints in their ability to select different providers – strong patient protections provided through robust and empowering system of appeal rights is vital.

We previously recommended that the Office of Patient Protection (OPP) craft and adopt clear and comprehensive regulations to implement these consumer rights. This is necessary both because we believe that M.G.L. c. 176O, § 24 does not give adequate guidance to ACOs in establishing their internal appeals processes, and also because the ACOs regulated under these rules (unlike health insurance carriers) are new to the process of consumer appeal rights. Thus, we recommend that the rules should be as comprehensive and detailed as possible, with sufficient detail so as to protect consumer rights to due process and to a full and fair review of any service denial.

Toward this goal, we wish to commend OPP in their development of these draft regulations, which go a long way toward providing clarity to both patients and ACOs regarding the appropriate procedures to protect consumer appeal rights. However, we also acknowledge that there are some areas that would benefit from further description and enumeration of uniform procedural safeguards to help ACOs and OPP fully implement consumer appeal rights in the ACO care delivery context.

The first theme reflected in a number our enclosed comments is the importance of allowing consumers full access to their medical records. Consumer's need ready access to all of their medical records, both from outside providers, and from their providers within the ACO, in order to effectively advocate for their own care. This is especially true when a patient is engaged in a dispute with their ACO, which may have a financial incentive to limit or choose different care. Without complete transparency between the ACOs, providers and the patient, a consumer's faith in the quality of care will be undermined, which can lead to noncompliance with recommended treatment, and compromised health outcomes.

The second theme in the comments below is that the appeals process adopted by OPP must be flexible enough to allow a consumer's fair participation in the appeal process, including their right to reasonably obtain and submit medical records from outside providers, and their right to access to a second, independent medical opinion from an outside provider. This flexibility would necessarily mean that proposed deadlines should be flexible to accommodate a patient's full participation in these ways, as circumstances require. In other contexts, we feel that ACOs and others should endeavor to decide appeals as quickly as possible, so that consumers are not left waiting on administrative processes before they can initiate treatment.

INTERNAL APPEALS (SECTIONS 11.03 TO 11.09)

We wish to commend many aspects of the proposed rule concerning internal appeals (sections 11.03 to 11.09). Specifically:

- We strongly support the clarity that section 11.03(2) provides regarding the specific types of denials that constitute an appealable decision. We also commend OPP for the broad scope of such denials that are impactful upon patient care, and are thus made subject to an internal appeal under section 11.03(2).
- We strongly support the flexibility under section 11.05(1) that requires the ACO to create a process to accept internal appeals by either phone, in person, mail, or electronically, as the patient prefers or is best able to submit.
- We commend and enthusiastically support the consumer's right to ongoing coverage of ongoing treatment while an internal appeal is pending, as provided under section 11.03(2)(c).
- We commend and enthusiastically support the requirement under Section 11:05(1) that the ACO "adopt a process to accept appeals . . . by electronic means . . . ." Such a requirement is a ground-breaking and very beneficial step toward bringing the consumer appeals process in line with the currently available technological capabilities that are widespread and de rigueur in many industries outside of health care.
- We commend and enthusiastically support the fact that the draft regulations do not include any deadline or time limit for a patient to file an internal appeal of a dispute regarding a requested treatment, service or referral. Given the ongoing nature of many types of medical care for chronic conditions, imposing such a deadline would be arbitrary and unfairly limiting to a patient.

We propose the following modifications or additions to help strengthen consumer rights and protect consumer interests in their internal ACO appeals as follows:

Re Section 11:04 concerning notice of appeal rights provided to patients

One fundamental concern about patient appeal rights that we have expressed is a fear that patient's will not adequately understand when they have the right to question their provider's decision regarding appropriate treatment. Many factors could cause patients to misunderstand their appeal rights. For example, there could be potential ambiguity, where the patient does not understand whether there are possible alternative treatments or not. Also, the patient could be afraid that asking about their appeal rights, or appealing a treatment decision, would be perceived by the patient's provider(s) as questioning their judgment in a way that would harm the doctor-patient relationship, and negatively impact the provider's future treatment of the patient. Toward that end, we feel that providers making decisions regarding treatment or referrals must have a duty to provide information about the patient's appeal rights at the time that a patient expresses an interest in alternate treatment, or if the patient expresses reservations about the proposed treatment in a manner that the provider should see as a request for alternative treatment. When a patient expresses an interest in different treatment, in addition to providing the patient with information about their appeal rights in general, the provider should also have a duty to provide the patient with a written description of the provider's treatment decision, and the rationale for that decision. Providing such information to the patient will either help crystalize and define the treatment issue that is subject to the dispute (and thus allow the patient to more clearly understand the proposed treatment, in order to prepare their internal appeal) or, in some cases, such a disclosure could help avoid disputes and appeals entirely, by helping the patient and doctor more thoroughly discuss the provider's reasons and rationale to choose that form of treatment, and to deny alternatives that their patient may be considering.

In addition, the ACO, and its medical providers and other staff should have a clear duty to refrain from any form of retaliation against a patient in response to the patient's exercise of their appeal rights, or in response to the patient inquiring about their appeal rights.

To effectuate these recommendations, we propose that Section 11:04 be amended with an additional Subsections (5), (6) and (7) as follows:

> (5) Whenever a provider at an RBPO or ACO decides on a treatment, service or referral for a patient, and:
>
> (a) The Patient expresses an interest in an alternate treatment, service, or referral; or
>
> (b) The patient expresses reservations about the proposed treatment, service or referral in a manner that the provider should see as a request for alternative treatment.
>
> the provider shall:
>
> (c) inform a Patient about their rights to appeal the decision by a provider regarding a treatment, service or referral; and
>
> (d) furnish the Patient with a written description of the proposed treatment, service or referral decision, including the provider's rationale for denying the treatment, service or referral requested by the patient and selecting another treatment, service or referral, if any.
>
> (6) Whenever a Patient clearly expresses an interest in alternative treatment, or interest in appealing any decision concerning a medical treatment, service or referral to any staff of the RBPO or ACO, the staff person will furnish the Patient with a copy of their appeal rights as implemented by the RBPO or ACU under these rules, either online or in a printed form.
>
> (7) No RBPO or ACO, or their agents, staff, employees, or affiliated providers shall retaliate against a Patient in response to:
>
> (a) The Patient's exercise of any appeal rights under section 958 CMR 11; or
>
> (b) The Patient's inquiry regarding any appeal rights under section 958 CMR 11.

