HUMAN SERVICES DEPARTMENT

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Letter of Direction #41

Date: **August 20, 2020**

To: **Centennial Care 2.0 Managed Care Organizations**

From: **Nicole Comeaux, Director, Medical Assistance Division**
Adrian R. Gallegos, Inspector General, Human Services Department

Subject: **Program Integrity Requirements**

Title: **MCO Program Integrity Requirements**

This Letter of Direction (LOD) is provided to define and clarify terms of the Medicaid Managed Care Services Agreement (Agreement) and Managed Care Policy manual related to Program Integrity. This LOD supplements the requirements of the Agreement.

The Centennial Care 2.0 **Managed** Care Organizations (CONTRACTOR) shall comply with all Program Integrity provisions of the Medicaid Provider and Managed Care Act (27-11 NMSA 1978, previously known as the Medicaid Provider Act) and the Audit of Pharmacy Records section of the Pharmacy Act (61-11 NMSA 1978).

1. RETENTION OF RECORDS

This section provides further guidance and clarifies the requirements set forth in section 7.16 of the Agreement (Records and Audit). Section 7.16.7 will be added to the Agreement to clarify record retention periods:

7.16.7 Record Retention Periods

The requirements of maintaining records, books, documents, and information will include all medical, business, and financial records. All other records, books, documentation, and information resulting from this Agreement and maintained by the CONTRACTOR, Subcontractors, Major Subcontractors or Contract Providers must be retained for a period of at least ten (10) years from the date of creation.

2. ACCESS TO RECORDS, BOOKS AND DOCUMENTS

This section provides further guidance and clarifies the requirements set forth in section 7.16.6 of the Agreement (Access to Records, Books and Documents).

Specifically, the requirements set forth in 7.16.6.1 state that access must be provided to any records. This must also include access to personnel of the CONTRACTOR, Subcontractors, Major Subcontractors or Contract Providers for the purposes set forth in 7.16.6.2.

Section 7.16.6.1 of the Agreement will be revised to state: Upon reasonable notice, the CONTRACTOR must provide, and cause its Subcontractors, Major Subcontractors, and Contract Providers to provide the officials and entities identified in Section 7.16.6.3 with reasonable and adequate access to any personnel or records that are related to the scope of work performed under this Agreement within two (2) business days after the date of the request, unless the records are held by a Subcontractor, Major Subcontractor, Contract Provider, agent, or satellite office, in which case the records shall be made available within ten (10) business days, NMSA 1978, § 27-11- 4(B) and 42 CFR 438.3(h). Failure to provide copies or to permit inspection of records requested shall constitute a violation of the Medicaid Provider and Managed Care Act.

Section 7.16.6.2 of the Agreement will be revised to state: The CONTRACTOR and its Subcontractors and Major Subcontractors must provide the access described in this section upon HSD's request through ten (10) years from the final date of the contract period or from the date of completion of any audit, whichever is later, in accordance with 42 CFR 438.3(h); 42 CFR 438.230(c)(3)(iii); and 42 CFR 438.3(k). This request may be for, but is not limited to, the following purposes:

7.16.6.2.1 Examination;
7.16.6.2.2 Audit;
7.16.6.2.3 Investigation;
7.16.6.2.4 Agreement administration; or
7.16.6.2.5 The making of copies, excerpts, or transcripts.

3. REFERRALS FOR CREDIBLE ALLEGATIONS OF FRAUD

This section provides further guidance and clarifies the requirements set forth in section 7.27.11 of the Agreement (Referrals for Credible Allegations of Fraud).

Specifically, subsections 7.27.11.3 and 7.27.11.4 will be added to the Agreement stating that:

7.27.11.3 Following the referral of a Provider or Subcontractor based on a determination of a credible allegation of fraud, and during the pendency of a dispute between HSD and a Provider or Subcontractor regarding an alleged overpayment, including an overpayment based in whole or in part on a credible allegation of fraud, HSD will direct the CONTRACTOR to not suspend participation or withhold payment to the Provider or Subcontractor if the Provider or Subcontractor:

7.27.11.3.1 Submits to the CONTRACTOR prepayment review of claims for ongoing services;
7.27.11.3.2 Demonstrates to the CONTRACTOR that its employees have completed remedial training or education required by HSD to prevent the submission of claims for payment to which the Medicaid Provider or Subcontractor is not entitled; and

7.27.11.3.3 Engages an independent third party approved by the CONTRACTOR to temporarily manage or provide technical assistance to the Provider or Subcontractor following the referral or during the pendency of the dispute.

