The Proper Use of the NCPDP® Telecommunication Standard Version D.0 as it applies to the Implementation of Medicaid Reimbursement Methodologies Based on Actual Acquisition Cost (AAC) Plus a Professional Dispensing Fee

Version 1.1
April 2017

This white paper provides Medicaid agencies and fiscal agents guidance in implementing new acquisition cost based reimbursement rules for covered outpatient drugs. The paper presents common issues experienced to-date in implementing cost based reimbursement with professional dispensing fees. It highlights how to best utilize the NCPDP Telecommunication Standard Version D.0 and leverages best practices for various scenarios such as preferred brands for multisource generic situations and the proper use of the Dispense As Written (DAW)/Product Selection Code (408-D8) field values to inform pharmacies of formulary requirements.
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Published by:
National Council for Prescription Drug Programs, Inc.

Publication History:
Version 1.0 January 2017
Version 1.1 April 2017
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1. BACKGROUND
The Covered Outpatient Drugs final rule with comment (CMS-2345-FC) (81 FR 5170) published on February 1, 2016 addressed key areas of Medicaid drug reimbursement and changes to the Medicaid Drug Rebate Program by the Affordable Care Act. This final rule assists states and the federal government in managing drug costs, establishes the long term framework for implementation of the Medicaid drug rebate program, and creates a reimbursement system for Medicaid programs and pharmacies that more accurately reflects drug cost and the cost of dispensing.

The final rule is designed to ensure pharmacy reimbursement is aligned with the acquisition cost of drugs and the states pay an appropriate professional dispensing fee. The final rule:

- Creates an exception to the Federal Upper Limits (FUL) calculation, which allows for the use of a higher multiplier than 175% calculating the FUL based on acquisition costs for certain multiple source drugs.
- Establishes Actual Acquisition Cost (AAC) as the basis by which states should determine their ingredient cost reimbursement so payments are based on a more accurate estimate of the prices available in the marketplace, while still ensuring sufficient beneficiary access.
- Implements the use of the term “professional dispensing fee” to ensure the dispensing fee paid to pharmacies reflects the cost of the pharmacist’s professional services and cost to dispense the drug product to a Medicaid beneficiary.

As discussed in Section II.J. (81 FR 5290) of the preamble for the final rule with comment, a state can implement an AAC model of reimbursement based on various pricing methodologies.

State Medicaid programs must comply with the requirements of this rule by submitting a State Plan Amendment (SPA) to CMS by June 30, 2017 to be effective no later than April 1, 2017. Therefore, causing all state Medicaid agencies to convert to an acquisition cost based reimbursement methodology.

NCPCP Work Group 9 Government Programs formed the Medicaid Best Practices Using NCPDP Standards to Implement Reimbursement Methodology Task Group to provide guidance to Medicaid programs on the use of the NCPDP Telecommunication Standard Version D.0 to reduce the frequency of reimbursement errors and to ensure compliance with the HIPAA-named standard.
2. PURPOSE

This white paper is intended to provide state Medicaid programs with assistance in utilizing the NCPDP Telecommunication Standard Version D.0 to implement new acquisition cost based reimbursement rules for covered outpatient drugs (CODs).

Implementation of new reimbursement methodologies in a consistent and compliant manner assists all stakeholders in implementing the Final Rule by April 1, 2017. It also minimizes the likelihood of reversals, rebilling, and reprocessing activities.

This white paper presents common issues experienced to-date in implementing cost based reimbursement with professional dispensing fees. It highlights how to best utilize the NCPDP Telecommunication Standard Version D.0 and leverages best practices for various scenarios such as preferred brands for multisource generic situations and the proper use of the Dispense As Written (DAW)/Product Selection Code (408-D8) field values to inform pharmacies of formulary requirements.

