DUR POLICIES AND PROCEDURES OF THE IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

The Omnibus Budget Reconciliation Act (OBRA) of 1990 requires that each State establish a Medicaid Drug Utilization Review (DUR) Program that consists of Prospective Drug Review (proDUR), Retrospective Drug Review (retroDUR), Application of Standards and an Educational Program. The program should ensure that prescriptions issued to Medicaid members are medically appropriate, necessary, and not likely to result in adverse events. To accomplish these goals, the DUR program uses criteria to screen for therapeutic problems, attempts to change prescribing practices through provider intervention, and then assess the impact of these activities. In addition, States are required to establish a DUR Board. In the state of Iowa, the DUR Board is referred to as the Iowa Medicaid DUR Commission (from this point on referred to simply as "Commission"). The state of Iowa established the Commission in 1984 prior to the enactment of OBRA '90. Complete OBRA '90 language regarding DUR programs is found in the section labeled OBRA '90 DUR Language.

Overview of OBRA '90 Language

OBRA '90 language requires each state to have an operational DUR program consisting of prospective DUR (proDUR), retrospective DUR (retroDUR), and an educational program. The goal of the DUR program is to ensure appropriate medication therapy, while permitting appropriate professional judgment to individualize medication therapy.

Commission Composition

The Commission is composed of four Iowa licensed physicians, four Iowa licensed pharmacists, the HHS Medicaid pharmacy director, and one MCO pharmacy director. The HHS and MCO pharmacists are non-voting members. Other participants in the Commission meetings may include HHS contractors and subcontractors and MCO pharmacy directors.

The Commission elects a Chairperson and Vice Chairperson annually from the Commission membership. The Chairperson and Vice Chairperson will be elected by a simple majority and serve for a period of one year. The Chairperson will facilitate the meeting and discussion of agenda items. In the event the Chairperson is unable to attend a meeting the Vice Chairperson will facilitate the meeting. The Project Coordinator and Iowa Medicaid staff will provide administrative support to the Commission. The annual election will occur in August of each year.

Commission Office and Staff

The office of the Commission is located at the Lucas State Office Building, Iowa Medicaid, 321 East 12th Street in Des Moines. Staff includes at least one Iowa licensed pharmacist who is available to the HHS during regular business hours. The staff shall also provide support for inquiries from Medicaid providers regarding the DUR program.

Commission Meetings

The Commission meets on the first Wednesday of four months of the year: August, November, February, and May. Meetings follow either a virtual or hybrid format. A virtual meeting involves real-time interaction using integrated audio, video, and other digital tools, where participants do not share a physical location. A hybrid meeting includes both remote participation and in-person attendance by Commission members. The DUR Commission uses Microsoft Teams or Zoom as platforms for these meetings. For hybrid meetings, in-person participants will convene in Des Moines, though the location may vary depending on availability. Changes in the meeting date, time, or location will be announced at least one month prior to the scheduled meeting. A simple majority of the voting members of the Commission is required to conduct business. No business can be transacted without a simple majority, except to adjourn the meeting; if no question is raised, debate is allowed but no vote can be taken.

Commission members will receive meeting packets containing pertinent information relating to the activities of DUR meetings in advance of each meeting. These packets may include select member profiles for review, if needed. Meeting materials will be distributed via email three weeks prior to each scheduled meeting. If additional information becomes available after the initial distribution but before the DUR meeting, these materials will be provided to Commission members in advance of the meeting. If a member would like a printed packet if attending in person, it will be provided the day of the meeting and staff must be notified at least a week in advance of the meeting to allow time for printing. Meeting packets without confidential information will also be made available on the DUR website (www.iadur.org) for any interested parties to view.

All meetings of the Commission are conducted in accordance with Chapter 21 of the Code of Iowa. Therefore, any person may attend the open sessions of the Commission meetings. Public notice of the meetings will be physically posted on the bulletin board in the lobby of the Iowa Medicaid building, if available, or on the bulletin board on the first floor of the Hoover State Office Building where other HHS meeting notices are posted in addition to being posted on the Commission website at www.iadur.org. Upon request, meeting notice shall be emailed to organizations with an interest in DUR activities.

