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July 19, 2024

Kimberly Alston, Contracting Agent
NC State Health Plan Division
North Carolina Department of State Treasurer
3200 Atlantic Avenue
Raleigh, NC 27604

RE: Response to RFI No. 270-20240419GLP

Dear Ms. Alston,

We are pleased to submit our response to the Request for Information (RFI) No. 270-20240419GLP issued by the North Carolina State Health Plan for Teachers and State Employees. Our response outlines detailed solutions to provide benefit coverage for GLP-1, GIP-GLP-1 agonists, and similar new molecular entities for weight loss in a fiscally responsible manner.

Executive Summary

Revelation Pharma (Revelation) is dedicated to delivering innovative healthcare solutions that align with the objectives of the North Carolina State Health Plan. Our extensive experience in compounding pharmacy together with our commitment to clinical excellence position us as a prime candidate to support the Plan in delivering weight loss therapies. The North Carolina State Health Plan (NCSHP) recently decided to not cover GLP-1 agonists and similar weight loss products due to their high cost. This leaves State employees, retirees, and dependents without access to these important medications that significantly improve short- and long-term health outcomes. Revelation is a national network of high-quality compounding pharmacies with a base in North Carolina that could meet all the GLP-1 agonist supply needs of NCSHP beneficiaries in a fiscally responsible manner. By comparison to current treatment modalities for managing chronic conditions like diabetes and weight management, Revelation Pharma, leveraging the strength of its network, can supply NCSHP members with consistent access to compounded GLP-1 agonists and similar agents at a cost that will yield significant savings for the state, by as much as [REDACTED]. Many of the products remain in short supply. The Institute for Clinical and Economic Review (ICER) concluded that semaglutide would be cost-effective at a drug price discount from the wholesale acquisition cost of [REDACTED] (approximately

██████████ per year). Revelation could guarantee no price increases for the first year of an agreement with NCSHP. It has been estimated that over 24,000 NCSHP beneficiaries could benefit from these medications. If coverage for GLP-1 agonists is reinstated with Revelation's compounded GLP-1 agonist and similar products instead of GLP-1 agonists and similar products obtained from pharmaceutical manufacturers and traditional pharmacies, the State could serve these beneficiaries with high quality drug product and utilization management with substantial ██████████.

Solution Outline

As we understand the NCSHP would consider reinstating benefit coverage of GLP-1 and similar weight loss products if they could obtain cost effective, easy access, and high-quality products, managed by a customized utilization management approach. Our compounded products meet USP 797 and 800 Standards. The Plan stated they are open to compounded solutions so that is what we are proposing. All proposed PBM systems for eligibility, formulary, network, claims processing, UM, and dispensing pharmacy management systems have been in operation for years, and though used in a customized fashion, do not introduce any risk. Our solution offers all the above.

A. Permit Coverage of GLP-1, GIP-GLP-1 Agonists

We propose a comprehensive plan to include GLP-1, GIP-GLP-1 agonists in the benefit coverage for Plan members. Our solution encompasses:

- Customized utilization management (UM) including upfront prior authorization and ongoing progress check-ins ensuring appropriate drug utilization
- Contact with patients and providers as needed to authorize and monitor progress
- Monitoring and reporting on adverse drug events (ADEs)
- Activities and materials to support adherence to the prescribed regimen
- High quality compounded GLP-1 GIP-GLP-1 receptor agonist in several strengths with all the attendant administration supplies and educational materials

Revelation together with our PBM/UM partner ProCare Rx, can support the NCSHP with an end-to-end solution meeting the unique requirements sought in this RFI. Here is an overview of our solution.

Whenever an FDA-approved product is in short supply from traditional manufacturers, section 503A of the Food, Drug, and Cosmetic Act allows compounding pharmacies to step in and help fill the shortage gap. In the case of GLP-1 agonists and similar products, the demand has completely exceeded the supply such that manufacturers simply cannot bring new manufacturing capacity that is sufficient to meet the demand. It takes large amounts of time and resources to build new factories, pass inspections, and begin production. In the meantime, safe, high-quality, and cost-effective compounded GLP-1 agonists and similar products are available from Revelation's compounding pharmacies.

As a result of a patient visit to a licensed prescriber, a patient is given a prescription for a compounded GLP-1 or similar product. E-prescribing is not reliable in compounded prescriptions. Through beneficiary communications from NCSHP via website and or patient benefit flyers, the prescription is presented to Revelation's NC pharmacy location (phone, fax or hand carry). Revelation pharmacy will attempt to adjudicate the claim through its PBM partner, ProCare Rx. If it is a new prescription, ProCare Rx will conduct customized UM meeting all the requirements of NCSHP. They will not accept attestation but will use primary source verification of the patient's weight, BMI, participation in legitimate lifestyle modifications, and credentials of the prescriber, prior to granting prior authorization (PA) to fill the initial prescription. Based on BMI and comorbidities, the variable copay will be assigned. We recommend maintaining the copay level throughout the treatment avoiding confusion. ProCare will need to maintain Plan eligibility and can take an electronic feed from NCSHP or designee.

