DEPARTMENT OF
BUDGET & MANAGEMENT

LARRY HOGAN
Governor

BOYD K. RUTHERFORD
Lieutenant Governor

DAVID R. BRINKLEY
Secretary

MARC L. NICOLE
Deputy Secretary

Amendment #11 to Request for Proposals (RFP)
NO. F10B6400005R
Department of Budget & Management
Pharmacy Benefit Management Services and Pharmacy Benefits
Purchasing Pool Management
November 17, 2016

This Amendment is being issued to amend and clarify certain information contained in the above named RFP. All information contained herein is binding on all Offerors who respond to this RFP. Specific parts of the RFP have been amended. The following changes/additions are listed below. New language has been double underlined and marked in bold (ex. **new language**), and language deleted has been marked with a strikeout (ex. ~~language deleted~~).

The Department is issuing the below extension to allow for its consideration of and response to additional vendor questions related to the RFP specifications.

1. AMEND RFP Section 1.2.5 "Brand Drug" definition as follows:

A drug that is approved by the U.S. Food and Drug Administration (FDA) and is ~~produced and~~ distributed under an **FDA Application Type of** ~~original~~ new drug application (NDA) **or biologic license application (BLA), and which is not an authorized generic (marketed as a generic under private label) and which is not processed with DAW code 5**, ~~marketed by a cross-licensed producer/distributor operating under the NDA, and which excludes authorized generic drugs. Discount~~**All financial** guarantees will be reconciled based on the above definition. In instances where the brand or generic status of a drug, as determined by the Contractor relying on an independent published source, differs from this definition, the Contractor may rely on its standard drug classification system for ~~the~~ **operational** purposes ~~of~~ **such as** claim adjudication.

2. AMEND RFP Section 1.2.24 "DESI" definition as follows:

Drug Efficacy Study Implementation. DESI refers to drugs identified by the Food and Drug Administration as lacking substantial evidence of effectiveness. **For the purpose of this RFP, DESI includes any drugs distributed under an FDA Application Type other than abbreviated new drug application (ANDA), new drug application (NDA), or biologic license application (BLA). DESI drugs will be excluded from reconciliation of guarantees for RFP FA 1 and FA 2.**

3. AMEND RFP Section 1.2.39 "Generic Drug" definition as follows:

~~A single-source or multi-source drug rated as therapeutically equivalent to the brand/reference drug, per FDA Orange Book. It is produced, and marketed under an abbreviated new drug application (ANDA) approved by the FDA.~~ **A drug that is approved by the U.S. Food and Drug Administration (FDA) and is distributed under an FDA Application Type of abbreviated new drug application (ANDA), or which is an authorized generic (marketed as a generic under private label) or which is processed with DAW code 5.** ~~Authorized generics marketed under the original brand NDA are classified as generics for purposes of pricing and Participant copay purposes. Discount~~**All financial** guarantees will be reconciled based on the above definition. In instances where the brand or generic status of a drug, as determined by the Contractor relying on an independent published source, differs from this definition, the Contractor may rely on its standard drug classification system for ~~the~~ **operational** purposes ~~of~~ **such as** claim adjudication.

Issued and authorized by

<signed>
Rachel Hershey
Procurement Officer