Re Section 11.05(1) regarding venues to request an internal appeal

- We recommend that the proposed section 11.05(1) be amended[2] slightly to clarify that regardless of the administrative 'process' that is created by the ACO, all appeal requests – verbal, or written in any form – must be accepted, regardless of the manner in which they are communicated.

[2] For instance, the regulation could be amended to state: "The RBPO or ACO shall accept appeals by telephone, in person, by mail, or by electronic means."

- We recommend that if the regulations are going to allow an ACO the discretion to limit the types of staff within the ACO that can receive a request for an internal appeal, that consumers be guaranteed the right to request an internal appeal directly from their medical provider without limitation. This is appropriate because in many cases, it is the provider who will understand most clearly what the disputed treatment decision is, and what the patient's interests are.[3] We fully anticipate that providers will face the administrative burden of registering internal appeal requests that they receive; however, we feel that allowing patients to raise their appeals directly with their providers will create an opportunity to negotiate and resolve some issues directly at an early stage, thus eliminating the need for further time and effort on some internal appeals.

Re Section 11.05(1) regarding acknowledgement of all internal appeal requests

- We recommend that the duty of the ACO to acknowledge receipt of an appeal request under section 11.05(1) not be limited to instances of verbal requests, or requests by the patient's authorized representative, as proposed. Rather, we feel it would be a useful practice that the ACO provide written confirmation of their receipt of any request for an internal appeal. Such a practice would help prevent misunderstandings concerning communications from a patient to their provider that were intended to be appeal requests. Written acknowledgement of all internal appeal requests is also justified by due process concerns, because the ACO has a duty to respond to an internal appeal within 14 calendar days under section 11.07(1). Given the access to electronic communication, or the simplicity of sending an acknowledgement letter by mail, providing such written notification to a patient is not burdensome. In fact, in some cases, providing such notice could help reduce the burden upon ACOs.[4]

Re Section 11:04(3) concerning prompt ACO recognition of a consumer's authorized representative(s)

We request that section 11.04(3) regarding authorized representatives be revised such that any ACO that requires an authorized representative designation to be in writing must:

- Provide a publicly available form online to designate such an authorization;
- Accept any other HIPAA-compliant written instrument that so designates an authorization representative for purposes of health care service denials and appeals;
- Provide a publicly available means to receive any such written authorization by fax or email, so that there are no barriers to a patient receiving assistance from their representative; and
- Accept a patient's designation of an authorized representative verbally or by phone in any urgent or time-sensitive treatment context.

[3] In contrast, forcing a patient to lodge their appeal with a specified person or office designated by the ACO would prejudice consumers who are less articulate regarding health care terminology, by forcing them to explain the nature of their dispute with their provider to a third party.

[4] For instance, in the event that a patient uses email as a ready form of electronic communications with their provider, an email request from a patient to revise their doctor's decision regarding treatment could in many cases amount to a request for an internal appeal, or it could be part of a dialogue between the provider and their patient.

HLA has encountered many instances where health plans have failed to allow a plan member to easily enlist the support of an authorized representative in the process of appealing a medical denial. Specifically, HLA has encountered health plans that have (1) refused to speak with an attorney about their client's imminent discharge from treatment without an authorized representative form on file, while simultaneously refusing to provide the attorney with a fax number or email to submit the required form; (2) refused to take action on a written appeal request when the client has used an attorney's own HIPAA-compliant medical release form; (3) refused to take action on a written appeal request when the consumer submitted the wrong version of an otherwise signed an authorized representative form issued online by that carrier; and (4) required that a consumer have their signature of an authorized representative form be notarized. These types of practices impede a consumer's access to the support provided by an authorized representative.

In the context of an ACO appeal, a patient's access to assistance from an advocate is even more important than in the insurance appeals context, because the patient is forced to disagree with their provider, rather than working with their provider to dispute an insurance denial. Because the patient has fewer possible allies to support their dispute, the ACO should be required to make it easier for the patient to draw on the support of others, including their authorized representative, in advocating for the patient during such an internal appeal dispute. This is especially true with respect to disputes regarding urgently needed care.

Re Section 11.03(3)(b): Coverage for outside medical professionals, with ready access to medical records

We also commend OPP for Section 11.03(3)(b), which proscribes an ACO from taking action to "[p]revent a Patient from seeking medical opinions outside of the RBPO or ACO." This regulation underscores the fact that importance of a second opinion in the context of a dispute between a patient and their ACO cannot be understated.

However, we would like to see the rules clarify this protection as follows:

- We recommend that OPP issue further clarification that this protection would apply broadly enough to include the patient's carrier[5] as well, to ensure that the patient has adequate and unimpeded insurance coverage for second opinions when they were desired.
- We recommend that OPP help ensure that a patient's access to outside opinions is effective, by providing patients with the right to full and ready access to their entire set of medical records[6] in a manner comparable to the access provided under draft Section 11.13, which currently requires the ACO to "assure that the Patient . . . has access to any

[5] Without access to coverage for these services, a patient's right to raise a dispute with their ACO over the proper and appropriate course of treatment would be a hollow right for nearly all consumers who lacked the financial resources to pay out-of-pocket for a second opinion. Given the cost of medical consultations with specialists in many fields, these costs could run to hundreds of dollars or more.

