DATE: May 10, 2017

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: REQUIREMENT TO PARTICIPATE IN THE MEDI-CAL DRUG UTILIZATION REVIEW PROGRAM

PURPOSE:
The purpose of this All Plan Letter (APL) is to clarify Medi-Cal managed care health plan (MCP) contractual requirements related to Medi-Cal drug utilization review (DUR) program requirements pursuant to Title 42, Code of Federal Regulations (CFR), Section 438.3(s).

BACKGROUND:
On May 6, 2016, the Centers for Medicare and Medicaid Services (CMS) released final rulemaking CMS-2390-F, which requires the MCPs to operate a DUR program that complies with the requirements of Section 1927(g) of the Social Security Act (SSA) and Title 42, CFR part 456, subpart K.\(^1\)

The DUR program educates physicians and pharmacists to better identify patterns, and reduce the frequency of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care, both among physicians, pharmacists, and patients, and fraud or abuse associated with specific drugs or groups of drugs.

POLICY:
Pursuant to Title 42 CFR Section 438.3(s)(4), CMS requires MCPs to include the following in their Medi-Cal DUR program:

- A prospective DUR process.
- A retrospective DUR process.
- Establishment of a DUR Board, either directly, or through a contract with a private organization, that meets the requirements of Section 1927(g) of the SSA.
- Education programs and resources designed to improve the ability of physicians and pharmacists to identify patterns, and reduce the frequency of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.
- A requirement to provide a detailed description of all of the MCP’s DUR program activities to Department of Health Care Services (DHCS) on an annual basis, allowing DHCS to compile and submit a single, annual Medi-Cal DUR report in

\(^1\) Title 42, CFR, Section 438.3(s)(4)
compliance with the Newly Revised Medicaid Drug Utilization Review Annual Report Survey.

CMS requires DHCS to monitor and provide approval of the MCPs’ Medi-Cal DUR program activities, and ensure that MCPs are compliant with Section 1927(g) of the SSA. Accordingly, DHCS maintains that the complexities of the federal DUR requirements necessitate that MCPs utilize the established Medi-Cal State DUR Board (DUR Board) and educational components of the Medi-Cal DUR program. However, MCPs will maintain their current proprietary claims processing procedures and protocols and MCPs will individually administer the systematic components related to the prospective and retrospective DUR processes. As is the case with the Fee-For-Service (FFS) program, MCPs are not required to implement all DUR Board recommended actions, nor are they required to mirror the Medi-Cal DUR activities.

Effective July 1, 2017, in collaboration with DHCS’ FFS Program for covered outpatient drugs, MCPs shall participate in a global Medi-Cal DUR program. The global Medi-Cal DUR program will assess data on drug use against predetermined standards, consistent with the following:

- Compendia, which shall consist of the following:
  - American Hospital Formulary Service Drug Information;
  - United States Pharmacopeia-Drug Information (or its successor publications);
  - The DRUGDEX Information System; and
- Peer-reviewed medical literature.

As part of the global Medi-Cal DUR program, each MCP will individually develop and implement a Prospective and Retrospective DUR, as defined in Section 1927(g)(2)(A) and (B) of the SSA, as follows:

- **Prospective Drug Review:** Each MCP will implement a systemic mechanism for drug therapy review before each prescription is filled or delivered to a beneficiary, typically at the point-of-sale or point of distribution. The drug therapy review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each MCP shall use the compendia and peer-reviewed medical literature referred to above as its source of standards for such review.
• **Retrospective Drug Use Review:** Each MCP shall continue, through its mechanized drug claims processing and information retrieval systems, the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, both among physicians, pharmacists and individuals receiving pharmacy benefits, and fraud and abuse associated with specific drugs or groups of drugs.