The white paper also includes a section for Frequently Asked Questions which will be updated as states, processors or pharmacies contact NCPDP with pricing and processing issues or questions. We invite all stakeholders to send questions to the Medicaid Best Practices Using NCPDP Standards to Implement Reimbursement Methodology Task Group by emailing Kittye Krempin (kkrempin@ncpdp.org). The Task Group will address all questions and maintain this white paper as implementation continues across the states.
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3. RECOMMENDATIONS TO ENSURE APPROPRIATE IMPLEMENTATION OF REIMBURSEMENT CHANGES

The following section contains challenges payers and providers have experienced as a result of early implementation of the new reimbursement methodologies. Each section recommendation contains a background, example scenario(s) and NCPDP guidance on the proper use of the NCPDP Telecommunication Standard Version D.0 for the claims adjudication process.

3.1 Appropriate Use of Dispense As Written (DAW)/Product Selection Code Values

3.1.1 Background

In the Claims Segment of the Telecommunication Standard Claim Billing transaction, the data field Dispense as Written (DAW)/Product Selection Code (408-D8) is required to be sent by the pharmacy to the processor/PBM. This field is intended to communicate to the processor/PBM the prescriber’s instructions as to whether generic substitution is allowed, or alternate reasons as to why the multi-source brand product is being dispensed.

Based on NCPDP DAW Code definitions, appropriate rules must apply to ensure proper claims editing and pharmacy reimbursement. The following DAW code values are a selection from the complete list, found in Appendix A, and require the pharmacy to dispense the brand product rather than the pharmacy electing to dispense the brand.

DAW Code 1 – Substitution Not Allowed by Prescriber
DAW Code 2 – Substitution Allowed-Patient Requested Product Dispensed
DAW Code 7 - Substitution Not Allowed-Brand Drug Mandated by Law
DAW Code 8 - Substitution Allowed-Generic Drug Not Available in Marketplace
DAW Code 9 - Substitution Allowed By Prescriber but Plan Requests Brand

Improper reimbursement or misuse of the code values above cause pharmacies and processor/PBMs the greatest difficulty when substituting branded drugs for generics. NCPDP recommends Medicaid programs review their generic substitution policy and ensure processing systems are coded to properly address each scenario outlined below.

Also, there have been past requests by certain Medicaid programs for pharmacies to submit DAW code values for situations other than the valid situations listed in Appendix A and defined within the NCPDP External Code List (ECL). Pharmacy systems are coded to maintain compliance with the HIPAA-named NCPDP Telecommunication Standard and cannot alter the DAW code logic to support other situations. Manual exception override processes also create significant barriers to pharmacy workflow processes and negate training and policies that ensure standardization and compliance with the Telecommunication Standard.

NCPDP recommends Medicaid programs take this opportunity to update their policy language and processing systems to align with the NCPDP definitions of DAW code values and eliminate any current use of DAW Code 6 - Other. Since the NCPDP ECL process, implemented with Telecommunication Standard Version D.0, allows the industry to add new DAW code values as business cases are presented,
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NCPDP is considering the removal of the DAW Code 6 - Other. NCPDP recommends Medicaid programs bring forward any business cases not consistent with DAW Code 1 or any other DAW code values for which DAW Code 6 has been used in the past, so new DAW code values can be created to address the specific Medicaid business case.

The COD final rule presents Medicaid programs an opportunity to use Federal matching funds to ensure compliance with the HIPAA-named NCPDP standard by further developing appropriate DAW code logic within their pharmacy claims processing systems for this purpose.

3.1.2 Scenario 1: The prescriber has indicated the brand is medically necessary, but the Medicaid program’s policy is not to pay for the brand-named product.

In this scenario, the prescriber has indicated the brand is “medically necessary” for a product having a generic alternative and the law requires the brand be dispensed. Therefore, substitution is not allowed by the pharmacy. All Medicaid program processor systems must support the use of the DAW code values to apply appropriate adjudication rules. Claims for brand products dispensed because the prescriber has indicated the brand product is medically necessary (DAW 1) should (a) be reimbursed at the brand reimbursement rate, or (b) rejected to indicate prior authorization is required for the brand medically necessary indication. It is not a compliant use of the standard to accept the claim with DAW Code 1 and pay based on the generic product.