[6] Meaningful access to outside medical opinions necessitates that the ACO provide the patient or an outside provider with timely access to the patient's full set of medical records, including the complete results of lab tests, scans, and other diagnostic procedures that are related to any diagnosis and proposed course of treatment. Without access to such information, consultations with outside medical providers will be under-informed, or they could lead to duplicative and redundant medical testing, incurring costs to patient, the carrier, or both. In the era of increased use of electronic medical records, policies regulating ACOs should encourage the ready sharing of this information between providers, in order to improve the quality of care and reduce unnecessary costs.

medical information and records relating to the Patient, in the possession of the RBPO or ACO." We recommend that this duty to readily share medical records with a client should exist broadly, not just when the patient has requested an external review under Section 11.14, but also in the context of any dispute between the patient and their provider. This would include for instance, when a patient is contemplating the reasonableness of an internal appeal, and the need for a second opinion. The patient needs access to medical records when getting a second opinion, so that the patient can share their applicable medical records with that outside provider, in order to get the full advantage of that outside provider's opinion and expertise.

Similarly, if the patient is concerned about the applicable treatment guidelines that are in place with their ACO and in use to direct their individual care, access to such guidelines would also be necessary to allow the patient to have a more meaningful and informed consultation with an outside provider. Therefore, we recommend that OPP amend draft Section 11.03 to append the additional subsections (5) and (6) as follows:

> **(5) The RBPO or ACO shall assure the Patient ready access to their medical records in the possession of the ACO, including by providing such records to the Patient in paper or electronic form, as requested, and mailed or delivered through an electronic means if requested, within five (5) calendar days of any such request.**
>
> **(6) The RBPO or ACO shall assure the Patient ready access to any medical necessity standards or guidelines used by the ACO in decisions concerning the Patient's care, including by providing such documents to the Patient in an electronic or paper form, as requested, and mailed or delivered through an electronic means if requested, within five (5) calendar days of any such request.**

Re Sections 11.02 and 11.08(2) and determinations of Urgent Medical Need and expedited review

The definition of 'Urgent Medical Need' determines when a patient can seek an expedited internal or external review. As proposed, the definition articulates a standard where "[t]he risk of serious harm to the Patient is so immediate that the provision of appealed services should not await the standard 14 day response time for an internal appeal or the standard 21 day response time for an external review." The definition subsequently states that "Urgent Medical Need occurs where a delay may seriously jeopardize the health of the Patient or otherwise jeopardize the Patient's ability to regain maximum function." Thus, the rule proposes a definition that factors in the risks of patient harm or the patient's inability to regain maximum function that could result from delayed treatment.

We commend OPP for adopting such a broad and flexible definition that accounts for both immediate risks to a patient health, and potential impacts on the patient's possible loss of function, because such flexibility allows for situations that are hard to anticipate. Under section

11.08(2), the determination of 'Urgent Medical Need' is a threshold determination by ACO reviewer before commencing any expedited internal appeal.

Re Section 11:07 concerning provision of written decisions on internal appeals in a timely manner

We commend OPP on their adoption of shorter time frames for RBPOs and ACOs to decide internal appeals than those applicable to insurance carriers under 958 CMR 3.305.

However, in the context of a dispute between a provider and their patient over the appropriate course of treatment, minimizing and avoiding unnecessary delay will help patients resume care more quickly, and it will likely increase the patient's satisfaction with the ACO. Toward this end, we recommend that OPP amend the regulation to encourage ACOs to help avoid any unnecessary delay in communicating these appeal decisions to waiting patients, rather than simply establishing deadlines. Avoiding all possible delay in this context is important because the patient would, in many cases, be awaiting the initiation of treatment. Additionally, it is in the ACO's interests to decide some internal appeals more quickly, especially when they are providing ongoing treatment pending the appeal, but the provider no longer agrees that the treatment is necessary or appropriate.

To emphasize and encourage such prompt and timely communication of appeal decisions, and minimize unnecessary delays to patient care, we recommend that the deadlines be framed as the outer limit of time for providing the patient with a response to their internal appeal, and that the standard be to respond to the internal appeal request *as soon as possible, under the circumstances*.

In addition, because the patient could potentially be awaiting care, we would also recommend that the rules require the ACO to call the patient to inform them of the outcome of the decision, and then to offer to send the written decision to the patient electronically, using any email address on file or provided by the patient. For instance, Sections 11.07(1) and (2) should be deleted, and replaced with the following:

> **(1) The RBPO or ACO shall communicate the results of the internal appeal to the Patient, or the Patient's Authorized Representative, as soon as possible under the circumstances, but in no event later than 14 calendar days from receipt of the request for a non-expedited appeal.**
>
> **(2) The RBPO or ACO shall communicate the results of the internal appeal to the Patient, or the Patient's Authorized Representative, as soon as possible under the circumstances, but in no event later than 3 calendar days from receipt of the request for an expedited appeal.**
>
> **(3) The RBPO or ACO shall call the Patient or the Patient's Authorized Representative, to inform them of the results of the**

appeal, and shall offer to send the written decision electronically.

With respect to any expedited internal appeal, such a requirement is especially warranted. A patient that qualified for an expedited review under section 11.07(2) – meaning a "risk of serious harm that is so immediate" for fear that a "delay may seriously jeopardize the health of the Patient or otherwise jeopardize [their] ability to regain maximum function" – should not be subjected to any unnecessary delay from an ACO administrator scheduling the decisions to be sent on the 3-day deadline under section 11.07(2) but not before, or waiting for two to three days for a mailed written decision to arrive.[7]

More generally, this additional, nominal procedural step to call the client and email the written decision is warranted, because the rules already require, under Section 11:05(1), that the ACO "adopt a process to accept appeals . . . by electronic means . . . ." Thus in some cases, the ACO will have a means to request a current email address at the outset of the appeal. Regardless, the potential administrative burden upon the appeals department of the ACO to call the patients and inform them of the decision, and request or confirm a patient's email address, if available, is nominal.