Only after receiving a PA approval, which includes the variable copay, will Revelation dispense the compounded drug product, subcutaneous or intramuscular injection supply kits, including syringes, needles, alcohol wipes, sharps container, and printed patient information. This information will guide the patient to online resources with videos teaching how to administer an accurate dose of medication. The material will also inform the patient as to how and when to report ADEs to Revelation or ProCare Rx.

Revelation is aware that some patients stop therapy prior to reaching their weight loss goals. Our team will work with each patient to ensure adherence as long as there are not untoward side effects and the patient is progressing on therapy. Our PBM solution includes:

- Electronic Eligibility Management
- Claim Adjudication
- Pharmacy Network Management, Administration, and Help Desk
- Program Reporting
- Implementation
- Account Management Support
- Custom Step Therapy Edits
- Concurrent DUR
- Program billing and administrative services
- Initial Prior Authorization for new patients and follow up PA each 6 months
- Utilization Management

Utilization Management assumes a quarterly check in call with each program participant that is supervised by a pharmacist.

We propose a periodic reauthorization of treatments. The initial PA could be good for 90 days, the next could last 180 days, and then annually after that. Intense and customized UM can save the Plan money but comes with real costs too. Our proposal includes all costs in one price per 28-day prescription: high quality drug product, supplies, UM and PBM administrative fees. We look forward to meeting with the Plan, finalizing program details, and pinpointing the prices.

B. Establish a Pricing Framework

To ensure financial sustainability, we recommend a tiered copay pricing model. We also are offering a [REDACTED] price guarantee. We will not increase the price of each package for one year if we are selected. We expect the net price to the Plan to be [REDACTED] lower than alternatives.

- Variable Unit Cost Payments: Implement a system where payments vary based on medical necessity and patient-specific factors such as BMI and comorbid conditions
- Net Effective Price Management: Ensure the Plan receives the same all-inclusive net price for medications, supplies, and UM regardless of additional FDA-approved indications the Plan chooses to cover
- Claims Auditing and Rebates: Regular internal audits to ensure compliance with all applicable regulations, program features, and to identify cost-saving opportunities

Large UM providers may not customize programs and criteria. Our team, Revelation and ProCare Rx support the Plan in its efforts to balance cost and access to high-quality GLP-1 agonists and similar products. Post award, or earlier if NCSHP desires, we would be happy to meet with you to further understand your goals in UM and help guide you to workable solutions. We certainly can support a variable copay solution based on BMI and comorbid solutions. All we need to do is agree on the cut points for BMI and which and how many comorbid conditions should be evaluated. Further, we see benefit in more direct collection of important UM factors like weight, BMI, and participation in appropriate lifestyle management programs focusing on diet and exercise. In partnership with patients, their prescribers, our UM provider, and Revelation, we will collect and act on each patient's progress, ADEs, and compliance to lifestyle management initiatives.

Regardless of the condition treated, Revelation will offer the same price to NCSHP. Obviously, the UM criteria and copays may change at the Plan's direction, but we will offer the same price for a 28-day supply of drug, attendant supplies, and condition specific UM.

PBMs rely on negotiating with traditional pharmacies for discounts and with pharmaceutical companies for discounts in the form of rebates. Because our program does not dispense pharmaceutical company manufactured products, there will be no rebates in the program. Criteria for rebates for the weight loss indication are rigid, and small variances in UM as compared to the product label can nullify rebates. But, even if another PBM offers rebates in their pricing framework, our net price will be lower. We will conduct continuous process improvements including internal audits to ensure program integrity. Audits will include UM, prescription processing, compounding, ADE monitoring, adherence, and billing/collection accuracy.

C. Eligibility Requirements and Parameters

We propose setting clear eligibility criteria and prerequisites, including:

- Completion of an approved weight loss program or nutrition classes.
- Implementation of step therapy protocols starting with lower-cost medications.
- Prescription by practitioners with specialized expertise.
- Accurate and accountable BMI measurements.

Key to continued success of this covered benefit include low unit cost and appropriate UM. We bring both to NCSHP. Our UM program will verify that a patient has completed an approved weight loss program and still meets BMI and comorbidity criteria to receive GLP-1 agonists and similar products. One cost driver we can remove is unnecessary or wasteful use of these products. As previously mentioned, when evaluating an initial prescription, we will assign the variable copay. By implementing verifiable monitoring of approved weight loss programs or nutrition classes and ensuring that product dispensed is actually used by the patient, our program can avoid waste of benefit dollars. We will meet with the Plan post award to agree on a list of approved programs and classes.