Individuals attending in person or virtual meetings of the Commission shall have an opportunity to address the Commission. This opportunity will be granted once during the open portion of the meeting. In order to accommodate all interested parties, all speakers are requested to limit their comments to 5 minutes or less. If the speaker represents a drug manufacturer as an employee, as a contractor, as a member of the manufacturer's Speaker Bureau, or by any other means, it is the expectation that the speaker will cover the individual product or entire product line in that five-minute time frame. Speakers who represent multiple manufacturers will share their 5 minutes with the other manufacturer representative(s) whose product they are speaking on. Individuals unable to attend Commission meetings can provide written public comment, to be shared with the Commission as a part of the meeting materials. Any individual speaking or providing written comment must register and complete a conflict-of-interest disclosure form. Registration and completed forms must be submitted to DUR staff at least one week prior to the scheduled meeting. Anyone wishing to provide public comment, either in person or written, should reference the Commission website (www.iadur.org) for the public comment policy and the process to sign up for in person comment or provide written comment.

Closed session will occur to discuss confidential information, if needed, as allowed by the Iowa Code. See the section labeled Iowa Code Chapter 21 for complete information.

Drugs for Rare Diseases

House File 653 established a requirement for the Pharmaceutical and Therapeutics (P&T) Committee and the Drug Utilization Review (DUR) Commission to request and consider information from individuals who possess scientific or medical training with respect to drugs and biological products for rare diseases and drugs and biological products that are genetically targeted when making recommendations or determinations regarding beneficiary access.

Information will be requested by Iowa Medicaid for drugs and biological products identified as meeting the above criteria which may be reviewed at upcoming P&T and/or DUR meetings. The information request will be in the form of a Public Notification: Request for Comment, posted on the Preferred Drug List (PDL) website under the Drugs for Rare Diseases link. Comment should be submitted to the contact indicated by the required response date, including a conflict-of-interest disclosure form.

Commission Term Limits

In accordance with HF 760 passed in the 1999 Legislative Session, the HHS shall ensure that the Commission incorporates term limits for physician and pharmacist members in its membership policy. Each voting member of the Commission will serve one four-year term. Terms will begin on July 1, of each year. Each year, the term of one physician member and one pharmacist member will expire on June 30. Commission members may apply to be considered for reappointment for up to two additional four-year terms for a lifetime limit of three terms of four years each. These terms may be served consecutively or separately. The pharmacist representing the HHS is not subject to term limits. The non-voting MCO pharmacy director representative is subject to a two-year term and will rotate between the MCO plans every two years, with no term limits.

New voting members for the Commission are recruited by announcing the upcoming vacancy during a Commission meeting and posted on the Commission website. Additionally, health care organizations and systems with an interest in the Commission may be contacted regarding vacancies, for dissemination to their groups for interested individuals to apply.

All interested individuals may submit a letter of application to the DUR Project Coordinator, along with documentation of qualifications. Applicants should have expertise in at least one of the practice areas described in the Centers for Medicare and Medicaid Services (CMS) language and serve Medicaid members in his or her practice.

The DUR Project Coordinator will review the applications received and select a slate of potential members based on the applicants' qualifications. As the Commission must maintain a diverse membership, other factors will also be considered to ensure an appropriate mix of members. These factors shall include, but are not limited to, practice specialty, professional designations, practice setting, and geographic location. Commission members are not appointed to serve a professional association, so membership in a particular association is not required. The DUR Project Coordinator will select qualified applicants who are most likely to complement the current mix of

Commission members and recommend these individuals to the HHS for their approval. If the HHS concurs with the recommendation, the recommendation is approved.

Confidential Information

In the course of service on the Commission, Commission members and staff may review information that is considered confidential. This information may include, but is not limited to, oral, written, or recorded information that indicates the identity of a provider's professional practice patterns or the eligibility status of a member. Confidential information shall be utilized only as necessary to conduct utilization review or quality control review, or as otherwise authorized by law. All persons viewing confidential information shall sign documents acknowledging this responsibility. Commission members will complete a confidentiality form for each term served. When it is necessary to discuss confidential information, the Commission will hold a closed session meeting.

The Confidentiality form, in the format of a Memorandum of Understanding and Business Associate Agreement, is located within this manual under the section labeled Forms.

Conflict of Interest Policy

Any conflict of interest will be considered when appointing members to the Commission. All Commission members will sign the Conflict of Interest form on an annual and as needed basis, if a change arises between annual completion of the form. The Commission member is responsible for keeping the disclosure form up to date. Any conflict of interest on the part of the Commission member, their practice setting, or immediate family member will be disclosed and be made a matter of public record. The Commission member will not participate in any vote or take affirmative action to influence any vote on any matter before the Commission where there is a conflict of interest.