The one circumstance that would warrant an exception to this overall goal of providing quicker decisions would be where a consumer has filed an internal appeal, and has also indicated an intention to obtain and submit either additional medical records from another provider that is not part of the ACO, including a second opinion from a new provider. The rules here, comparable to the rules for insurance carrier internal appeals under 958 CMR 3.000 et seq., should suspend the deadline for the ACOs decision, in order to allow the patient sufficient time to supplement the record for their internal appeal, based on the real-life practices of obtaining medical records or second opinions from outside medical providers. For instance, the deadline to submit medical records for consideration in the internal appeal should be no earlier than 5 calendar days from the date the patient receives medical records that they have requested. Similarly, the deadline should be no earlier than 5 days from the date that the patient receives a second opinion regarding the ACO's proposed treatment or service.

Such a policy is in accord with the current internal appeal procedures for carriers under 958 CMR 3.305(2)[8], which requires the 30-day deadline for the carrier's response to the internal appeal request be tolled during the time that the carrier is awaiting submission of a medical release from the patient, in order to allow the carrier to obtain necessary medical records.

Therefore, we recommend that Section 11:07 be further amended by the addition of the following section:

[7] Simply requiring the ACO to mail (postmark) the decision by the deadline(s) under sections 11.07(1) and (2) would mean that the client must, in effect, wait an additional 2-3 days for the postal system to deliver the decision.
[8] 958 CMR §3.305(2) states: "When a grievance requires the review of medical records, the 30 day period will not begin to run until the insured or the insured's authorized representative submits a signed authorization for release of medical records and treatment information as required in 958 CMR 3.302(2)."

(4) When the internal appeal requires the review of medical records or a pending medical opinion from medical providers outside the RBPO or ACO, with consent from the Patient, the 3 day period under subsection (2) and the 14 day period under subsection (1) will not begin to run until five (5) calendar days after the Patient or the Patient's authorized representative receives medical records or receives an pending second opinion form a medical provider outside the RBPO or ACO.

Re Section 11.09 concerning the Form of Written Resolution of the Internal Appeal

We commend OPP for describing the types of information under Section 11.09(a) through (c) concerning a patient's rights to further appeal that must be included with a written decision on an internal appeal.

However, given the fact that these rules are new to both ACOs and to patients, we recommend that OPP draft a model notice that ACOs may use, in order to prevent inadvertent misinformation or miscommunication by the ACOs as these new rules are implemented. In addition, we recommend that such a model notice also include guidance[9] concerning how to communicate with patients clearly about their continuing rights under these regulations. In addition, given the importance of the patient's rights to both ongoing coverage and to an External Review, we recommend that any adverse decision of an internal appeal should include, in prominent and conspicuous type, on the first page of the written decision, the statements providing a patient with notice that:

(i) If the patient disagrees in whole or in part with the decision by the ACO, they have the right to request a further EXTERNAL REVIEW appeal.
(ii) The patient must request an EXTERNAL REVIEW appeal within thirty (30) days of the date that they received the written decision on their internal appeal.
(ii) If the patient was receiving ongoing treatment that is subject to the appeal, the patient may continue to receive that treatment during their EXTERNAL REVIEW appeal.

EXTERNAL APPEALS (SECTIONS 11.10 TO 11.21)

We wish to commend OPP for including many vital consumer protections in the draft sections 11.10 to 11.21 concerning external review appeals. Specifically:

- We strongly support the clear description of the kinds of denials that constitute an appealable decision, and we also commend OPP for the broad scope of such denials that are impactful upon patient care and thus made subject to an external appeal under section 11.10.
- We commend and enthusiastically support the consumer's right to **ongoing treatment** while an external review is pending, as provided under section 11.03(2)(c).

[9] For instance, we recommend that any such a Model Notice and any related Guidance by OPP prohibit the use of the word "final" in relation to any description of the internal appeal decision by the ACO. This is based on our experience reviewing many decision letters from group health plans, which often describe their internal appeal decision as "final." This has the unfortunately effect of implying that the Patient has no further appeal rights in response, when in fact they do under both state and federal regulations that provide for External Review.

Re Section 11.14 concerning materials included with a request for External Review

Section 11.14 should be amended slightly, consistent with Section 11.15, to address external review requests for which no written resolution of the internal appeal exists. For instance, the current draft Section 11.14(c) should be amended to state:

> (c) Include a copy of the written resolution of the internal appeal issued by the RBPO or ACO**, if any such copy was provided to the Patient or the Patient's Representative**.

[Note: Recommended changes are in **bold, underline**.]

Re Section 11:15(1)(c) and screening requests for external review

We are concerned that under section 11.08(2), the ACO's Internal Reviewer has exclusive discretion to determine whether an appeal concerning a denial or disputed course of treatment amounts to an Urgent Medical Need. In this capacity, the ACO's Internal Reviewer has the capacity to deny a patient the right to an expedited internal appeal, which would require the patient to wait for the ACO's internal decision for as long as 14 days.[10] In some medical situations involving urgently needed treatment, forcing a consumer to face a delay of 14 days without recourse to meaningfully challenge the ACO's decision that the medical situation is not 'Urgent' would be procedurally unfair.