In addition to prior authorization of prescriptions as described earlier, we will also ensure that patients progress through step therapy protocols beginning with lower cost medications. Our UM partner, ProCare Rx and Revelation will meet with the Plan post award to agree on which drugs should be included in step therapy and the duration of an adequate trial.

Part of our regular prescription dispensing and claim adjudication verifies whether prescribers are currently licensed to practice, are alive, and do not appear on any CMS restricted lists. We will be collecting some UM information directly from prescribers, for example, BMI. We will not allow the patient to estimate BMI or self-attest to any other parameters in the UM process.

D. Utilization Management Program

Our utilization management program will include:

- Detailed tracking of BMI, current weight, and lifestyle modifications.
- Enrollment verification in dietary and nutritional programs.
- Evaluation of comorbid conditions and other medical factors.
- Robust data analytics and reporting tools for effective program evaluation.

Our UM program is enhanced by our organizational commitment to continuous quality improvement. We will provide reports to NCSHP detailing program information: number of participants by copay level, prescription claim detail, and overall program costs including UM. And we will continuously monitor to ensure that important UM criteria like weight, BMI, comorbid conditions, and lifestyle modifications are reported and documented in the most reliable way. We will always favor in-person visits to providers for patient evaluation and monitoring and only allow telehealth visits when necessary, by patient geography or mobility

E. Cost and Pricing Information

We provide a transparent cost structure to facilitate budget planning and financial oversight. Detailed pricing information, including drug costs, administrative fees, and potential savings through kit pricing including supplies, UM, and PBM administrative fees. We will guarantee our pricing for one year from contract date. We are presenting price ranges as we do not yet know the final program requirements.

[REDACTED]	[REDACTED]	[REDACTED]	Utilization Management Program	PBM administrative fees	All-Inclusive Price Range
[REDACTED]	[REDACTED]	[REDACTED]	Prior Authorization		Drug
[REDACTED]	[REDACTED]	[REDACTED]	Step Therapy		Supplies
[REDACTED]	[REDACTED]	[REDACTED]	Weight and BMI tracking		Shipping
[REDACTED]	[REDACTED]	[REDACTED]	Compliance with Behavioral Health programs		UM and PBM Fees
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]	Utilization Management Program	PBM administrative fees	All-Inclusive Price Range
[REDACTED]	[REDACTED]	[REDACTED]	Prior Authorization		Drug
[REDACTED]	[REDACTED]	[REDACTED]	Step Therapy		Supplies
[REDACTED]	[REDACTED]	[REDACTED]	Weight and BMI tracking		Shipping
[REDACTED]	[REDACTED]	[REDACTED]	Compliance with Behavioral Health programs		UM and PBM Fees
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	Utilization Management Program Prior Authorization Step Therapy Weight and BMI tracking Compliance with Behavioral Health programs	PBM administrative fees	All-Inclusive Price Range Drug Supplies Shipping UM and PBM Fees
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]			
[REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	Utilization Management Program Prior Authorization Step Therapy Weight and BMI tracking Compliance with Behavioral Health programs	PBM administrative fees	All-Inclusive Price Range Drug Supplies Shipping UM and PBM Fees
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]			

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Prices for average dose in the two solutions

Revelation's all-inclusive solution is between [REDACTED] [REDACTED] [REDACTED] with the biggest difference being whether the Plan will qualify for rebates when GLP-1 agonists and similar products are used for weight loss and subjected to UM.

Conclusion

Revelation is committed to working collaboratively with the North Carolina State Health Plan to achieve the shared goal of improving health outcomes for Plan members while maintaining financial sustainability. Lack of adequate supply of GLP-1 agonists and the cost to NCSHP are the primary reasons for these medications not remaining on the plan's formulary, while a strong desire by the State to have these medications available for their beneficiaries remains. The Revelation solution enables the State to reconsider adding GLP-1 agonists and similar products back to the plan's formulary utilizing high-quality compounded medications delivered directly to the NCSHP beneficiaries' homes with our temperature-controlled shipping. Our solution is fiscally responsible and economically feasible solution while maintaining quality assurance, service, and patient care. Including GLP-1 agonists and similar products on the NCSHP formulary for weight loss could dramatically improve the health outcomes and morale of the plan's beneficiaries while avoiding an additional [REDACTED]

[REDACTED] We are confident that our proposed solutions will meet the Plan's needs and look forward to the opportunity to partner with you.

Thank you for considering our response. Should you require any additional information or clarification, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Jon Pritchett". The signature is written in a cursive, flowing style.

Jon Pritchett, Pharm.D., RPh., BCSCP, FAPC
Chief Operating Officer
Revelation Pharma Corporation