1. The Pharmacy will submit the claim billing with DAW Code 1 (Substitution Not Allowed by Prescriber).
2. If Medicaid will not pay for the brand in this scenario, they should not accept DAW Code 1 and the processor/PBM should REJECT the claim back to the pharmacy with Reject Code (511-FB) 75 (Prior Authorization Required) and/or AJ (Generic Drug Required) depending upon program policy.
3. The pharmacy will notify the patient that the prescriber needs to be contacted to authorize the brand or a prior authorization is required and pursue the appropriate process.

3.1.3 Scenario 2: Even though the prescriber has allowed for substitution, the patient has requested the brand be dispensed.

In this scenario, the patient has requested the brand. Medicaid may not pay for the brand and the pharmacy needs to determine whether this is true per Medicaid policy.

1. The Pharmacy will submit the claim billing with DAW Code 2 (Substitution Allowed-Patient Requested Product Dispensed).
2. If Medicaid will not pay for the brand in this scenario, they should not accept DAW Code 2 and the processor/PBM should REJECT the claim back to the pharmacy with Reject Code (511-FB) 8K (DAW Code Value Not Supported) and also Reject Code (511-FB) AJ (Generic Drug Required).
3. Upon receiving the reject codes, the pharmacy will notify the patient that Medicaid will only pay for the generic equivalent and resubmit the claim for the generic equivalent with DAW Code 0.
3.1.4 **Scenario 3: State law prohibits generic substitution for the drug prescribed, even though the prescriber indicated substitution is acceptable.**

Narrow Therapeutic Index (NTI) drugs are drugs where small differences in dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that are life-threatening or result in persistent or significant disability or incapacity. In this scenario, because the drug prescribed is an NTI drug, by State law the pharmacy is prohibited from substituting the generic for a multi-source branded product even though the prescriber has authorized substitution.

1. The pharmacy must submit the brand in this NTI scenario with a **DAW Code 7 (Substitution Not Allowed-Brand Drug Mandated by Law)**.
2. The processor/PBM should accept DAW Code 7 in this example and reimburse the pharmacy according to the Ingredient Cost and Professional Dispensing Fee formula for the multi-source branded drug submitted on the claim billing.

Note: This is only applicable in states with Narrow Therapeutic Index (NTI) requirements.

3.1.5 **Scenario 4: There is a marketplace shortage of the generic product for the prescribed drug. Only the brand-named product is available at this time.**

In this scenario, the pharmacy would normally dispense the generic product but it is currently unavailable in the marketplace. Only the brand-named product is available at this time. This can also occur when the patient has previously been receiving the generic form of the product in the past. Discontinuance or an interruption in manufacturing of a product is likely to lead to a meaningful disruption in supply for a drug and similar products for some period of time.

1. The pharmacy must dispense the brand with a **DAW Code 8 (Substitution Allowed-Generic Drug Not Available in Marketplace)**.
2. The processor/PBM should accept DAW Code 8 in this example and reimburse the pharmacy according to the Ingredient Cost and Professional Dispensing Fee formula for the multi-source branded drug submitted on the claim billing.
   a. Alternatively, the processor/PBM could reject the claim with Reject Code (511-FB) 8K (DAW Code Value Not Supported). The processor/PBM should also send Additional Message Information (526-FQ) on how the pharmacy can override the edit for the brand drug since no substitute is available.

3.1.6 **Scenario 5: Medicaid program formulary rules require the brand product be dispensed.**

Medicaid programs often place the multi-source brand product on the formulary or preferred drug list and do not cover the generic alternative regardless of the prescriber’s designation of substitution allowed. To ensure alignment with the intent of the NCPDP Telecommunication Standard, the following application of the DAW code values must apply.

1. For the initial fill of the prescription, pharmacies are likely unaware of Medicaid formulary details and that the branded product is required. The pharmacy would likely dispense the
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generic equivalent and submit a claim for the generic equivalent with **DAW Code 0 (No Product Selection Indicated)**.