Persons providing written comment, speaking or presenting to the Commission are asked to disclose any financial or other affiliation with organizations that may have a direct or indirect interest in the business in front of the Commission. All participants providing comment, whether written or verbal, at a DUR meeting will disclose this information by signing the Conflict of Interest disclosure form.

Meeting Attendance

Meeting attendance by Commission members is critical to the success of the DUR program. Members are expected to attend all regular meetings of the Commission. If a Commission member is unable to attend regular meetings at the expected level, that member may be replaced for the remainder of his or her term. Please notify the Project Coordinator if you are unable to attend a meeting as soon as known.

Members are expected to be fully prepared to discuss agenda items. Members are also to return all profiles to the DUR Project Coordinator with comments regarding potential therapeutic or cost-saving interventions, should profiles be provided as part of the meeting materials. During the closed session, each member will present several patient profiles to the Commission for discussion.

Members must arrive or join in a timely fashion, attend through the completion of the meeting, and avoid meeting disruptions from cell phones and other electronic devices.

Those attending remotely are expected to remain engaged for the entire duration and keep their cameras on to facilitate effective communication and participation.

Communication

The DUR contractor shall coordinate all activities related to the Commission. The DUR contractor shall appoint a pharmacist as the DUR Project Coordinator to serve as the primary communication link between the HHS and the Commission. Any Commission member experiencing problems or difficulties concerning their service on the Commission shall discuss these issues with the DUR Project Coordinator. If resolution is not found, the Commission member shall consult the HHS pharmacist on the Commission.

Commission members shall not represent the HHS in any capacity unless specifically requested to do so by the HHS. Commission members shall not represent themselves as possessing any authority to affect Medicaid policy, as the Commission only serves in an advisory capacity for the HHS.

Commission members are under no obligation to meet with manufacturer representatives at their place of business, and this may create a conflict of interest. Public comment sessions are held at all Commission meetings so any person may provide comments to all Commission members at the same time.

Activities of the Iowa Medicaid DUR Commission

Established in 1984, the Commission is charged with promoting the appropriate and cost-effective use of medications within the Iowa Medicaid member population. Acting as a professional advisory group, the Commission analyzes medication utilization by the members of Iowa Medicaid and performs educational initiatives to optimize member outcomes. The Commission performs retroDUR and educational outreach through patient-focused reviews and problem-focused reviews. The Commission supports the proDUR program through criteria review and acts as a resource to the HHS on other issues concerning appropriate medication use.

Patient-Focused Reviews

Patient-focused reviews are completed with the review of select Fee-for-Service (FFS) member profiles coinciding with each meeting (four times annually). The DUR contractor generates these profiles through a complex screening process. The first step of the screening process subjects member profiles to a therapeutic criteria screen. If a profile is found to have failed one or more therapeutic criteria, the member profiles are then assigned a level of risk based on their medication history and potential for adverse events regarding medication. The profiles with the highest level of risk are then selected for review. Six months of prescription claims data and medical claims data, if available, are assessed to determine this risk factor.

The member profiles selected from this process are manually reviewed by the voting members of the Commission or the DUR Project Coordinator to minimize false positives generated by the computer selection process. Situations where educational intervention might be appropriate are identified. Through these interventions, suggestions regarding medication therapy are communicated to the care providers. Templates are developed for

suggestions that are frequently communicated to providers. The reviewer may also author an individualized suggestion if a template suggestion is not applicable.

Educational interventions are generally done by letters to prescribers and pharmacists but may also be done by telephone or in person. The suggestions made by the Commission are educational and informative in nature. Suggestions may be classified as either therapeutic or cost saving in nature. In addition, these suggestions are classified by problem identified for reporting purposes. The classifications are as follows:

- Not Optimal Drug
- Not Optimal Dose
- Not Optimal Duration
- Unnecessary Drug Use
- Therapeutic Duplication
- High-Cost Drug
- Drug-Drug Interaction
- Drug-Disease Interaction
- Adverse Drug Reaction
- Patient Overuse
- Patient Underuse
- Therapeutic Alternative
- Missing Drug Therapy
- Not Optimal Dosage Form
- Potential Generic Use
- Inappropriate Billing

Suggestions are intended to promote appropriate and cost-effective use of medications. When suggestions result in cost savings, these savings are calculated based on decreased cost of medications. However, several of these classes of interventions are intended to increase the use of medications. Examples are member underuse and missing drug therapy. In these cases, the addition of medication therapy will increase medication expenditures, but will be beneficial to the member and should result in cost savings in medical services or improved quality of life. Cost savings in these situations cannot be calculated due to data limitations. Therefore, these suggestions are considered to have a positive impact on the program with no medication cost savings. Cost savings on medical services are assumed, not calculated.