7.27.11.4 The CONTRACTOR shall not unreasonably withhold approval of a third party proposed by the Medicaid provider or subcontractor pursuant to subsection C of this section. The CONTRACTOR shall submit evidence that the above requirements have been met to the State's Office of the Inspector General (OIG) and the OIG will determine compliance with the requirements and report back to the CONTRACTOR.

7.27.11.4.1 A Provider or Subcontractor that has been found to have successfully complied with the above requirements shall be reimbursed for each clean claim for ongoing services within ten (10) Calendar Days of receipt if submitted electronically or thirty (30) Calendar Days if submitted manually.

Section 4.19.1.6.2 of the Agreement will be revised to state:

4.19.1.6.2 For all other Claims, except Claims which have undergone a pre-payment review as noted in 7.27.11.3, ninety percent (90%) of all Clean Claims must be adjudicated within thirty (30) Calendar Days of receipt and ninety-nine percent (99%) of all Clean Claims must be adjudicated within ninety (90) Calendar Days of receipt;

4. AUDIT OF PHARMACY RECORDS

For the purposes of this Section, entity means a managed care organization, insurance company or third-party payor, or representative of a managed care organization, insurance company or third-party payor, or a pharmacy benefits manager or a subcontractor of a pharmacy benefits manager.

As noted in Section 61-11-18.2 NMSA 1978 (Audit of Pharmacy Records), when auditing provider pharmacies, the CONTRACTOR shall adhere to the following:

A. An audit of the records of a pharmacy by an entity shall be conducted in accordance with the following criteria:
   (1) The entity conducting the initial on-site audit shall give the pharmacy notice at least two (2) weeks prior to conducting the initial on-site audit for each audit cycle;
   (2) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;
   (3) A clerical or recordkeeping error, regarding a required document or record, shall not necessarily constitute fraud, and that error:
      (a) Shall not be the basis for recoupment unless the error results in overpayment to the pharmacy, and any amount to be charged back or recouped due to overpayment shall not exceed the amount the pharmacy was overpaid; and
      (b) Shall not be subject to criminal penalties without proof of intent to commit fraud;
   (4) A pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the

pharmacy record with respect to orders or refills of a dangerous drug or controlled substance;

(5) A finding of an overpayment or underpayment shall be based on the actual overpayment or underpayment of a specific individual claim;

(6) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(7) A pharmacy shall be allowed at least twenty-one (21) business days, with reasonable extensions allowed, following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by an audit shall not exceed two (2) years from the date the claim was submitted to or adjudicated by an entity, unless it conflicts with state or federal law;

(9) An audit shall not be initiated or scheduled during the first five (5) calendar days of a month;

(10) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty (120) days, with reasonable extensions allowed, after conclusion of the audit, and the final report shall be delivered to the pharmacy within six (6) months after receipt of the preliminary audit report or final appeal, as provided for in Subsection B of this section, whichever is later;

(11) Notwithstanding any other provision in this section, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits;

(12) The auditing entity conducting a pharmacy audit shall not compensate an employee or contractor with which an auditing entity contracts to conduct a pharmacy audit based on the amount claimed or the actual amount recouped from the pharmacy being audited;

(13) An entity shall not charge a fee for conducting an on-site or a desk audit unless there is a finding of actual fraud;

(14) As a result of an audit finding, a pharmacist or pharmacy may resubmit a claim within twenty-one (21) business days to correct clerical or recordkeeping errors in lieu of recoupment of a claim where no actual financial harm to the patient has occurred; provided that the prescription was dispensed according to prescription documentation requirements pursuant to the Pharmacy Act (61-11 NMSA 1978);

(15) The requirements for a valid prescription or a pharmacy benefits manager's required operational standards for pharmacies shall not be more stringent than federal or state requirements;

(16) With notice to the prescriber, a pharmacy or pharmacist may satisfy state and federal requirements for a valid prescription by affixing or writing additional information on the front or back of a prescription or if the required information is electronically recorded on a patient's profile and is readily retrievable;

(17) The days' supply for unit-of-use items, such as topicals, drops, vials and inhalants, shall not be limited beyond manufacturer recommendations;

(18) If the only commercially available package size exceeds an entity's maximum days' supply, the dispensing of such package size must be accepted by the entity and shall not be the basis for recoupment;

(19) If the only commercially available package size exceeds an entity's maximum days' supply and the entity accepts the refill of such prescription, the entity shall not recoup such claim as an early refill; and

(20) The failure of a pharmacy to collect a copayment shall not be the basis for recoupment if the pharmacy provides documentation of billing of the claim and a reasonable attempt to collect the copayment.