2. Since the Medicaid program has identified the brand product as the preferred drug, the processor/PBM should **reject** the claim submitted with DAW Code 0. The processor/PBM should use **Reject Code (511-FB) 606 (Brand Drug/Specific Labeler Code Required)**. Additional information should be supplied by the processor/PBM in the **Response Claim Segment** regarding the preferred product in the **Preferred Product ID (553-AR)**. At a minimum, the following additional fields should be provided:
   - 551-9F Preferred Product Count
   - 552-AP Preferred Product ID Qualifier
   - 556-AU Preferred Product Description

3. Upon receiving Reject Code 606, the pharmacy will **resubmit** the claim with the preferred brand drug and **DAW Code 9 (Substitution Allowed By Prescriber but Plan Requests Brand)**.

4. Based on the current service date covered formulary status, the processor/PBM accepts DAW Code 9 and must reimburse the pharmacy according to the Ingredient Cost and Professional Dispensing Fee for the Preferred Product dispensed.

   *Note: Until the pharmacy is alerted to a formulary change by the processor/PBM through the claim adjudication process, the pharmacy dispensing system will retain the DAW Code 9 and dispensed product from the previous fill. As a result, the appropriate use of DAW code values and reject codes is critical to ensure adherence to formulary rules and appropriate reimbursement.*

   *If the formulary status changes in the future and the brand drug is no longer covered on the formulary, future prescription claims submitted by the pharmacy for the preferred brand drug and DAW Code 9 should be rejected by the processor/PBM with **Reject Code (511-FB) AJ (Generic Drug Required)**.*
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4. FREQUENTLY ASKED QUESTIONS

We encourage Medicaid programs to submit questions in order for NCPDP to provide further guidance.

**Question 1:**
How is the Professional Dispensing Fee applied to the NCPDP claim response?

**Response:**
The Professional Dispensing Fee as defined with the State Medicaid Plan would be returned in the Dispensing Fee Paid (507-F7) field. Determining when the Professional Dispensing Fee applies to a prescription claim is based on whether “lower of logic” is incorporated into the Medicaid program’s reimbursement formula. “Lower of logic” does not apply at the individual field level meaning the submitted dispensing fee is not compared to the allowed dispensing fee.

In order to properly process the claim, appropriate use of the “Prescription Pricing Formula,” Basis of Cost Determination (423-DN) and Basis of Reimbursement Determination (522-FM) fields as defined with the NCPDP Telecommunication Standard must be incorporated into the “lower of logic.”

**NCPDP Implementation Guidelines:**
The pricing fields submitted on the claim are based on the plan’s Payer Sheet designation of the situational fields. For example, if the payer only requires the Usual and Customary Charge as their “lower of logic,” this may be the only field set required. If a payer requires the Gross Amount Due value for lower of calculation, the pharmacy would also submit the corresponding pricing fields that make up Gross Amount Due (refer to the Prescription Pricing Formula in the NCPDP Telecommunication Standard vD.0, Section 35.8). The Basis of Cost Determination field defines the cost basis in which the Ingredient Cost Submitted value was derived, where the Dispensing Fee Submitted may change based on the Basis of Cost. For example, a Dispensing Fee may not apply to the Basis of Cost Determination of Usual and Customary.

To adhere to the Prescription Pricing Formula:
1. Determine the Basis of Reimbursement Determination (522-FM) that will apply to the claim based on the state’s reimbursement rules (e.g. AAC, NADAC).
2. Calculate the Ingredient Cost Paid (506-F6) based on the Basis of Reimbursement Determination and add the Dispensing Fee Paid (507-F7) (Professional Dispensing Fee) associated to the Basis of Reimbursement rule to determine the “claim allowed amount.”
3. If “lower of logic” applies, compare the calculated “claim allowed amount” to the Gross Amount Due (430-DU) and/or the Usual and Customary Charge (426-DQ).
   - If the submitted Gross Amount Due or Usual and Customary Charge is lower than the “calculated allowed amount” then the submitted value would be returned as Ingredient Cost Paid with the applicable Basis of Reimbursement value.
   - If the “calculated allowed amount” is lower, the associated Ingredient Cost Paid and Dispensing Fee as determined in Step 2 would be returned, with the associated Basis of Reimbursement value.
Question 2:
A. How should Medicaid process a claim when the drug status which was originally “preferred formulary” changes to “non-preferred formulary”?