To remedy this potential procedural shortcoming, we would recommend that any instance where the patient requests an expedited internal appeal, but the ACO determines that the medical situation does not meet the standard of Urgent Medical Need, the patient shall have the right to immediately request an external review, regardless of the fact that an internal appeal may be pending and incomplete. During the initial screening stage of that external review, if the External Review Agency (ERA) finds an Urgent Medical Need exists, the patient may commence their external review. Alternatively, if the ERA determines that the situation *does not* present an Urgent Medical Need, then the patient's External Review application can be put on hold, pending the outcome of the internal appeal. To effectuate such a change, we recommend that OPP revise section 11:15(1)(c) to read as follows:

> (c) Result from an RBPO's or ACO's written resolution of the internal appeal upholding the decision that is the subject of the appeal; provided, however, that no written resolution is necessary where the RBPO or ACO has failed to comply with timelines for the internal appeals**, or if the consumer disputes a determination by the RBPO or ACO's Internal Reviewer that the internal appeal does not meet the standard for an Urgent Medical Need**.

[Note: Recommended changes are in **bold, underline**.]

[10] See Section 11.07: Time Limits for Resolution of Internal Appeals. "(1) The RBPO or ACO shall provide the Patient, or the Patient's Authorized Representative, with a written resolution of the appeal within 14 calendar days of receipt of the original appeal."

Re Section 11.10 concerning the deadline to request an External Review

Given the relatively short 30-day deadline that a consumer faces with respect to filing an external review request, we make the following recommendations:

- Section 11.19 should be amended with an additional subsection, as follows:

> **(3) The RBPO or ACO shall provide the Patient or the Patient's Authorized Representative with any medical records requested, in an electronic format, delivered through an electronic means if requested, within two (2) business days of any such request.**

In the instances that the patient and provider clearly disagree about a proposed treatment or referral, and the ACO denies the patient's internal appeal, the patient will be at a distinct disadvantage. Because the patient is not a medical professional, and yet they are forced to rebut the opinions of their doctors in the ACO, the patient will need to resort to both their own medical records, and to second opinions by independent and non-conflicted providers outside the ACO. Because collecting medical records from providers alone can take as long as 30 days, and scheduling second opinions from specialists can take even longer, we feel that the imposition of the 30-day deadline under Section 11.10 would be procedurally unfair, potentially forcing patients to file requests for external review before they have a chance to receive and review their records, or to consult with a second opinion. Therefore, we recommend that the deadline to request an external review be tolled in instances where the patient has made good faith efforts to obtain medical records or a second opinion, but could not complete such tasks under the rather stringent 30-day deadline. Also, the deadline should also be tolled in any instance where the ACO's decision in the internal appeal is procedurally or substantively lacking.

To effectuate these recommendations, we propose that Section 11.10 be amended with addition of the following sentences:

> **The 30 calendar day deadline under this section shall be tolled for any time period that:**
> **(1) The patient has requested but not received medical records or other documents and information documents and information relied upon by the RBPO or ACO in the internal appeal, as described under section 11.09(2)(c)**
> **(2) The patient has requested, but not yet received any other of their medical records in the possession of the RBPO or ACO.**
> **(3) The patient has requested, but not yet received any other medical records, relevant to their diagnosis or condition, from any other medical provider.**
> **(4) The patient has requested but not yet received a second medical opinion from an independent outside provider.**
> **(5) The decision letter from the RBPO or ACO failed to include adequate information as to the basis for its denial, including the application of the ACO's protocols to the facts in the case.**
> **(6) The decision letter from the RBPO or ACO failed to include adequate information concerning the Patient's right to seek an**

External Review, including inadequate notice of the deadline to file an External Review request.

Re Section 11.13(1) and OPP's Implicit Offer to Secure Medical Records

The proposed section 11.13 requires the patient to sign a medical release "authorizing the release and forwarding of medical information and records relevant to the subject matter of the external review . . . ." Such an obligation implies that OPP will then take affirmative steps to request and obtain medical records from any of the enumerated medical providers (including but not limited to the ACO) that the patient lists on the release. The proposed regulations, and the medical release form used by OPP in the application for External Review under Section 11.13, should be amended to clearly and definitively state:

a. whether OPP will request appropriate medical records from any provider for whom the patient provides a release, or
b. whether it is incumbent upon the patient to request and obtain medical records from their providers, and then submit such medical records to OPP for consideration in the External Review.

We recommend that OPP assume the duty to request and obtain medical records from all the providers that the patient lists, subject to any restrictions that the patient includes in the release form. This is warranted for the following reasons:

- Patient requests for medical records from a hospital or other entity can become a lengthy process, with some hospitals taking a week or more to provide the records.[11] In contrast, providers would respond to a request from OPP more quickly.
- Patients and their families who are dealing with a service denial and dispute with their providers at an ACO may be less well equipped to go through the administrative steps of this process, e.g. to request documents by obtaining, completing and submitting a medical records request (which may in some cases require access to a fax machine); then to obtain them and submit them to OPP.
- For OPP to mandate the completion of a medical release form for enumerated providers, without either a practice of requesting such medical records (as the form implies) or a clear and explicit disclosure that OPP will not request any medical records on behalf of the consumer's External Review appeal, is inherently deceptive and misleading. [12]

[11] Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524, HHS website, noting that medical providers may take up to 30 days to provide medical records, pursuant to HIPAA regulation 45 CFR 164.524(b)(2). At https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

[12] We recognize that in the context of External Review appeals for members of fully-insured health plans under 958 CMR 3.403 et. seq., which are also managed by OPP, the agency inexplicably requires a signed medical release as part of the application for External Review, but that OPP does not use the form to request medical records on a Patient's behalf, as that form inherently implies. Current litigation in the First Circuit is addressing the liability of a commercial health plan for the plan's failure to take even minimal steps to request and obtain readily available medical records in the context of an internal and external appeal under ERISA. See Doe v. HPHC, Docket 17-2078 (1st Cir, Nov. 3, 2017). Regardless of the context, we feel that OPP should be careful not to mislead consumers, by being clear in the regulations and on the External Review application that either a) the agency is assuming the duty to use of the form to request the Patient's medical records for inclusion in their External Review, or b) the agency clearly discloses that it is not assuming such a duty, and that the Patient themselves must request, secure and submit medical records for consideration in the External Review.

