**Idaho State Board of Pharmacy**
1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 http://bop.idaho.gov
P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

**December 12, 2018**
**To: Licensees of the Idaho State Board of Pharmacy**
**From: Nicole Chopski, PharmD**
**Re: Patient Assessment Protocols**

The Idaho State Board of Pharmacy recently promulgated Rule Docket 27-0104-1701, Rules Governing Pharmacist Prescriptive Authority. This rule docket was unanimously approved by the germane legislative committees and takes effect on July 1, 2018.

In furtherance of the prescribing authority set forth in Idaho Code Section 54-1704(5)(e),the rules specifically authorize certain drugs, drug categories, and devices that may be prescribed by an Idaho pharmacist subject to certain requirements.

One specific requirement in Rule 020.03 is that for each drug or drug category the pharmacist intends to prescribe:

> "…the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following:
>
> i. Patient inclusion and exclusion criteria; and
>
> ii. Explicit medical referral criteria."

While the term "protocol" may have different meanings in different settings, the Idaho rules indicate that the patient assessment protocol is to be used to identify patients who may not be appropriate candidates for treatment by the pharmacist and who may need referral to a more appropriate venue for care. Moreover, the rule notes that the pharmacist "must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings."

Enclosed in this packet are several *template* protocols that may serve as a useful starting point for pharmacists in fulfilling their obligations under the general requirements. Use of these template protocols is subject to the Pharmacist Prescriptive Authority Protocol Terms of Use (available here). These template protocols were developed collaboratively by physicians and pharmacists at various Protocol Workshops held between November 2017 and March 2018. We are grateful for the efforts of the many participants who contributed constructively to their development!

We hope you find these template protocols useful as you implement Rule Docket 27-0104-1701.

# IDAHO STATE BOARD OF PHARMACY
## Pharmacist Prescriptive Authority Protocol Terms of Use

1. Any pharmacist prescriptive authority protocol ("protocol") made available by the Idaho State Board of Pharmacy ("Board") represents the certain prescribing standards and considerations pertaining the drugs, drug categories, or devices addressed therein. All Board protocols are intended to serve as a reference for pharmacists licensed by the Board ("pharmacists"). All Board protocols are for informational purposes only and should not be construed as any form of medical advice related to any specific facts or circumstances.

2. Board protocols shall not be used as a substitute for professional judgment. When making prescribing decisions, pharmacists must exercise their own professional judgment based on their education and experience, and, if necessary, consult with other prescribers or health care authorities. Further, Board protocols are not intended to guard against all potential negative outcomes based on patient specific facts and circumstances. Any reliance by a pharmacist on the information contained within a Board protocol is solely at the risk of the pharmacist.

3. Before relying on a Board protocol, pharmacists are encouraged to carefully evaluate the relevance and application of the protocol in the context of the facts and circumstances of their particular situation. Pharmacists are also encouraged to consult with other licensed prescribers and health care authorities on an as needed basis at the discretion of the pharmacist.

4. All Board protocols were developed by the Board, through its staff, in good faith, based upon then current clinical guidelines and evidence based research and in collaboration with Idaho licensed pharmacists, physicians, and other prescribers. Changes in circumstances after a protocol is made available by the Board may impact the use and application of the protocol and the Board offers no assurances as to the accuracy or applicability of any protocol after it is made available.

5. Board protocols shall satisfy Board Rules 27.01.04.020.03.a. through c. However, Board rules require that "a pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings." See IDAPA 27.01.04.020.03.d. The Board has no obligation to, and makes no assurances that it will, revise any Board protocols once made available.

6. The State of Idaho, the Board, its officers, agents, and employees shall not be responsible or liable for any loss, damage, personal injury or death caused by or arising from a pharmacist's use of, or reliance upon, any Board protocol. Any pharmacist, or other person, relying upon or making any use of a Board protocol expressly agrees to defend, indemnify, and save harmless the State of Idaho, the Board, and its officers, agents, and employees from and against any and all liability, claims, damages, losses, expenses, actions, settlements, attorneys' fees, and suits whatsoever caused by, arising out of, or in connection with, any such pharmacist's, or other person's, reliance or use of a Board protocol.

7. These Terms of Use shall be governed by and construed under the laws of the State of Idaho. If any part of these Terms of Use is declared invalid or becomes inoperative for any reason, the remaining provisions shall continue in full force and effect.

