STATE OF NORTH CAROLINA **Department of State Treasurer** NC State Health Plan for Teachers and State Employees	**REQUEST FOR INFORMATION NO.** 270-20240419GLP Due Date: May 31, 2024, 2:00 PM ET
Refer ALL Inquiries to: Kimberly Alston, Contracting Agent	Issue Date: April 19, 2024 Commodity: 851017 Health Administration Services
E-Mail: Kimberly.Alston@nctreasurer.com with a copy to SHPContracting@nctreasurer.com	Using Agency Name: NC State Health Plan for Teachers and State Employees

MAILING INSTRUCTIONS: Respondents shall submit one (1) signed, original paper response, and one (1) electronic copy on a flash drive and one (1) redacted electronic copy on a flash drive, if applicable pursuant to Section 3.0.D. The address label shall clearly note the RFI number as shown below. It is the responsibility of the submitting entity to have the RFI in this office by the specified time and date of opening.

DELIVERY ADDRESS
RFI NO. 270-20240419GLP NC Department of State Treasurer State Health Plan Division Attn: Kimberly Alston, Contracting Agent 3200 Atlantic Avenue, Raleigh, NC 27604

NOTICE TO RESPONDENTS

Responses to this RFI will be received at the address above until May 31, 2024, 2:00 PM ET.

QUESTIONS

Email written questions no later than April 30, 2024, 5:00 PM ET to Kimberly.Alston@nctreasurer.com with a copy to SHPContracting@nctreasurer.com.

EXECUTION

RESPONDENT NAME: Signature Rx	E-MAIL: Hughes.david@signature-rx.com Anthony@signature-rx.com	
STREET ADDRESS: 1107 Wallace Dr.	P.O. BOX:	ZIP: 33444
CITY & STATE: Delray Beach FL	TELEPHONE NUMBER: 954-856-0656	TOLL FREE TEL. NO:
TYPE OR PRINT NAME & TITLE OF PERSON SIGNING: David Hughes	FAX NUMBER:	
AUTHORIZED SIGNATURE: DocuSigned by: David Hughes 59D469BA5CFF43A...	DATE: May 29, 2024	

1.0 EXECUTIVE SUMMARY

The North Carolina State Health Plan for Teachers and State Employees ("Plan"), a division of the North Carolina Department of State Treasurer, provides health care coverage to more than 740,000 teachers and school personnel, State Employees, retirees, current and former lawmakers, state university and community college personnel, and their dependents. The mission of the State Health Plan is to improve the health and health care of North Carolina teachers, State Employees, retirees, and their dependents, in a financially sustainable manner, thereby serving as a model to the people of North Carolina for improving their health and well-being.

2.0 PURPOSE AND OBJECTIVES OF THE REQUST FOR INFORMATION

The Plan's net spend on glucagon-like peptides (GLP-1s) and gastric inhibitory polypeptide (GIP) agonists for weight loss exceeded $100 million in 2023 and was projected to exceed $170 million in 2024. In order to limit this financially unsustainable expense, the Board of Trustees for the State Health Plan for Teachers and State Employees ended coverage of GLP-1s, GIP-GLP-1 agonists and other similar molecular entities used for weight loss as a benefit effective April 1, 2024.

The Board further directed Plan staff to explore options that may allow members who need these medications the most to obtain them, informed by medical necessity and long-term cost effectiveness, under a fiscally sustainable model, budgeted over at least the next five years. To that end, the Plan is issuing this Request for Information (RFI) to gather ideas and solutions from the marketplace.

This RFI is intended to collect information, recommendations, and potential solutions for the Plan to consider respecting the feasibility of providing benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss in a manner that is financially sustainable for the Plan.

The Plan is seeking responses outlining detailed solutions that would address the following:

A. Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss.

B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:

    1. Pay for varying percentages of the unit cost according to medical necessity considerations.
    2. Receive the same effective net price if the Plan only choses to pay for a medication for an additional FDA indication without paying for it for all other indications.
    3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.

C. Potential for establishing a program outlining certain eligibility requirements, parameters, or other prerequisites for Plan members to follow in order to receive benefit coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for weight loss. As a result, the Plan seeks the ability to:

1. Require that an approved weight loss program or nutrition classes be completed before approval of payment for the medication.
2. Develop step therapies involving lower cost medications.
3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.
4. Prohibit Body mass index (BMI) measurements from being estimated via telehealth visit to ensure accuracy and accountability, while enabling a data collection process that supports the successful implementation of the benefit.

D. Potential for establishing a program wherein the Plan has the flexibility to establish parameters for utilization management of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss, which may include considerations such as, but not limited to:

1. BMI;
2. Current weight;
3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity;
4. Documented enrollment and measurable participation in other nutritional or dietary programs;
5. Consideration of evidence for one or more comorbid conditions or other obesity-related medical conditions;
6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;
7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or
8. Any other considerations or parameters that would support a program to achieve the Plan's objectives of serving the members who need these medications the most.

