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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. Our solution relies on customized utilization management from your current PBM vendor Caremark. The pharmacy management software in our dispensing pharmacy has been operational for years, and does not introduce any risk to the solution.

### **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 provided by Caremark
- 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 your PBM/UM partner CVS Caremark, 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, effective, and cost-effective compounded GLP-1 agonists and similar products are available from Revelation's high quality 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 CVS Caremark. If it is a new prescription, CVS Caremark will conduct customized UM meeting all the requirements of NCSHP. The Plan can work with them to not accept attestation but 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. CVS Caremark currently hosts up-to-date eligibility. Caremark will need to add Revelation to its pharmacy network for NCSHP and add our compounded product kits to the Plan formulary.

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 Caremark.

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

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. All authorizations would be conducted by Caremark.

## **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. 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].

- **Variable Unit Cost Payments:** Implement a system where payments vary based on medical necessity and patient-specific factors such as BMI and comorbid conditions
- **Claims Auditing:** Regular internal audits to ensure compliance with all applicable regulations, program features, and to identify cost-saving opportunities

Revelation is a compounding pharmacy. We do not provide UM, rather we act on the UM decisions of other organizations, in this case CVS Caremark. In partnership with patients, their prescribers, your UM provider, we will collect and act on each patient's progress, ADEs, and adherence to treatment.

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 generated by compounded products. Terms and conditions for rebates for the weight loss indication of GLP-1 agonists and similar manufactured products 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 prescription processing, compounding, ADE monitoring, adherence, and collection accuracy.

### **C. Eligibility Requirements and Parameters**

We propose setting clear eligibility criteria and prerequisites with CVS Caremark, 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.

Caremark will implement your customized UM program including PA, step therapy, accurate and accountable weight and BMI measurements, and completion of approved behavioral modification programs. Revelation will follow their lead and dispense high-quality compounded products and attendant supplies.

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 in direct contact with prescribers as part of the dispensing role. This direct communication will serve to improve progress to treatment goals for participating patients.

### **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.

Your UM program will be provided by CVS Caremark. They will instruct us on whether or not to fill or refill a prescription. We will provide reports to NCSHP detailing program information: number of participants by copay level and duration of therapy.

**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. We will guarantee our pricing for one year from award.

[REDACTED]	[REDACTED]	[REDACTED]	All-Inclusive Price Range Drug Supplies Shipping
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	All-Inclusive Price Range Drug Supplies Shipping
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	All-Inclusive Price Range Drug Supplies Shipping
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED] Blank on purpose

[REDACTED]	[REDACTED]	[REDACTED]	All-Inclusive Price Range Drug Supplies Shipping
[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] Revelation's discounts are available at the time of dispensing whereas rebates would be paid 180 or more days after dispensing.

## Conclusion

Revelation is committed to working collaboratively with the North Carolina State Health Plan and its UM provider 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 a 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]. We are confident that our proposed solution 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,



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