- In the commercial appeals context, there is a duty upon the carrier to request and obtain relevant medical records from providers at the outset of an External Review appeal, under section 958 CMR 3.409(1) and (2).[13] However, the draft rules require no such "good faith efforts" by the ACO to obtain medical records that the patient makes the ACO aware of. Because many ACOs may be dealing with new patients who have a relevant medical history that is documented in the medical records of the patient's prior medical providers, the ACO and the independent ERA contracted by OPP should have a duty to investigate and obtain records that are identified by the patient as relevant.

Re Sections 11.13(2) and 11.19(1): patient access to medical records and information relevant to the external review

We commend OPP for the broadly articulated right that the patient would have to "access any medical information and records relating to the Patient, in the possession of the RBPO or ACO" under Section 11.13(2). It is critical that the patient have access to their own medical records and information, so that they can meaningfully exercise their rights to appeal a denial. More specifically, with respect to the External Review process, the draft Section 11.19 proposes that the "RBPO or ACO shall forward the Patient's medical and treatment records relevant to the review and created by or in the possession or control of the RBPO or ACO, to the identified External Review Agency." Thus the ACO makes a decision regarding which medical records, tests, treatment notes, etc., are "relevant" to the medical necessity questions that are before the ERA. In light of these two considerations, we recommend that Section 11.19 be amended to require that the ACO must contemporaneously provide a complete copy of the same medical records and information it sends to the ERA to the patient as well. This will allow the patient to review what medical records the ACO has included, and to compare that information to the patient's own recollection of their treatment, symptoms and diagnoses by the ACO, and by any other providers, external or otherwise, that the ACO may have missed. Thus the patient should receive a copy of the ACO's submitted set of relevant records, as a safeguard against any potential inadvertent exclusion or omission of medical records that the patient feels are relevant.

For example, Section 11.19(1) should be revised as follows:

> (1) The RBPO or ACO shall forward the Patient's medical and treatment records relevant to the review and created by or in the possession or control of the RBPO or ACO, to the identified External Review Agency**, and also to the Patient or the Patient's Authorized Representative**.

[Note: Recommended changes are in **bold, underline**.]

Without full access to the ACO's record, including all medical records and medical guidelines relied upon by the ACO, in a prompt manner simultaneous to the External Reviewer, the patient will be deprived of meaningful opportunities to understand the ACO's proposed scope of relevant information, or to take action to secure additional medical records in the possession of

[13] "The carrier shall make good faith efforts to obtain records relevant to the review and not in the possession of the carrier from providers, whether the providers are in the carrier's network or outside of the carrier's network. Failure to make such good faith efforts shall be subject to the penalties listed at 958 CMR 3.412(2)(b)." 958 CMR 3.409(1).

the ACO or of other outside providers, for potential submission by the patient to the external review as allowed under Section 11.19(2). Also, access to the medical records will also allow the patient to submit their own testimony or explanation of any of the descriptions of their symptoms or current condition that they may wish to dispute as inaccurate or incomplete.

Accordingly, the proposed deadline under Section 11.19(2) for the patient's submission of information should be revised. The proposed deadline is currently described as 5 days from the patient's receipt of a general notice from OPP of their right to submit medical records. However, the patient should be provided with the necessary amount of time to submit records, taking into account any delay that the patient faces in receiving medical records from a past provider that is not part of the ACO.

Re Section 11.19 and the ERA's authority to request information from the ACO or the patient

We recommend that, comparable to external reviews for commercial insurance carriers under 958 CMR 3.412(2) and (3), the ERA be authorized to request additional medical or other information or documentation from both the ACO and from the patient. Without this authority, the ERA reviewer cannot take affirmative steps to do things such as requesting older medical records from the ACO or the patient that the reviewer thinks could be relevant. Such authority could be included as an amendment to proposed Section 11.19, as follows:

> **(3) The assigned external review agency may request the RBPO or ACO to provide such additional information or documentation as the external review agency deems necessary in order to render a decision. Such additional information shall be provided within 24 hours of the request in expedited review cases and within two business days for all other reviews.**
>
> **(4) The assigned external review agency may request the Patient or the Patient's Authorized Representative provide such additional information or documentation as the external review agency deems necessary in order to render a decision. Such additional information shall be provided within 24 hours of the request in expedited review cases and within 5 days for all other reviews, if possible, in order to be considered by the external review agency. The External Review Agency shall collaborate with the Patient or the Patient's Authorized Representative in order to facilitate the request and receipt of medical records that are in the possession of the Patient's non-ACO providers, but not in the possession of the Patient.**

Re Section 11.21 concerning the standard of review for External Review

We initially had concerns regarding the specific standard of review for the Reviewer to evaluate in determining that the treatment or referral desired by the patient is "likely to produce a more clinically beneficial outcome" that the treatment or referral proposed by the ACO. The average

patient, acting without a second opinion from another medical provider, may have significant difficulty overcoming such a standard.

Nevertheless, we commend OPP for broadening this analysis, by including a number of patient-centered factors and considerations in the broad list of factors under Section 11.21(2). The inclusion of factors, such as the "Patient's clinical history" and their "prior clinical relationships" under subsection 11.21(2)(a) should prevent, for instance, a patient being referred to treatment or to a specialized facility that has previously not proved successful for the patient. Other factors described under draft subsection 11.21(2)(e), such as a patient's "ability to access the requested referral, treatment or service" are also very important factors to consider. Patients and their families routinely face challenges to accessing treatment as they must balance competing needs, such as work or school schedules, family responsibilities, and transportation.[14] Recognizing that patients may face logistical barriers related to geography and access to transportation, or related to work or school schedules for themselves or their family members is an important step to empowering consumers to have more control over, and investment in, their care.

