Maryland
DEPARTMENT OF HEALTH

Office of Pharmacy Services
Drug Use Review (DUR) Board

Pharmaceutical Industry Code of Conduct

Introduction

The DUR Board is responsible for advising the Office of Pharmacy Services (OPS) on point of service prospective DUR criteria alerts, retrospective educational letters to providers, other educational programs and recommending clinical prior authorization criteria and quantity and dosage form limitations on specific drugs. Because of its responsibilities and the impact on drugs dispensed in the State as a result of its recommendations, the pharmaceutical industry is interested in discussions and conduct of the DUR Board meetings.

This document establishes a protocol for interactions between the pharmaceutical industry and DUR Board members and interactions between the pharmaceutical industry, OPS and the DUR contractor. This Code's intent is to streamline the communication process between all interested parties, facilitate the flow of information from the OPS and on to the DUR Board members, if appropriate, and establish reasonable and respectable boundaries for how and when all interested parties may interact.

This Code of Conduct does not address procedures for conducting DUR Board meetings; rather it identifies key interaction opportunities prior to DUR Board meetings. The DUR Board members must recognize that industry representatives have objectives to meet. At the same time, industry representatives must realize that the DUR Board members are volunteers, performing a public service and have their regular day-to-day responsibilities besides the DUR Board. Both must respect the time of each other. The issue becomes particularly acute when the DUR Board members are trying to interact with their patients, as patient/physician or patient/pharmacist interaction should proceed as scheduled and uninterrupted.

Meetings between Pharmaceutical Industry Sales Representatives and DUR Board Members

One-on-one Meetings with DUR Board members – Pharmaceutical industry sales representatives may, in their normal conduct of business, contact providers, i.e. doctors and pharmacists, even though such providers may be DUR Board members. Pharmaceutical industry sales representatives should always make an appointment before visiting with any DUR Board member if the discussion is related to a DUR Board meeting agenda item. A pharmaceutical industry representative is not required to make a formal appointment if their visit in unrelated to a specific agenda item and is part of their normal course of business with the DUR Member. No DUR Board member has to meet with pharmaceutical industry sales representatives or account executives. The State will not intervene on a pharmaceutical industry sales representative's behalf to arrange, facilitate or moderate a meeting with any DUR Board member. DUR

Board members are not expected to or encouraged to discuss any upcoming DUR Board meeting agenda items with industry representatives and industry representatives will abide by a DUR member's decision. Industry representatives will refrain from practices that attempt to exert undue pressure or distort facts.

Materials for DUR Board members related to DUR Meeting Agenda Items – When a pharmaceutical industry sales representative provides materials for a DUR Board Member in response to a DUR Board Meeting Agenda item, the representatives are encouraged to provide the most condensed and minimal amount of material to DUR Board members, if they elect to provide any at all. If a pharmaceutical manufacturer believes that the DUR Board must consider certain information as part of its decision making, the company should give that detailed information to the appropriate individual at the OPS or the DUR contractor. Written materials related to DUR Board Meeting agenda items should be provided as follows:

- **Written material** - If account executives have printed material they wish to send to the DUR Board members, they may send it to the Clinical Pharmacy Services Division or the DUR Contractor at the MDH headquarters and it may be forwarded to the DUR Board. Please enclose at least 15 copies packaged in individual envelopes with sufficient postage attached. Mail or deliver your material to the Maryland Medicaid DUR Board, Maryland Department of Health, Room 410, 300 W. Preston Street, Baltimore, Maryland 21201. The OPS will place labels on your packages and forward them to the DUR Board members. Materials received with insufficient postage will not be forwarded. Binders and heavy material must be placed in individual padded envelopes. To ensure sufficient time for review, the material must be received at MDH at least ten days prior to the relevant meeting. This material may be submitted via U.S. Postal Service or commercial delivery service.

- **E-mailed material -** E-mail communication is preferred; however, it must be compatible with the latest version of MS-Word or Adobe® Acrobat® format. The Pharmacy Program may forward your e-mails as deemed appropriate. Charts and graphs may be submitted in MS-Excel® or Adobe® Acrobat®. You may E-mail material for the DUR Board by attaching them to a message to: Shawn Singh: shawn.singh@maryland.gov. Please do not expect a response other than an acknowledgment that your material was received.

Meetings with People in Organizations Involved with the DUR Board

Meetings with the OPS - The OPS has a long-standing policy not to meet with pharmaceutical industry representatives to avoid the appearance of any improper influence on OPS decision. In rare instances, the OPS will make exceptions to this policy if the OPS identifies issues that need specific clarification, explanation or demonstration from a drug manufacturer. Pharmaceutical industry representatives are therefore highly discouraged from requesting a meeting with the OPS to introduce a new product or to elaborate on an existing product. Submission of printed material is welcome.

Meetings with the DUR Contractor - If a pharmaceutical manufacturer thinks it is necessary to meet with persons involved with DUR Board, the DUR contractor would be the appropriate point of contact. At the DUR contractor's discretion, relevant substantiated information will be given to the OPS and DUR Board members in their packets prior to the DUR Board meeting.

Communications - Inquiries to the State will be responded in a like manner or as deemed appropriate by MDH, OPS or unless otherwise requested. Thus, if an inquiry is via e-mail, the response will be via e-mail. If an inquiry is by phone, the response will be by phone, and so on for letters and faxes.

Investigation of Denied Claims - From time to time, pharmaceutical industry representative wants to know why claims for their products do not adjudicate according to their expectations. There are multiple reasons why claims will deny. The Clinical Pharmacy Services Division is available to research any problems, but its investigations are predicated on having sufficient information. Each denial is accompanied by a text message to the pharmacist as to the nature of the denial, such as "Refill too soon", "Exceeds quantity limits", "Exceeds dollar limit", or "Invalid NDC number". To perform the research, the OPS needs more than just the name of the drug and the prescriber's name. The exact text of the denial message that the pharmacy receives would be extremely helpful. The claims processor assigns a number to each online transaction. Try to find out the denied claim transaction number, the NDC number, the number that the pharmacy assigns to the "script," the participant number, the date of the denial, etc. Pharmaceutical industry representatives can give pharmacies the phone number for the OPS (410-767-1455) and have them call the Department directly.

Submitting Allegations of Impropriety - From time to time, pharmaceutical industry representatives, DUR Board members, and the DUR contractor experience what they may perceive as questionable practices. In such instances, the concerned individual or company should report the situation by phone to the OPS' Clinical Services Division at 410-767-1455, by fax to 410-333-5398, or by e-mail to *Shawn Singh, shawn.singh@maryland.gov*. The concerned individual or company should include as much information as possible, such as examples of marketing material, the name of the offending company, the name(s) of the individual(s) implicated and the name(s) of any witness(es). When deemed appropriate, the OPS will initiate an official inquiry.