

STATEMENT OF CONSIDERATION RELATING TO
907 KAR 17:020

Department for Medicaid Services
Not Amended After Comments

(1) A public hearing regarding 907 KAR 17:020 was not requested and; therefore, not held.

(2) The following individuals submitted written comments regarding 907 KAR 17:020:

<u>Name and Title</u>	<u>Organization/Agency/Other Entity</u>
Kathy Adams, Director of Public Policy	The Children's Alliance; Frankfort, KY
Nancy C. Galvagni, Senior Vice President	Kentucky Hospital Association; Louisville, KY

(3) The following individuals from the promulgating agency responded to comments received regarding 907 KAR 17:020:

<u>Name and Title</u>	<u>Organization/Agency/Other Entity</u>
Christina Heavrin, General Counsel	Cabinet for Health and Family Services
Dr. Michael Cornwall, Behavioral Health Director	Department for Medicaid Services
Stuart Owen, Regulation Coordinator	Department for Medicaid Services

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Section 2: Covered Services

(a) Comment: Kathy Adams, Director of Public Policy of The Children's Alliance, stated the following:

"Comment regarding: Section 2.(5)(e) and (6), which state:

'(5)(e) Be responsible for the provision and reimbursement of a covered service as described in this section beginning on or after the beginning date of enrollment of a recipient with an MCO as established in 907 KAR 17:010.

(6)(a) If an enrollee is receiving a medically necessary covered service the day before enrollment with an MCO, the MCO shall be responsible for the reimbursement of continuation of the medically necessary covered service without prior approval and without regard to whether services are provided within or outside the MCO's network

until the MCO can reasonably transfer the enrollee to a network provider.

(b) An MCO shall comply with paragraph (a) of this subsection without impeding service delivery or jeopardizing the enrollee's health.'

Children Alliance members report that MCOs are not consistently complying with these requirements. For example, members report that some clients receiving PRTF services (an out-of-home placement) have had their MCO switched during their placement and the new MCO would not pre-authorize the PRTF services or even provide any covered days for transition home. This practice impedes service delivery and jeopardizes the enrollee's health, safety and well-being. The Children's Alliance requests that provisions to provide oversight and address non-compliance be added to the regulation."

(b) Response: The Department for Medicaid Services (DMS) monitors this requirement and welcomes any detailed or specific information that can be provided so that DMS can investigate the matter.

Regarding the regulation, DMS has a contract with each managed care organization (MCO) and among the terms and conditions of the contracts are requirements regarding the continuation of services as well as DMS's remedies for addressing MCO failure to comply with contractual requirements. The contracts possess the necessary authority for DMS to police this issue.

(2) Subject: Section 8: Lock-In Program

(a) Comment: Nancy C. Galvagni, Senior Vice President of the Kentucky Hospital Association, stated the following:

"Section 8 of this rule sets out requirements for use of a Lock-in program by an MCO. KHA has concerns with the provisions contained in (2)(b) which would allow an MCO to use its own criteria, and not be limited by the Cabinet's criteria, to place an enrollee on lock-in. KHA has serious concerns with this provision. Under the lock-in program, an enrollee is limited by the MCO to a single PCP, a single hospital, and a single pharmacy. We believe allowing an MCO to make up their own criteria for placing enrollees into lock in has potential for abuse since it could be over-used simply as a mechanism by the MCO to direct their enrollees to use a certain provider and thereby circumvent the state's any willing provider requirement as well as enrollee freedom of choice to chose their physician, pharmacy or hospital. We urge that this provision of the rule be changed to require MCOs to follow the Cabinet's criteria for lock-in. In that way, all Medicaid enrollees, regardless of which MCO they are enrolled in, are treated fairly with regard to being subjected to lock-in. Also, any changes to the Cabinet's criteria for lock-in would be subject to promulgation through administrative regulation and subject to public comment, unlike the proposed rule which would allow MCOs to adopt their own internal criteria without public review."

(b) Response: Lock-in provisions have proven very beneficial in not only altering

enrollee behavior but in improving health outcomes for enrollees as well as managing costs. One of the major differences between “fee-for-service” Medicaid and managed care Medicaid is that managed care limits enrollees’ choices for physicians, pharmacies and hospitals. Those limitations are recognized and endorsed by the federal agency (the Centers for Medicare and Medicaid Service) which oversees and provides federal funds to states’ Medicaid programs.

(3) Subject: Section 9: Pharmacy Benefit Program.

(a) Comment: Kathy Adams, Director of Public Policy of The Children’s Alliance, stated the following:

“Comment regarding: Section 9.(4), which states:

‘(4) If a prescription for an enrollee is for a non-preferred drug and the pharmacist cannot reach the enrollee’s primary care provider or the MCO for approval and the pharmacist determines it necessary to provide the prescribed drug, the pharmacist shall:

(a) Provide a seventy-two (72) hour supply of the prescribed drug; or

(b) Provide less than a seventy-two (72) hour supply of the prescribed drug, if the request is for less than a seventy-two (72) hour supply.’