Providers are invited to respond to the Commission’s suggestions and to request additional information from the Commission. Reponses are voluntary and response rates are calculated for prescribers and pharmacists.

Once a member's profile is reviewed, it is excluded from the selection process for nine months to eliminate repeat selections. After this waiting period, the current profile for each member is generated and reviewed to determine if the Commission's suggestion was implemented. If so, fiscal considerations resulting from that change are also calculated.

Problem-Focused Reviews

Problem-focused reviews narrow the emphasis of review to a specific issue that has been determined to be an area where a targeted educational effort to providers may be valuable. Topics for review are selected from findings of patient-focused reviews or from reviews of medical literature. Criteria are developed to identify the members who may

benefit from intervention and educational materials are disseminated to their providers. Providers are encouraged to voluntarily respond. The member profile is generated again in an appropriate amount of time (typically 6 to 9 months) to determine the impact rate of the intervention, along with any fiscal considerations.

Advisory Role for HHS

The Commission will review utilization data and medical literature to make recommendations to the HHS regarding policy issues. These recommendations are made to promote the appropriate use of medications and positive member outcomes. Recommendations are made at the request of the HHS or at the Commission's discretion. Primary areas for recommendations include proDUR, drug prior authorization (PA), coverage of medications, and administrative and billing procedures. The Commission has the authority to modify a recommendation, request more information prior to making a recommendation, or determine no recommendation is necessary. The Commission may make recommendations to the HHS but does not make policy. All authority to accept or reject Commission recommendations lies with the HHS. The HHS takes many items into account when determining to accept or reject a recommendation, such as timeline for implementation and budgetary impact.

The Commission reviews the proDUR criteria utilized by the POS contractor and provides input regarding its therapeutic validity for the proDUR program. Special attention is given to eliminating false positive messaging and easing administrative burdens. When available, reports regarding the impact of the proDUR program are reviewed by the Commission. If warranted, suggestions to improve the system are relayed to the HHS.

Upon the request of the HHS, the Commission will recommend medications where the use of prior authorization may decrease inappropriate use and/or result in cost savings to the Medicaid program. Medications appropriate for prior authorization are identified through the Commission's review process. On at least an annual basis, the Commission reviews the current categories of medication requiring prior authorization and renders an opinion if each category should remain on the prior authorization program.

New and revised prior authorization guidelines are based on reviews of medical literature in addition to comparisons with other public and private sector programs. Input from providers outside the Commission, particularly specialists, may be sought when developing these guidelines. A meeting notice shall be disseminated via the pharmacy listserv, which includes health care organizations and systems with an interest in the Commission. This notice serves to inform recipients of the upcoming meeting agenda and to solicit comments on agenda topics. Input will be considered by the Commission prior to the final recommendation going to the HHS. The HHS may or may not accept the recommendation, may alter the recommendation, and/or hold the recommendation until a later time. When a recommendation is accepted by the HHS, the timeline to implementation is at the discretion of the HHS.

The Commission makes recommendations to the Iowa Medicaid Pharmacy and Therapeutics (P&T) Committee. In certain instances, the Commission may request that the P&T review the status of a particular drug on the Preferred Drug List (PDL) if inappropriate utilization is determined by the DUR. In addition, the Commission receives referrals to review from the P&T Committee.

The Commission also makes recommendations regarding coverage of medication. As most coverage requirements are defined by CMS, these recommendations generally encourage coverage of optional services. An example would be the coverage of select over-the-counter medications. If the HHS accepts the Commission's recommendation, the proposed coverage change could also be subject to the Administrative Rules process and possibly the State Plan Amendment process prior to implementation.

Communication and Education

As an educational initiative, the Commission generates a newsletter called the *DUR Digest* twice per year. The *DUR Digest* newsletter is posted on the website for all Iowa Medicaid prescribers and pharmacies. This newsletter may include updates on therapeutic alternatives and guidelines, Medicaid policy, and Commission activities. The Commission maintains the website to improve communication and education regarding activities of the Commission. The website includes timely information regarding meeting schedules, location, and agendas. Minutes are posted on the website following approval by the Commission. Other pertinent information that is periodically reviewed and updated includes the *DUR Digest* newsletter, Commission members, meeting attendance and Commission activities.

Evaluations and Reporting

The Commission provides the HHS with information regarding the Commission's activities as necessary to complete the annual CMS report as required for the federal fiscal year, for fee-for-service and managed care.