Despite the breadth of the 'catch all' provision in subsection 11.21(2)(e), recommend that the list of explicitly enumerated factors under Section 11.21(2) should include reference to a patient's timely access to care. For instance, if a patient was facing a provider's waiting list of six to nine months for a specialized service, such as neuropsychological evaluation, the patient should clearly be able to rely upon such a fact in an appeal to get a referral to a more quickly available out-of-network provider.

Re Subsections 11.21(3) concerning requirements for External Review decisions

We commend OPP for requiring a decision to include an "explanation of why the requested . . . service was found or was not found to [be] likely to produce a more clinically beneficial outcome for the Patient . . . ." under Subsection 11.21(3)(b). The adequacy of such an explanation could significantly impact a patient's ability to feel that their concerns were considered in the process of the appeal, regardless of the outcome. Because the patient will presumably have an ongoing relationship with their providers at the ACO, a written decision that shows that the ERA fully considered and evaluated the patient's wishes, but then also explains how the proposed treatment should fully meet the needs of the patient, is needed.

To help improve the quality of the decisions, and to recognize some basic procedural rights, the requirements for a "final decision of the External Review Agency" under Section 11.21(3) should be amended as follows:

- We recommend that the decision should include a clear and concise description of the treatment or referral that ACO proposed, and that the patient sought, to help ensure that there was no miscommunication, especially with respect to the patient's desired treatment. In the context of an ACO appeal, with the patient's provider articulating one course of treatment, and the patient acting on their own behalf, or acting in concert with external providers who may support an alternative treatment, miscommunication could

[14] For example, an HMO plan's limited network attempted to force one adolescent HLA client living near Worcester to miss a half-day of school each month, in order to travel round-trip to Boston each month to see an in-network specialist, rather than be seen by a nearby specialist in Worcester who was out-of-network.

easily arise, especially regarding the treatment alternative that the patient desired. Any decision that misconstrued or misunderstood the treatment that the patient was seeking would be unable to fairly resolve the dispute at the heart of the appeal. Thus, subsection 11.21(3) could be amended and renumbered with an additional subsection as follows:

> (1) A concise description of the treatment, service or referral proposed by the RBPO or ACO, and a concise description of the treatment, service or referral desired by the Patient.

We recommend that the decision should list the materials that were reviewed, to ensure that any medical records submitted by the patient were not inadvertently overlooked.[15] We recommend that the regulations be as explicit as possible, given that these ACO appeals would be a new type of practice by the external review agencies. Thus, subsection 11.21(3) could be amended and renumbered with an additional subsection as follows:

> (2) A list of all the materials submitted by the RBPO or ACO, and by the Patient or the Patient's Authorized Representative, that were considered in the review.

Re Subsection 11.21(8) concerning rights to seek revision when a decision is erroneous

We commend OPP for the draft of subsection 11.21(8), which allows that "the External Review Agency may be directed to retract and revise a decision only upon a finding of clear procedural or factual error . . . ." We also commend the fact that this standard of review is not as narrow as the standard articulated under 958 CMR 3.415(8) for private insurance appeals.

In our experience, the medical reviews by OPP's contracted ERAs for commercial insurance appeals are very thorough and fair. Similarly, the staff of the ERAs have also been helpful and accommodating to our efforts to submit medical records on a client's behalf. Nevertheless, mistakes can happen, and in this context, a mistake can have a profound impact upon the medical care that a patient receives.

We have a concern with the requirement that the "procedural or factual error" must be "evident on the face of the decision." under Section 11.21(8). Some procedural errors could include the ERA's administrative staff erroneously not allowing the patient to submit medical records (inadvertently by failing to include them, or intentionally refusing to do so due to an incorrect interpretation of the patient's deadline to submit records under these newly proposed rules). Such a procedural error would be clear to the patient who experienced it, but it would not necessarily be revealed "on the face of the decision" that was written by a medical reviewer at the ERA who may have no knowledge that the error took place. Therefore, we recommend that the requirement that the error be evident on the face of the decision be removed.

[15] OPP regulations for commercial insurance appeals currently require that a carrier's decision on an internal appeal must include "identification of the specific information considered" under 958 CMR 3.307(1). With respect to external review decisions under 958 CMR 3.415(2), OPP does not explicitly require ERA's to list the information they have received and reviewed, but in actual practice, these reviewers do so. Therefore we recommend that including this obligation would provide greater clarity to the Patients, without imposing a burden upon the ERAs and their reviewers.

We would also recommend that OPP consider including an open-ended and non-exhaustive list of the types of procedural or factual errors that could warrant such a review, either as part of these rules, or in subsequent subregulatory guidance. We would suggest that two such circumstances would include:

- The failure of the ERA to consider medical records timely submitted by the Patient;
- An ERA reviewer's error in correctly identifying the treatment or referral sought by the Patient, including any error with respect to a provider to whom a referral is sought.

We also have a concern regarding the short seven (7) day deadline to request that OPP to revise or review an erroneous decision. Specifically, proposed Section 11.21(8). the draft rule states:

> Any such written request must be received by the Office of Patient Protection within seven calendar days of the date of the External Review Agency's final decision, in order to be considered.

As proposed, Subsection 11:21(8) measures the Patient's seven (7) day deadline based on "date of the External Review Agency's final decision" and not, for instance, *the date that the Patient* ***receives*** *that decision*. If OPP's continues the current practice of contracting with out-of-state ERAs (as they do for commercial insurance appeals) patients who do not have ready access to email will receive these decisions 2-3 days after the decision is mailed. This leaves the patient with only a few days to request a review. Reliance on the date of the decision, and not the *date that the Patient actually receives the decision*, does not conform to the basic principles of notice and due process.