**Pharmacist Prescriptive Authority Protocol for**
**Cold Sores (Herpes Labialis)**

**Purpose:**
To provide timely and accessible treatment for low-risk patients with recurrent herpes labialis, including episodic treatment **and** short-term prevention.

**Patients Eligible for Treatment Under This Protocol (Inclusion Criteria):**

- Patients 6 years of age or older who report a previous history of cold sores and who present with:
    - Prodromal symptoms that are typical of a cold sore; or
    - A lesion that is typical of a cold sore that has lasted <48 hours.

**Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria):**

- Patients under the age of 6 years
- Patients who report no prior history of having a cold sore
- Patients who have one or more of the following:
    - Lesion appears excessively red, swollen, or contains pus
    - Lesion appears on area other than around the mouth and lips
    - Lesions have not healed from a prior episode
    - Reports symptoms of systemic illness are present (fever, swollen glands, malaise)
    - Reports being immunocompromised by medication or condition
    - Reports that lesions have occurred more than 6 times in the past 12 months

**Follow-Up to Assess Need for Referral**

- Follow-up in 7 days. Referral needed if lesions spread or persist without improvement despite treatment.

**Pharmacist Prescriptive Authority Protocol for**
**Seasonal Influenza Treatment with Neuraminidase Inhibitors**

**Purpose:**
To provide accessible and timely treatment of influenza for low-risk patients in consideration of the clinical guidelines of the Infectious Diseases Society of America (IDSA).

**Patients Eligible for Neuraminidase Treatment Under this Protocol (Inclusion Criteria):**

- Patients 6 years of age or older exhibiting signs of influenza-like illness (e.g., fever, cough, sore throat, nasal congestion, muscle/body aches, etc.) for 48 hours or less who test positive to a CLIA-waived test indicated for influenza.

**Patients Ineligible for Neuraminidase Treatment Under this Protocol (Exclusion and Referral Criteria):**

- Patients exhibiting signs of influenza-like illness (ILI) for greater than 48 hours
- Patients who report they are pregnant or breastfeeding
- Patients who report they are immunocompromised by medication or condition
- Patients who have one or more of the following:
    - Systolic hypotension <100mgHg
    - Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
    - Tachycardia >100 beats/min (>119 beats/min for patients <18 years)
    - Oxygenation <90% via pulse oximetry
    - Body temperature >103$^{0}$F (>102$^{0}$F for patients <18 years)
- Patients who report any of the following:
    - History of renal dysfunction
    - History of allergic reaction to any previous neuraminidase therapy
    - History of psychologic side effects from any previous neuraminidase therapy
    - Use of antiviral therapy in past 4 weeks

**Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.**

**Pharmacist Prescriptive Authority Protocol for**
**Seasonal Influenza Prophylaxis with Neuraminidase Inhibitors**

**Purpose:**
To provide prophylactic therapy to high-risk household contacts of a patient being treated for active influenza in a timely and accessible fashion in accordance with guidelines of the Centers for Disease Control and Prevention.

**Patients Eligible for Neuraminidase Prophylaxis Under this Protocol (Inclusion Criteria):**

- Patients who are 6 years of age or older who meet at least one of the following criteria:
    - Has asthma or other chronic pulmonary disease
    - Has diabetes mellitus
    - Has congestive heart failure or coronary artery disease
    - Is immunocompromised by medication or condition
    - Has HIV
    - Has sickle cell anemia or other hemoglobinopathies
    - Has chronic renal dysfunction
    - Has cancer
    - Has neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise handling of respiratory secretions
    - Has not yet received influenza vaccine during this influenza season
    - Is age 65 years or older

**Patients Ineligible for Neuraminidase Prophylaxis Under this Protocol (Exclusion and Referral Criteria):**

- Patients under the age of 6
- Patients who are pregnant or breastfeeding
- Patients with current symptoms of influenza-like illness
- Patients who report any of the following:
    - History of allergic reaction to any previous neuraminidase therapy
    - History of psychologic side effects from any previous neuraminidase therapy
    - Use of antiviral therapy in past 4 weeks

**Pharmacist Prescriptive Authority Protocol for**
**Group A Streptococcal Pharyngitis (Strep Throat)**

**Purpose:**
To provide timely and accessible treatment of group A streptococcal (GAS) pharyngitis for low-risk, symptomatic patients in consideration of the clinical guidelines established by the Infectious Diseases Society of America (IDSA).