Response:
When a product changes status from preferred to non-preferred, the processor should reject the claim to indicate the formulary status of the product ID submitted (e.g. Prior Authorization Required (75); Product Not On Formulary (MR), Product/Service Not Covered – Plan/Benefit Exclusion (70), Step Therapy, Alternate Drug Therapy Required Prior To Use Of Submitted Product Service ID (608), etc.). If only the Additional Information Message (526-FQ) field is used to communicate this information, it creates a challenge for this information to be electronically communicated and managed within the appropriate workflows, thereby creating delayed patient access to care.

Additional information should be returned in the response that identifies formulary alternative products. The following distinct fields within the Response Claim Segment should be used to communicate the formulary alternatives:
- 551-9F Preferred Product Count
- 552-AP Preferred Product ID Qualifier
- 556-AU Preferred Product Description

The processor may also use the Additional Information Message (526-FQ) field to provide a free text message outlining the formulary alternatives.

The pharmacy communication process will initiate the appropriate actions that may result in prescribing an alternative drug or initiating the Prior Authorization/Medical Necessity process.

B. What if a preferred product is a multi-source brand (brand named product where generic is available)?

Response:
In this case the pharmacy would need to dispense the branded product and resubmit using DAW Code 9 which indicates substitution allowed by prescriber, but the Medicaid program requires the brand named product.

Until the pharmacy is alerted to a formulary change by the processor/PBM through the claim adjudication process, the pharmacy dispensing system will retain both the DAW Code 9 and the dispensed product from the previous fill. As a result, the appropriate use of DAW code values and reject codes is critical to ensure adherence to formulary rules and appropriate reimbursement.

If the formulary status changes and the brand drug is no longer set as the preferred formulary drug, prescription claims submitted by the pharmacy for the preferred brand drug and DAW Code 9 should be rejected by the processor/PBM with Reject Code (511-FB) AJ (Generic Drug Required).
C. How is the Medicaid program/PBM processor expected to process the claim if the Date of Service is prior to the date of a change in formulary status?

Response:
The Medicaid program/PBM processor should process the claim based on the formulary status of the product dispensed on the Date of Service. See response to Question 2A.

Question 3:
Should a Professional Dispensing Fee apply to all prescribed products covered by the Medicaid program?

Response:
Yes. According to the Professional Dispensing Fee definition, a dispensing fee would apply to all claims, regardless of the drug category if the reimbursement is determined to be the Medicaid program’s allowed amount for ingredient cost + dispensing fee (if lower than the pharmacy’s Usual and Customary Charge for the product).

Question 4:
Should the Professional Dispensing Fee be applied to Coordination of Benefits claims that leverage Other Payer Amount Paid (OPAP) methodology?

Response:
The Professional Dispensing Fee is included in the Medicaid program’s allowed amount as defined in the reimbursement rate. Therefore, the fee must be included when determining whether the sum of applicable Other Payer Amount Paid amounts is greater than the Medicaid allowed amount. Based on the Medicaid program’s reimbursement policy or contractual agreement with the pharmacy, the Professional Dispensing Fee should also apply to Coordination of Benefits claims reimbursed.
5. CONCLUSION

The Medicaid Covered Outpatient Drugs Final Rule assists states and the federal government in managing drug costs, establishes the long term framework for implementation of the Medicaid drug rebate program, and creates a reimbursement system for Medicaid programs and pharmacies that more accurately reflects drug cost and the cost of dispensing.

This regulation changes the Medicaid reimbursement formula by replacing the current Estimated Acquisition Cost (EAC) with Actual Acquisition Cost (AAC). In order to comply with the Final Rule, states have the option to either use the Centers for Medicare & Medicaid Services National Average Drug Acquisition Cost (NADAC) or state-specific AAC. In addition, the rule also allows states to use other benchmarks such as Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC) as long as such alternatives reflect the true cost of the drug. In addition to moving to a cost-based reimbursement methodology, the Final Rule also implements the Affordable Care Act Average Manufacturer Price (AMP) based federal upper limits for reimbursement of generic drugs.