Children Alliance members overwhelmingly report that MCOs are not consistently complying with these requirements. The Children’s Alliance requests that provisions to provide oversight and address non-compliance be added to the regulation.”

(b) Response: DMS monitors this requirement and would appreciate any detailed or specific information so that DMS can investigate the specific cases.

Regarding the regulation, DMS has a contract with each managed care organization (MCO) and among the terms and conditions of the contracts are requirements regarding the dispensing of drugs to enrollees as well as DMS’s remedies for addressing MCO failure to comply with contractual requirements. The contracts possess the necessary authority for DMS to police this issue.

(c) Comment: Kathy Adams, Director of Public Policy of The Children’s Alliance, stated the following:

“Comment regarding: Section 9. The Children’s Alliance recommends that there be consistency between the MCO ‘preferred medications list’ and this requirement be added to this regulation. The different ‘preferred medications lists’ cause unnecessary disruption of client’s medications when their MCO changes. These changes in medications due to ‘preferred medications lists’ can be extremely detrimental to children and adults with mental health issues.”

(d) Response: Each managed care organization (MCO) maintains their own preferred drug list. DMS operates under contractual relationships with the MCOs and the

contracts do not require the MCOs to adopt a uniform preferred drug list.

If an enrollee changes MCOs, his or her established medications would be reimbursed by the new MCO through the current prescription period.

If an enrollee is prescribed a medication that is not on the MCO's preferred drug list, the enrollee's prescribing physician can request reconsideration.

Successful reconsiderations are based on medical necessity and the potential of undue harm to the patient.

At the time the prescribing physician makes a request for reconsideration, the physician should provide the MCO with information that would establish a foundation for medical necessity, undue hardship and/or the potential harm if the patient were to change from the patient's traditional medications to an alternative.

If the MCO denies the physician's request for reconsideration, the enrollee may appeal that decision. The enrollee may continue on with his/her traditional course of treatment until the appeal process has been completed, but only if the prescribing physician establishes a foundation for medical necessity, undue hardship and/or the potential harm if the patient were to change from his/her traditional medications prior to completing the appeal process.

Additionally, ensuring the appropriate utilization of prescription drugs is a fundamental responsibility of a managed care organization.

(e) Comment: Kathy Adams, Director of Public Policy of The Children's Alliance, stated the following:

"Comment regarding: Section 9. MCOs require 'prior authorizations' (PA) for too many medicines, which results in additional burdens upon medical prescribers and delays in clients receiving their medications. Often these delays cause interruptions in the client's medication regimen, placing the client at risk and/or causing undue complications for the client. This is especially true to psychotropic medications and medications needed to treat DSM IV diagnosis."

(f) Response: DMS welcomes any specific information regarding the origin of the delays, how the medications are being delayed and who delayed them.

Psychotropic medications do not treat mental health diagnoses, but, rather, treat symptoms of mental disease. A psychotropic medication should not be prescribed on the basis of a diagnosis.

"Medication regimes" are expected to be interrupted – often, especially for children. There should be a process for reconsidering all psychotropic medications for children as often as possible and have a direct relationship to the talking therapy that the child is

receiving in combination with the medication. It is insufficient to prescribe medication for a child simply on the basis that the talking therapy is not working or that the child's home life is not optimal.

The real risk the child faces is withdrawal from the chemicals he/she is ingesting.

(g) Comment: Kathy Adams, Director of Public Policy of The Children's Alliance, stated the following:

"Examples of problems related to prior authorization problems from Children's Alliance members include:

When prescription medications require a PA we sometimes, not always, are given a 3 day supply. Most times, the PA takes an average of 2 weeks to be approved so the child goes without the medication for that length of time. If a PA is not granted, and the MCO wants the prescribing doctor to change to a lesser expensive alternative, and the doctor refuses because they believe the medication they prescribed is the best alternative, then the child goes without the medication for weeks while the battle between the MCO and doctor ensues. We are experiencing this more often lately. Our program has 20 kids when at capacity and we average about 2-3 of these a month."

(h) Response: Is this occurring for a first prescription? Are all of the children in the program medicated? If that is true, that would defy the odds that some children (more often than not) would ***not*** need prescription drugs in order to address their emotional issues. DMS is interested in learning how the prescribing physician is making decisions to prescribe these chemicals to 100% of the children under his or her care.

Regarding the timeframe turnaround, the managed care organization must give notice as expeditiously as the member's health condition requires and within the required timeframes. Those timeframes may not exceed two (2) business days following receipt of the request for service with a possible extension of up to fourteen (14) additional days if the member, or the provider, requests an extension or the managed care organization justifies a need for additional information and how the extension is in the member's interest.

If the managed care organization extends the time frame, the managed care organization must give the member written notice of the reason for the decision to extend the timeframe and inform the member of the right to file a grievance if she or he disagrees with that decision and issue and carry out the determination as expeditiously as the member's health condition requires and no later than the date the extension expires.