In addition to individually implemented prospective and retrospective DUR processes, each MCP will participate in the following:

• **Educational Program:** The global Medi-Cal DUR program will provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. MCPs must conduct these educational efforts in collaboration with its DUR Board, either directly or through contracts with accredited health care educational institutions, state medical societies or state pharmacists associations/societies or other organizations, as specified by DHCS, and use data on common drug therapy problems. A Medi-Cal DUR team will be created as a subgroup to the DUR Board. The Medi-Cal DUR team (comprised of, but not limited to, DHCS staff, DHCS' fiscal intermediary, and subcontracted academia institutions), in collaboration with the DUR Board, will identify issues of interest and develop provider education programs and materials designed to improve the ability of physicians and pharmacists to identify patterns, and reduce the frequency, of fraud, abuse, misuse, and clinically inappropriate or medically unnecessary care. The Medi-Cal DUR team’s specific member composition will be determined in a separate workgroup comprised of both DHCS and MCP representatives and will meet every other week. The developed educational program materials will be reviewed by DHCS and disseminated to MCPs that will then distribute them to their providers via MCP established mechanisms. MCPs may also distribute additional educational materials or articles based on the demographics and trends specific to their beneficiaries and providers.

• **State DUR Board:** The membership of the DUR Board must be made up of at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 licensed and actively practicing pharmacists. The activities of the DUR Board include but are not limited to the following:
  
  o Retrospective DUR.
o Application of current clinical standards.
o Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews.
o Review and discussion of potential issues based on the analysis of aggregate claims data from the MCPs.

The membership of the DUR Board includes health care professionals who have recognized knowledge and expertise in one or more of the following:

o Prescribing clinically appropriate covered outpatient drugs.
o Dispensing and monitoring clinically appropriate covered outpatient drugs.
o Drug use review, evaluation, and intervention.
o Medical quality assurance.

MCPs must actively participate, either individually, or by means of an entity selected to represent multiple MCPs (e.g. California Association of Health Plans, Local Health Plans of California), in activities involved with the DUR Board. Participation may include select MCP representatives volunteering to serve as DUR Board members. DHCS will convene a stakeholder process with the MCPs and applicable representatives to determine the most effective and equitable manner in which to proceed. Although MCPs are expected to participate directly and indirectly in DUR Board activities, the recommendations and advisory positions offered by the DUR Board will not result in a mandate that MCPs adopt or implement such recommendations or advisory positions. MCPs will retain the ability to decide what recommendations, if any, the MCP will adopt. If the MCP chooses not to adopt the DUR Board recommendations, the rationale for not adopting the recommendation must be included as part of the annual reporting process mentioned below. The rationale will be used solely for informational purposes only and not as part of the assessment of the MCP’s efficiency or compliance. Please note that all representatives chosen to attend DUR Board meetings must do so in-person.

• **Annual Report**: Each MCP is required to prepare an MCP-specific annual report describing the MCP’s DUR activities (as noted above) and submit it to DHCS on an annual basis by April 1. The report will be used to identify MCP DUR activities that occur outside of the global DUR. The report will include information related to the methodology by which MCPs meet the requirements for the Prospective and Retrospective DUR. Additional information may be required to inform the State regarding educational DUR activities performed by the MCP that are
outside of the global educational activities, the rationale for not implementing DUR Board recommended actions, and any other DUR related activities performed outside of the global DUR activities. DHCS will submit a combined report, reflecting the information submitted by each MCP, to the Secretary of Health and Human Services on an annual basis. A template for the MCP-specific annual reports, including information required by CMS in the global annual report submitted by the State, will be developed in a separate workgroup comprised of both DHCS and MCP representatives.

MCPs must submit their Medi-Cal DUR program policies and procedures to DHCS for review and approval. The Medi-Cal DUR program policies and procedures must demonstrate how the MCP will fulfill the requirements of this APL.

If you have any questions regarding this APL, please contact your Managed Care Operations Division contract manager.

Sincerely,

Original Signed by Nathan Nau

Nathan Nau, Chief
Managed Care Quality and Monitoring Division