### **Comments of the Independent Regulatory Review Commission**



### Department of Human Services Regulation #14-544 (IRRC #3388)

#### **Covered Outpatient Drugs**

#### **February 1, 2024**

We submit for your consideration the following comments on the proposed rulemaking published in the December 2, 2023 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Human Services (Department) to respond to all comments received from us or any other source.

#### 1. Legislative comments.

Representative Dan Frankel, Democratic Chair of the House Health Committee, and the Black Maternal Health Caucus (Caucus) in the House of Representatives submitted comments regarding the supply of contraceptives as provided for in Section 1121.53(c). Representative Frankel and the Caucus encourage the Department to go further than the 90-day supply in the proposed regulations and provide for a 12-month supply of contraception in a single prescription fill. In addition, Representative Frankel commented on new language added to Section 1121.54 that would make agents used to promote fertility noncompensable. He states exemptions to this standard may be warranted in certain situations. We ask the Department to consider and address these comments in the Preamble to the final-form regulation.

# 2. Section 1121.53. Limitations on payment. – Reasonableness; Implementation procedures; Clarity.

Subsection (c) provides that "payment for systemic contraceptives may exceed the 90-day supply limit as specified by the Department." The method for specifying the exception to the supply standard is not included in this provision nor was it explained in the Preamble. We ask the Department to explain how this supply limit will be implemented. We also ask the Department to consider revising this subsection to improve the clarity of the contraceptives payment provision so that it is easily understood by the regulated community.

## 3. Section 1121.54. Noncompensable services and items. – Implementation procedures; Clarity.

This section lists services and items for which payment will not be made to a pharmacy. The Department is proposing to amend Paragraph (10). The paragraph currently states the following, "Drugs prescribed in conjunction with sex reassignment procedures or other noncompensable procedures." The amendment would delete "sex reassignment procedures or other" from the paragraph. The Preamble of the proposed rulemaking explains the language is being deleted because the Department "currently covers drugs prescribed for gender dysphoria without regard to sex reassignment procedures." In the Preamble to the final-form rulemaking, we ask the Department to explain if there is difference between drugs that may be prescribed specifically for "sex reassignment procedures" and drugs prescribed for "gender dysphoria."