For cases in which a prescriber indicates, or the managed care company determines, that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function, the managed care company shall make an expedited authorization decision and provide notice as

expeditiously as the member's health condition requires and no later than two (2) business days after receipt of the request for service. If there are modifications to this requirement, the provider should contact the managed care organization and speak with his or her customer service representative.

(i) Comment: Kathy Adams, Director of Public Policy of The Children's Alliance, stated the following:

"A client was admitted to our program from a hospital. During the hospitalization the client was prescribed Straterra, and became stable on this medication. We could not get this prescription filled because it required a prior authorization (PA). The prescribing doctor (from the hospital) would not do the PA. The site's doctor would not do the PA as he had not yet seen this client and was not able to schedule an initial evaluation immediately. When we thought we finally had things figured out the client was switched to a new MCO that also wanted a PA, and we had to start the process all over again. In the meantime, the child is without this medication."

(j) Response: DMS is interested to know why the prescribing physician was unwilling to complete the prior authorization. The physician's reluctance to seek continued chemotherapy for the child indicates something that is not being reported. Why did the physician not want to seek the prior authorization? Was the medication intended to be temporary? It would be considered best practice for a prescribing physician to see his or her patient before prescribing a harsh chemical to a child.

Only enrollees or their primary caregivers initiate changes to their MCOs. Enrollees are not arbitrarily switched to new MCOs. This could possibly be a child who is committed to the Department for Community Based Services. In that case, all children in Region 3 were moved to the incumbent managed care organization in that region and that was a temporary inconvenience.

DMS is uncertain as to why a physician would prescribe a medication to a child and then abandon that child once the child was taking a medication prescribed by the physician. Was the child expected to be "stable" on that medication? Or was the child provided that medication for a short period?

(k) Comment: Kathy Adams, Director of Public Policy of The Children's Alliance, stated the following:

"We have had residential clients admitted to a psychiatric hospital in need of a medication change due to an exacerbation of mental health symptoms. During the hospitalization the client is stabilized with a specific medication/s. The client is then discharged back to residential care with a prescription/s. The MCO then requires a PA (which is very difficult if not impossible to obtain as most hospital discharges occur late in the day and the prescribing physician is not accessible) or denies payment of that medication/s and indicates the client should be tried on another medication/s first (in most cases the other drug indicated was tried first). This results in missed doses of

psychotropic medication and disrupts the continuity of care and overall stability and safety of the client.”

(l) Response: Instead of asking for more medication, why not find out if the program the child is attending is providing adequate care? Children are not expected to be stabilized on psychotropic medication. They are expected to be exposed to medication for a reason related to their inability to participate in therapy. Children are expected to be tapered and removed from mood-altering medications as therapy progresses and skills are enhanced as a result of therapy. DMS is uncomfortable with this agency depending on medication as a primary source of treatment.

(m) Comment: Kathy Adams, Director of Public Policy of The Children’s Alliance, stated the following:

“A client has been stable taking Vyvanse since admission. We now have a prior authorization stating that he cannot be on Vyvanse and needs to be on Methylphenidate or Adderall instead. There are no provisions that would allow continuation of the Vyvanse until the doctor can change the prescription, which may not be in the best interest of the client.”

(n) Response: Again it appears that some are “stabilizing” children on medication, ostensibly as a primary source of treatment. In any event, if the physician who is prescribing Vyvanse believes that the child would be harmed if she or he were to change medications, the physician can request an override accompanied by a medical necessity statement.

(o) Comment: Kathy Adams, Director of Public Policy of The Children’s Alliance, stated the following:

“A client is prescribed Zoloft, Abilify and Adderall. All three medications require a prior authorization. The MCO will not approve the dosing of Zoloft and Abilify and wants the client prescribed Vyvanse instead of Adderall. This client’s medication dosing has been closely monitored and titrated by the psychiatrist, in order for the client to reach and maintain stability.”

(p) Response: Is this individual a child? If so, is this child taking three (3) psychotropic medications? If so, there is a clear and present danger to this child’s health and development. If the individual is a child is the notion that the child is “stabilized” by being placed on these chemicals?

With what type of talking therapy is the individual being treated? Is there no other way of helping this individual other than with medications? DMS believes that the managed care organization should investigate and monitor this issue more closely.

(q) Comment: Kathy Adams, Director of Public Policy of The Children’s Alliance, stated the following:

“The Children’s Alliance requests that the number and types of prior authorizations that can be required by an MCO be limited, set forth in regulation and monitored.”

(r) Response: The contracts between DMS and the managed care organizations do not establish the numbers and types of prior authorizations that an MCO can set. DMS does monitor this component of MCO activity. Ensuring the appropriate utilization of care and services, including prescription drugs, is a fundamental responsibility of a managed care organization.

SUMMARY OF STATEMENT OF CONSIDERATION
AND
ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The Department for Medicaid Services (DMS) has considered the comments received regarding 907 KAR 17:020 and is not amending the administrative regulation.