Additionally, a patient who sees a clear error in the decision must ask OPP to review and revise an erroneous decision by a "written request." This must be received by OPP under the 7-day deadline, which is defined as "seven calendar days" and thus could expire on a Saturday or Sunday when OPP is not staffed. For example, a hypothetical patient who lacks access to email could be mailed a decision dated Monday, May 14, which could be received by Thursday, May 17, leaving the patient only one day (Friday, May 18), to prepare their written request for a revision, and two days to mail this request to OPP by Saturday, May 19, for receipt by OPP on the deadline of Monday May 21. For patients lacking email, the 7-day window to request a revision of an erroneous decision can shrink to as little as 1-2 days. In addition, the short deadline will favor ACOs over Patients, because ACOs will universally have access to fax machines, and will be able to receive decisions and submit requests for revisions more promptly than nearly all consumers, who almost always lack access to a fax machine.

We recommend that OPP not impose such stringent time restrictions on Patients who may have a clear claim that the ERA made an error in a decision concerning their access to appropriate referrals or treatment. We would also argue that if OPP is to be granted "sole discretion" to seek a reconsideration and potential revision of an ERA decision, OPP should also exercise appropriate discretion in deciding whether a Patient's request for a revision or reconsideration of an erroneous decision is timely, based on the abilities of the patient, under the facts and circumstances of their condition, treatment, and other circumstances. There certainly could be instances when a patient lacks the training and understanding of the medical terminology involved, and thus may not understand or recognize an error that their provider would. Allowing

a patient in that circumstance sufficient time to arrange to share the decision with their outside provider, and then purse a request for revision of an erroneous decision, is reasonable. In addition, the deadline to request reconsideration should also reasonably be extended where a patient is hospitalized, or undergoing significant illness, and as a result, cannot adequately assess and then request reconsideration of the ERA decision due to the conditions of the patient's condition or treatment.

To remedy these problems, we propose the following changes.

- Draft rule Subsection 11.21(8) be replaced with the following:

> **(8) Upon a written request by the Patient, the Patient's Authorized Representative or the RBPO or ACO, and at the sole discretion of the Director of the Office of Patient Protection, the External Review Agency may be directed to review, retract and revise a decision upon a finding of clear procedural or factual error. Such a written request should be submitted to the Office of Patient Protection within seven calendar days of the date the Patient, the Patient's Authorized Representative or the RBPO or ACO submitting the request received the External Review Agency's final decision, unless circumstance reasonably warrant an extension. OPP shall create a process to receive such requests by email, or through some online submission portal.**

Re Section 11.21(7) concerning the binding nature of the ERA decision

We are concerned with the language in Section 11.21(7) regarding how the decision "shall be binding on the RBPO and the Patient, or the ACO and the Patient." We have two concerns with this provision.

First, the description of the decision as "binding" upon the patient could be interpreted to give the decision greater weight than is reasonable, if the patient has a change to their medical diagnosis or medical condition, and wishes to revisit with their ACO whether they need different treatment. An ACO administrator could easy and inadvertently misinterpret the "binding" nature of the ERA decision as foreclosing the patient's future rights to dispute their treatment, or their future rights to request alternative treatment. Clearly if the patient's condition changes, treatment options should be able to change accordingly.

Second, the provision could be interpreted as binding upon the ACO and the provider themselves, even in the instance that the ACO's proposed treatment could have inadvertently missed or overlooked a particular symptom or factor. In some rare instances, such an error by a provider could amount to medical malpractice. There is no intent under these proposed rules to insulate providers from their duty to follow the appropriate standards of medical care, regardless of their involvement in an ACO/RBPO organization in which they may have additional financial incentives to reduce or limit unnecessary or costly treatments in favor more affordable, higher value treatments. Like the comparable OPP regulations relative to commercial insurance appeals, this draft regulation should include a 'savings clause' to clarify that the binding nature of the ERA decision is not intended to inadvertently interfere with or foreclose a patient's other legal rights.

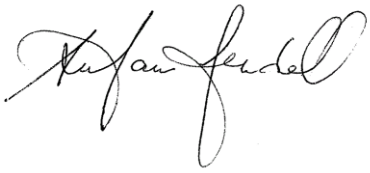
Therefore, we propose that Section 11.21(7) be amended, comparable to the established regulatory language under 958 CMR § 3.415(7)[16], to read as follows:

> **(7) The decision of the external review agency shall be binding on the RBPO or ACO and the Patient, except to the extent other remedies are available under state or federal law, and except that the requirement that the decision is binding shall not preclude the RBPO or ACO from otherwise providing benefits based upon any change to a Patient's diagnosis, condition, or response to treatment, at any time. Nothing in 958 CMR 11.21 shall prohibit the parties from voluntarily proceeding with any informal efforts to resolve the matter under review prior to the issuance of a final decision.**

Thank you for the opportunity to submit testimony regarding these vital consumer protections for patients enrolled in these emerging models for health care delivery. If you have any questions regarding these recommendations, or need more information, please contact Wells Wilkinson at wwilkinson@hla-inc.org or (617) 275-2983.

Sincerely,

Wells G. Wilkinson, J.D.
Senior Staff Attorney
healthlawadvocates



Susan Fendell
Senior Attorney
Mental Health Legal Advisors Committee

[16]Regulation 958 CMR § 3.415(7) provides as follows: "(7) The decision of the external review agency shall be binding on the carrier and the insured, except to the extent other remedies are available under state or federal law, and except that the requirement that the decision is binding shall not preclude the carrier from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. Nothing in 958 CMR 3.415 shall prohibit the parties from voluntarily proceeding with any informal efforts to resolve the matter under review prior to the issuance of a final decision."

Alyssa Vangeli, Esq., MPH
Associate Director, Policy and Government Relations
Health Care For All