**Patients Eligible for Antibiotic Therapy Under this Protocol (Inclusion Criteria):**

- Symptomatic patients between the ages of 6 and 45 who score a 2 or higher on the Centor Score and then test positive to a CLIA-waived test indicated for GAS pharyngitis.

**Patients Ineligible for Antibiotic Therapy Under this Protocol (Exclusion and Referral Criteria):**

- Patients younger than 6 years of age or older than 45 years
- Patients who received antibiotic therapy within the previous 30 days
- Patients who report they are pregnant or breastfeeding
- Patients who report they are immunocompromised by medication or condition
- Adult patients who have one or more of the following:
    - Systolic hypotension <100 mgHg
    - Tachypnea >25 breaths/min (>20 breaths per minute for patients <18 years)
    - Tachycardia >100 beats/min (>119 beats/min for patients <18 years)
    - Oxygenation <90% via pulse oximetry
    - Body temperature >103$^0$F (>102$^0$F for patients <18 years)
    - History of renal dysfunction

**Follow-up within 48 hours after initial interaction to determine efficacy of treatment initiated or need for referral.**

**Pharmacist Prescriptive Authority Protocol for Uncomplicated Urinary Tract Infections (UTI)**

**Purpose:**
To provide timely and accessible treatment of uncomplicated urinary tract infections (UTI) for low-risk patients in accordance with the clinical guidelines of the Infectious Disease Society of America or the American Congress of Obstetricians and Gynecologists.

**Patients Eligible for Treatment Under This Protocol (Inclusion Criteria):**
- Women aged 18 or older who present with at least two of the following symptoms: dysuria, urinary frequency, urinary urgency, or suprapubic pain.

**Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria):**
- Men
- Women who meet or report one or more of the following:
    - Under the age of 18
    - Pregnant
    - Immunosuppressed by medication or condition
    - No previous history of uncomplicated UTI
    - Has had previous antibiotic therapy within the past 4 weeks
    - Has had surgical changes or birth defects relevant to the urinary tract
    - Has undergone urinary tract instrumentation in the past 4 weeks or has any current catheterization
    - Has or reports any symptoms suggestive of systemic illness, including:
        - Fever
        - Sweating
        - Flank pain
        - Shaking chills
        - Nausea
        - Vomiting
        - Systolic hypotension <100mgHg
        - Tachypnea >25breaths/min
        - Tachycardia >100beats/min
        - Oxygenation <90% via pulse oximetry
        - Body temperature >103$^{0}$F
    - Abnormal vaginal discharge or other symptom suggestive of a sexually transmitted infection
    - Poorly controlled diabetes

# Pharmacist Prescriptive Authority Protocol for Statins for Patients with Diabetes

**Purpose:**
To reduce cardiovascular (CV) risk in patients with diabetes and promote optimal patient care in accordance with the guidelines of the American College of Cardiology/American Heart Association.

**Patients Eligible for Treatment under This Protocol (Inclusion Criteria):**

- Patients between the ages of 40 and 75 years who report a previous diagnosis of diabetes.

**Patients who must be referred by the pharmacist to a more appropriate venue of care (Exclusion and Referral Criteria):**

- Patients younger than 40 years or older than 75 years
- Patients who do not report a previous diagnosis of diabetes
- Patients who report they are pregnant, may become pregnant, or are breastfeeding
- Patients who have or report one or more of the following:
    - Active liver disease
    - Unexplained elevated hepatic transaminase levels (ALT) >3 times upper limit of normal
    - History of statin-induced rhabdomyolysis
    - On hemodialysis or peritoneal dialysis
    - Hypersensitivity to any component of a statin

**The pharmacist should investigate further the appropriateness of initiating statin therapy for patients who report one or more of the following:**

- NHYA class II-IV ischemic systolic Heart Failure
- History of cognitive impairment
- Previous statin intolerance

**Follow-Up to Assess Need for Referral**

- Follow-up 4 to 12 weeks after initiation of a statin to assess medication adherence and to assess the safety and tolerability of statin therapy.
- Notify the patient's provider of record within five business days of any clinically significant information collected upon follow-up.

**Pharmacist Prescriptive Authority Protocol for**
**Short-Acting Beta Agonists (SABA)**

**Purpose:**
To fill a gap in care for low-risk asthma patients who run out of refills of their short-acting beta agonist (SABA) rescue inhaler prescription in consideration of the National Heart, Lung, and Blood Institute clinical guidelines.

