



HEALTH SYSTEMS DIVISION

Kate Brown, Governor

Oregon
Health
Authority

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May 20, 2019

By Registered Mail and Email

Tayo Akins, President and CEO
Cascade Health Alliance, LLC
2909 Daggett Ave., Ste. 225
Klamath, OR 97601-7200

**NOTICE OF NONCOMPLIANCE, AND ORDER REQUIRING CORRECTIVE
ACTION RELATING TO HEPATITIS C MEDICATIONS**

Dear Mr Akins:

Cascade Health Alliance LLC (CHA) is party to a Health Plan Services Contract with the Oregon Health Authority (OHA) for Coordinated Care Organization (CCO) services originally effective January 1, 2014, and now expiring December 31, 2019, Contract No. 143110 (the "Contract"). OHA, as the single-state Medicaid agency for Oregon, is authorized to monitor compliance with the requirements of the Contract by Exhibit D, Section 32 of the Contract.

AGENCY AUTHORITY

Each CCO must comply with all applicable federal and state laws and regulations, state plan requirements, and contract provisions applicable to its participation in the Oregon Health Plan and in the provision of services to Medicaid members. As the single state Medicaid agency for Oregon, OHA is responsible for monitoring CCOs to ensure their compliance with these requirements and to audit and verify the accuracy and appropriateness of payment, utilization of services, medical necessity, medical appropriateness, grievances, quality of care, and access to care.

In recognition of this oversight role, OHA has broad authority under the CCO Contract, and as the single state Medicaid agency to perform audits and request information as necessary to determine the CCO's compliance with the terms of the CCO Contract, as well as compliance with applicable state and federal laws. If OHA determines a CCO is not in compliance, OHA may impose a sanction including requiring contractor to develop and implement a time specific plan of correction, as defined in OAR 410-141-3000 (22), for the correction of identified areas of noncompliance pursuant to Exhibit D (34)(h) of the Contract.

As set forth in Exhibit D (33) of the Contract, conditions that may result in the imposition of a Sanction under this section may include when Contractor acts or fails to act as follows:

- a.** Fails substantially to provide medically appropriate services that the Contractor is required to provide, under law or under its Contract with OHA, to a member covered under this contract;

c. Acts to discriminate among Members on the basis of their protected class (such as race, color national origin, religion, sex, sexual orientation, marital status, age, or disability), their health status or their need for health care services. This includes, but is not limited to, termination of Enrollment or refusal to reenroll a Member, except as permitted under this Contract, or any practice that would reasonably be expected to discourage Enrollment by individuals whose protected class, medical condition or history indicates probable need for substantial future medical services;

k. Fails to comply with Grievance and Appeal requirements, including required notices, continuation or reinstatement of benefits, expedited procedures, compliance with requirements for processing and disposition of Grievances and Appeals, and record keeping and reporting requirements;

n. Fails to make timely claims payment to providers or fails to provide timely approval of authorization requests.

EVALUATION AND FINDING OF NONCOMPLIANCE

Finding of Facts.

On February 12, 2016, OHA sent written notice to all CCOs that they must provide Direct Acting Antiviral (DAA) coverage that is no more restrictive than OHA Fee for Service (FFS) criteria. The letter requested that CCOs provide OHA with information concerning the CCO's coverage criteria for treatment of persons with Hepatitis C and DAAs. OHA reviewed each CCO's criteria against OHA's FFS criteria. OHA followed this with a detailed guidance letter to CHA on April 28, 2016. The April 28 letter included an assessment of differences between CHA's criteria and FFS criteria. CHA had 90 days to remedy any shortcomings. OHA identified multiple required changes for CHA and asked for additional information regarding CHA's Hepatitis C Virus committee. In particular, OHA expressed concern that the committee may be limiting the number of affected members being treated at any one time. CHA sent revised criteria, and on September 21, 2016, OHA notified CHA they could use a committee but only "so long as this arrangement provides adequate access to patients such that no barrier or delay to treatment is created."

In 2017, OHA executed an agreement with the Oregon Law Center that, in part, increased OHA's monitoring of CCOs' treatment of members with Hepatitis C and utilization of DAA medications. OHA increased agency oversight of CCO authorization and denials of Hepatitis C medications in 2018 upon identification of performance issues, indications that access goals were being compromised and deficiencies in treatment of persons with Hepatitis C. Based on a review of sample DAA treatment denials and corresponding documentation submitted in May 2018, OHA documented the following issues with CHA including:

1. The use of a waitlist for its members which resulted in prior authorization requests not being responded to within the required timeframes which in turn delayed treatment for its members;
2. Upon identification of members that met the criteria for DAA treatment, these members were put on wait lists and no notification was sent out to the member and provider indicating that the treatment had been approved;
3. Members who had been determined not to meet DAA treatment criteria were also put onto a wait list without notification; and
4. Notice of Adverse Benefit Determinations were not mailed to the member and provider denying the requested treatment and providing the member the right to appeal the denial decision.

In July 2018, CHA was informed by Dana Hargunani, OHA's Chief Medical Officer, that having a wait list is not acceptable in Medicaid and that treatment must follow appropriate timelines and must not be delayed.

In December 2018, OHA received a complaint that CHA had approved treatment for a member but was delaying the start of treatment. Upon review of the case file, the following issues were noted:

- The prior authorization request for this member was dated August 23, 2018;
- An approval letter was issued to the member on October 8, 2018;
- On December 21, 2018, the member went to pharmacy to pick up prescription and was informed that there was not a prescription for the member and that the member needed to contact CHA;
- On December 21, 2018 member called CHA and the phone log shows that CHA informed the member that CHA had run out of money for the year and the member would be considered for treatment the following year beginning the 3rd week in January 2019.