B. Recoupment of any disputed funds shall occur after final internal disposition of the audit, including the appeals process set forth in Subsection C of this section. Should the identified discrepancy for an individual audit exceed twenty-five thousand dollars ($25,000), future payments to the pharmacy may be withheld pending finalization of the audit.

C. Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the entity finds that an unfavorable audit report or any portion of the audit is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the report of the audit without the necessity of any further proceedings.

D. This section does not apply to any investigative audit that involves probable or potential fraud, waste, abuse or willful misrepresentation.

E. In a wholesale invoice audit conducted by an entity:

(1) An entity shall not audit the claims of another entity;

(2) The following shall not form the basis for recoupment:

(a) The national drug code for the dispensed drug is in a quantity that is a sub-unit or multiple of the purchased drug as reflected on a supporting wholesale invoice;

(b) The correct quantity dispensed is reflected on the audited pharmacy claim; or

(c) The drug dispensed by the pharmacy on an audited pharmacy claim is identical to the strength and dosage form of the drug purchased;

(3) The entity shall accept as evidence:

(a) Supplier invoices issued prior to the date of dispensing the drug underlying the audited claim;

(b) Invoices from any supplier authorized by law to transfer ownership of the drug acquired by the audited pharmacy;

(c) Copies of supplier invoices in the possession of the audited pharmacy; and

(d) Reports required by any state board or agency; and

(4) Within five (5) business days of request by the audited pharmacy, the entity shall provide supporting documentation provided to the entity by the audited pharmacy's suppliers.

5. REPORTING PARTY-OF-INTEREST

This section adds a new section, 4.17.5, Reporting Party-of-Interest, to the Agreement and provides guidance and clarifies the requirements set forth in the Section 1903(m)(4) of Social Security Act (SSA) and Section 1318 of the Public Health Service Act.

4.17.5 Reporting Party-of-interest

4.17.5.1 For the purposes of this section “party-in-interest” (party) is defined as:

4.17.5.1.1 Any director, officer, partner, or employee responsible for management or administration of a CONTRACTOR, any person who is directly or indirectly the beneficial owner of more than five percent (5%) of the equity of the CONTRACTOR, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and

valuing more than five percent (5%) of the CONTRACTOR, and, in the case of a CONTRACTOR organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

4.17.5.1.2 Any entity in which a person described above in 4.17.5.1.1:

4.17.5.1.2.1 Is an officer or director;

4.17.5.1.2.2 Is a partner (if such entity is organized as a partnership);

4.17.5.1.2.3 Has directly or indirectly a beneficial interest of more than five percent (5%) of the equity of the CONTRACTOR; or

4.17.5.1.2.4 Has a mortgage, deed of trust, note, or other interest valuing more than five percent (5%) of the assets of the CONTRACTOR.

4.17.5.1.3 Any person directly or indirectly controlling, controlled by, or under common control with the CONTRACTOR; and

4.17.5.1.4 Any spouse, child, or parent of an individual described above in Sections 4.17.5.1.1 – 4.17.5.1.3.

4.17.5.2 Each CONTRACTOR, must report to HSD and, upon request, to the Secretary of the Department of Health & Human Services (DHHS), the Inspector General of the DHHS, the Comptroller General, and to its Members, upon reasonable request, a description of transactions between the CONTRACTOR and a party, the following transactions:

4.17.5.2.1 Any sale or exchange, or leasing of any property between the CONTRACTOR and such a party;

4.17.5.2.2 Any furnishing for consideration of goods, services (including management services), or facilities between the CONTRACTOR and such a party, but not including salaries paid to employees for services provided in the normal course of their employment; or

4.17.5.2.3 Any lending of money or other extension of credit between the CONTRACTOR and such a party.

4.17.5.3 The CONTRACTOR shall disclose transactions subject to this Section 4.17.5 annually and such disclosures shall provide the following information:

4.17.5.3.1 The name of the party for each transaction;

4.17.5.3.2 A description of each transaction and the quantity or units involved;

4.17.5.3.3 The accrued dollar value of each transaction; and

4.17.5.3.4 A justification of the reasonableness of each transaction.

This LOD will sunset upon inclusion in the Medicaid Managed Care Services Agreement and the Managed Care Policy Manual.