## Patients Eligible for Treatment Under this Protocol (Inclusion Criteria)

- Patients with asthma over the age of 6 years old who meet all of the following conditions:
    - Reports a previous prescription for a SABA rescue inhaler that is out of refills; and
    - Reports a current prescription for a long-term asthma control medication (e.g., inhaled corticosteroid, long-acting beta agonist, etc.); and
    - Reports a previous medical office visit in the past fifteen (15) months.

## Patients Who Must Be Referred By the Pharmacist to a More Appropriate Venue of Care (Exclusion and Referral Criteria)

- Patients under the age of 6 years
- Patients who report no previous diagnosis of asthma
- Patients who report no previous SABA prescription
- Patients who report no current prescription for a long-term asthma control medication
- Patients who report no medical office visit in the past fifteen (15) months
- Patients who report or present with one or more of the following:
    - Current shortness of breath, chest pain, or other acute symptoms; or
    - Current productive cough (e.g. colored mucus); or
    - Pregnancy or breastfeeding; or
    - Evidence of SABA overuse (e.g., use >2 days/week for >4 weeks) or more than 2 inhalers in the past month for no explainable reason (e.g., recent travel loss)
    - Has already received two albuterol inhalers through independent pharmacist prescribing in the past twelve (12) months

**Pharmacist Prescriptive Authority Protocol for Mild Acne**

**Purpose:**
To provide timely and accessible treatment in patients with mild acne (Acne vulgaris).

**Patients Eligible for Treatment Under this Protocol (Inclusion Criteria):**

- Patients 12 years of age or older who exhibit signs and symptoms of mild acne such as:
    - Estimated < 20 open/closed comedones (blackheads/whiteheads)
    - Estimated < 30 total lesions (Small tender, red papules, pustules)
    - Few to several papules and pustules but no nodules

**Patients Ineligible for Treatment under this Protocol (Exclusion & Referral Criteria):**

- Patients less than 12 years of age
- Patients who report they are pregnant or breastfeeding
- Patients who report a history of hypersensitivity to first line medications or their excipients
- Patients who show lack of or poor response to treatment after 6 months
- Suspected drug-induced acne
- Patients who report or show any of the following:
    - History of scarring from acne
    - Moderate to severe signs and symptoms of acne such as:
        - Estimated > 20 open/closed comedones (blackheads/whiteheads)
        - Estimated > 30 total lesions (Small tender, red papules, pustules or nodules)
        - Several to numerous papules, pustules, and nodules
        - Suspected rosacea, perioral dermatitis, Hidradenitis suppurativa, or non-acne infection
    - Signs of hyper-androgenism
    - Systemic signs and symptoms such as:
        - Fever
        - Arthralgia
        - Dissecting cellulitis of the scalp
    - Unable to confirm acne diagnosis

**Follow-up within 8 weeks after dose or medication changes to determine efficacy of treatment initiated. Patients should be referred after 6 months of treatment without improvement.**

**Pharmacist Prescriptive Authority Protocol for Allergic Rhinitis**

**Purpose:**
To provide timely and accessible treatment for patients with allergic rhinitis.

**Patients Eligible for Intranasal Antihistamines and Corticosteroid Treatment Under this Protocol (Inclusion Criteria):**

- Patients 6 years of age or older who report signs and symptoms of allergic rhinitis
- Patients who report a previous history of allergic rhinitis or report of one or more of the following symptoms:
    - Sneezing
    - Rhinorrhea
    - Itchy throat and/or eyes
    - Watery eyes
    - Nasal congestion

**Patients Ineligible for Nasal Antihistamines and Corticosteroid Treatment Under this Protocol (Exclusion & Referral Criteria):**

- Patients less than 6 years of age
- Patients who report they are pregnant or breastfeeding
- Patients who report a history of hypersensitivity to the first line agents or their excipients
- Patients who report any of the following
    - Shortness of breath
    - Persistent headache
    - Eye or facial pain
    - Persistent/recurrent nosebleeds
    - Thick, green-yellow nasal discharge
    - Moderate to severe or persistent (occurs more than four weeks per year)
    - Trouble breathing during sleep
    - Ear pain
- Patients who report any history of the following
    - Asthma
    - Recurrent sinusitis
    - Recurrent or recent otitis media
    - Thyroid disorder

**Follow-up within 4 weeks of initial interaction to determine efficacy of treatment initiated. If failure evaluate compliance or need for referral.**