CHA is still not timely responding to authorization requests, not determining approvals and denials timely or appropriately, and not providing medication timely, or at all, to members that qualify for treatment.

Conclusions of Law.

CHA is not compliant with the Contract and state or federal law as follows:

1. CHA did not provide medically appropriate services that Contractor is required to provide (Direct Acting Antiviral drugs for treatment of Hepatitis C) under law or under its Contract with OHA, to a member covered under the Contract. CHA's Hepatitis C Committee resulted in unreasonable barriers and delays to care that limited treatment access in comparison to what was available for FFS clients. (Exhibit B, Part 2 (1)(a),(c) and (d) and Exhibit B, Part 2 (2)(a) and (b); OAR 410-141-3225(5); 42 CFR 438.210(a)).
2. CHA's process and procedure for authorization and denial of medications for treatment of Hepatitis C does not comply with Federal, State law and contract provisions for authorization of covered services (Exhibit B, Part 2 (3)(g),(i),(n) and (o) and Exhibit I (3); OAR 410-141-3225(9)(b) 42 CFR 438.210(a)).
3. CHA did not timely dispense authorized medications to treat Hepatitis C to members who met OHP prior authorization criteria as required. (Exhibit B, Part 2 (2)(a) and(b); Part 4 (2)(a);42 CFR 438.210(a)).
4. CHA did not provide notice to members and providers within federal, state and contractually required timeframes of its adverse benefit determinations for Hepatitis C medications (42 CFR 438.404; Exhibit B, Part 2 (3)(g),(i),(n) and (o); OAR 410-141-3225(9)(d)).

ORDER

Based on the findings outlined above, OHA finds that CHA is not in compliance with federal and state law and with the Contract as cited above. Therefore, pursuant to OAR 410-141-3259 and Exhibit D, Sections 33 through 36 of the Contract, in order to protect the health of CHA members diagnosed with Hepatitis C and to prevent further harm to members' health, OHA is imposing a sanction on CHA and hereby requires CHA to:

- (1) Take immediate action to correct its non-compliance which shall include:
 - i. Within two business days from the date of service of this Order, have authorizations loaded for immediate claims processing for all members already authorized for Hepatitis C treatment by

CHA, and notify Members of the authorization for treatment and that the prescription for medication may be filled immediately;

- ii. Within three business days from the date of service of this Order, appropriately approve or deny all received requests for Hepatitis C treatment authorization, load all resulting approvals for immediate claims processing, and notify Members and prescribing providers of the determination; and,
- iii. Within five business days following completion of actions i. and ii. above, submit to OHA evidence of compliance and confirmation that medication has been dispensed by a pharmacy to the members.

(2) Pursuant to Exhibit D (34)(h) of the Contract, develop and implement a plan (the “Corrective Action Plan”) that is acceptable to OHA for correcting the issues set forth in this Notice and Order. The Corrective Action Plan shall:

- i. Describe actions and activities designed to correct non-compliant authorization processes including notification to providers of CHA’s change of practice, gathering supplementary data to identify causes and trends, and interventions that are targeted to improve outcomes in the problem and maintain compliance in areas of noncompliance as set forth in this Notice and Order;
- ii. List data that will be submitted to OHA as evidence of remediation and compliance; and,
- iii. Be submitted to OHA within 30 days from the date of this Notice and Order at the following address:

CCO.MCOCDeliverableReports@dhsoha.state.or.us

Lori.A.Coyner@dhsoha.state.or.us

April.S.Gillette@dhsoha.state.or.us

(3) Submit quarterly reports to OHA of all Hepatitis C requests and their resulting actions, including time to decision and time to member notification. The first quarterly report shall be submitted no later than July 15, 2019, and quarterly reporting shall continue for a period of at least one (1) year and until such time as notified by OHA quarterly reporting is no longer required. The reports shall be sent to the following address:

CCO.MCOCDeliverableReports@dhsoha.state.or.us

Lori.A.Coyner@dhsoha.state.or.us

April.S.Gillette@dhsoha.state.or.us

This sanction is not considered an “intermediate sanction” for purposes of 42 CFR 438.702 and 438.710. OHA reserves the right to exercise additional remedies available to it under the Contract or as provided by law based on the violations set forth in this Notice and Order.

If CHA’s response to the requirements set forth above is deemed inadequate, or OHA determines that there is continued violations of the Contract or violation of the Corrective Action Plan and there is substantial risk to members’ health, OHA may impose additional sanctions pursuant to Exhibit D, Sections 33 through 36, up to and including termination of the Contract.

APPEAL RIGHTS

If CHA believes it has not violated the provisions set forth as stated above and has information relevant to its compliance that it believes OHA should consider and wishes to appeal this Notice of Noncompliance and Order, CHA has the right to file a request for Administrative Review with the Director of OHA in writing within 30 days of issuance of this notice pursuant to Exhibit D(35) and OAR 410-141-3259 (7). The request for Administrative Review shall be sent to:

Oregon Health Authority
Patrick Allen, Oregon Health Authority Director
500 Summer St. NE, E-20
Salem, OR 97301

Patrick.Allen@dhsoha.state.or.us

Dated this 20 day of May, 2019.

Sincerely,



Lori Coyner, State Medicaid Director
Health Systems Division
Oregon Health Authority

CC: Maggie Polson, Chief Operations Officer, CHA
David Shute, Medical Director, CHA
Dawn Jagger, OHA Chief of Staff
Margie Stanton, Health Systems Division Director
April Gillette, Governance and Performance Improvement Director
Allison Tonge, Interim CCO Contract Administrator