State Medicaid programs must comply with the requirements of this rule by submitting a State Plan Amendment (SPA) to CMS by June 30, 2017 to be effective no later than April 1, 2017. Therefore causing all state Medicaid Programs to convert to an acquisition cost based reimbursement methodology.

Accordingly, NCPDP has prepared this document to provide guidance in implementing these changes in order to maintain compliance with the NCPDP standards while ensuring proper reimbursement of claims.

It is the intention of this task group that this document will be distributed to the appropriate members each state Medicaid Program, including those responsible for implementation of any changes to the pharmacy system related to this legislation.
Appendix A – Dispense As Written (DAW)/Product Selection Code (408-D8)²

Definition of the Field: Code indicating whether or not the prescriber’s instructions regarding generic substitution were followed.

Valid values for DAW Codes are below. Of primary interest to Medicaid Programs implementing new reimbursement methodologies are the proper use of DAW Codes 1, 2, 7, 8, and 9.

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>0</td>
<td>No Product Selection Indicated - This is the field default value that is appropriately used for prescriptions for single source brand, co-branded/co-licensed, or generic products. For a multi-source branded product with available generic(s), DAW 0 is not appropriate, and may result in a reject.</td>
</tr>
<tr>
<td>1</td>
<td>Substitution Not Allowed by Prescriber – This value is used when the prescriber indicates, in a manner specified by prevailing law, that the product is Medically Necessary to be Dispensed As Written. DAW 1 is based on prescriber instruction and not product classification.</td>
</tr>
<tr>
<td>2</td>
<td>Substitution Allowed-Patient Requested Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the patient requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.</td>
</tr>
<tr>
<td>3</td>
<td>Substitution Allowed-Pharmacist Selected Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.</td>
</tr>
<tr>
<td>4</td>
<td>Substitution Allowed-Generic Drug Not in Stock-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation exists due to the buying habits of the pharmacist, not because of the unavailability of the generic product in the marketplace.</td>
</tr>
<tr>
<td>5</td>
<td>Substitution Allowed-Brand Drug Dispensed as a Generic-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity.</td>
</tr>
<tr>
<td>6</td>
<td>Override-This value is used by various claims processors in very specific instances as defined by that claims’ processor and/or its client(s).</td>
</tr>
<tr>
<td>7</td>
<td>Substitution Not Allowed-Brand Drug Mandated by Law-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted but prevailing law or regulation prohibits the substitution of a brand product even though generic versions of the product may be available in the marketplace.</td>
</tr>
<tr>
<td>8</td>
<td>Substitution Allowed-Generic Drug Not Available in Marketplace-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed, or is temporarily unavailable.</td>
</tr>
<tr>
<td>9</td>
<td>Substitution Allowed By Prescriber but Plan Requests Brand - Patient’s Plan Requested Brand Product To Be Dispensed - This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted, but the plan’s formulary requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.</td>
</tr>
</tbody>
</table>

² Reference: NCPDP External Code List, October 2010
Appendix B – History of Changes

Version 1.0
Initial release of the paper.

Version 1.1
Section 4.0 Frequently Asked Questions
The following Frequent Asked Questions were added:

**Question 1:**
How is the Professional Dispensing Fee Applied to the NCPDP Claim Response?

**Question 2:**
A. How should Medicaid process a claim when the drug status which was originally preferred formulary changes to non-preferred formulary?
B. What if a preferred product is a multi-source brand (brand named product where generic is available)?
C. How is the Medicaid program/PBM processor expected to process the claim if the Date of Service is prior to the date of a change in formulary status?

**Question 3:**
Should a Professional Dispensing Fee apply to all prescribed products covered by the Medicaid program?

**Question 4:**
Should the Professional Dispensing Fee be applied to Coordination of Benefits claims that leverage Other Payer Amount Paid (OPAP) methodology?