E. Provide cost, price structures, or other relevant expense information related to the recommendations and potential solutions submitted.

3.0 RFI PROCEDURES

A. Schedule

Responses must be received by the date, time and the location specified on the cover sheet of this RFI. Respondents may be requested to present and discuss their submissions at the Plan's offices in-person or remotely. If the Plan requests such a presentation, respondents will be notified of the specific date and time at least two weeks in advance of any presentation.

B. Clarification Questions

Clarification questions will be accepted until April 30, 2024, 5:00 PM ET as specified on the cover sheet of this RFI (the "Clarification Period"). All questions must be submitted in writing. Responses to all questions received shall be addressed and issued as an addendum to this RFI. During the Clarification Period, respondents are strongly encouraged to raise any and all

questions or concerns about the RFI. Any questions or concerns not raised during this period are considered waived by the respondent.

Question submittals should include a reference to the applicable RFI section and be submitted in the format shown below:

No.	Reference	Respondent Question
1.	RFI Section, Page Number	Respondent Question . . . ?

C. Response

The Plan recognizes that considerable effort will be required in preparing a response to this RFI. However, please note this is a request for information only, and not a request for services. The respondent shall bear all costs for preparing this RFI. **Under no circumstances will any documents, information, recommendations, or potential solutions submitted in response to this RFI, or any communications between the Plan and a respondent, create a binding agreement or contract, or expectation thereof, between the Plan and respondent or between the State of North Carolina and respondent.**

1. Content and Format

The Plan expects a comprehensive, detailed explanation of the workings of each component of the response. Each component of the response will explain how it will operate to address the needs and objectives of the Plan as identified in Section 2.0. The Plan is not interested in brochures or "boilerplate" responses. Instead, responses should clearly define how the proposed solution(s) would meet the Plan's needs. Any issues or exceptions to the Plan's requirements should also be identified and explained.

The response may include charts, graphs, or other visuals that assist in demonstrating how a component of a response operates or how that component would meet the Plan's objectives.

A comprehensive, detailed equipment list including software, applications and other information technology components required for the proposed solution should be provided. The Plan is not interested in participating in any field trials of new equipment or software.

The response should define all services that would be required by the proposed solution. The response should also include:

- The respondent's understanding of the project and services by addressing the Plan's objectives; and
- An estimated total cost of ownership for the solution including continued compliance with emerging industry standards.

2. Multiple Responses

Multiple responses, or alternative individual solutions will be accepted from a single respondent provided that each response is comprehensive, meets all of the Plan's requirements, and is truly unique. If submitting multiple responses, place each response in a separate envelope and clearly mark responses as "Response #1, Response #2, etc.

D. Confidentiality

Responses obtained by the Plan under this RFI and items derived therefrom are subject to the State Public Records Act, Chapter 132 of the North Carolina General Statutes (the "SPRA").

If a response contains any proprietary or confidential information protected from public disclosure under the SPRA, the respondent shall submit a redacted electronic copy on a flash drive to the Plan with its response. Any proprietary or confidential information under the SPRA must be clearly redacted by the respondent in black markings fully covering and obscuring such information within the redacted electronic copy of the RFI response. By submitting a redacted electronic copy, respondent warrants that it has a good faith opinion that the redacted information in fact meet the requirements of the SPRA and the SPRA prevents their public disclosure. Blanket assertions of confidentiality are not permitted.

In the Plan's unfettered discretion and without notification to any respondent, the Plan may post any responses obtained by the Plan under this RFI, and items derived therefrom, on the Plan's public website (www.shpnc.org). In posting such items to the Plan's website, the Plan will post the redacted version of such items, if respondent has provided redactions in compliance with this section. If no redacted version of such items has been provided to the Plan in compliance with this section, the Plan will post such items on the Plan's website in the manner they were provided to the Plan.

Redacted copies provided by respondents to the Plan may be released in response to SPRA requests without notification to the respondent. Further, respondent's information that cannot be shown to be prohibited from disclosure by the SPRA may be subject to public disclosure under the terms of the SPRA.

If a legal action is brought to compel the Plan to disclose any of the respondent's redacted information, the Plan will notify the respondent of such action and consent to intervention of the respondent in the action and to the respondent's defense of the confidential status of the redacted information. In such legal action, the duty and responsibility to defend such information shall solely be the respondent's, and the Plan shall have no liability to the respondent for the Plan's failure to defend such action.

E. Respondent Materials

All responses, inquiries, or correspondence relating to or referenced in this RFI, and all documentation submitted by the various respondents shall become the property of the Plan when received. Ideas, approaches, information, recommendations, potential solutions, and options (but not proprietary material) presented by respondents may be used in whole or in part by the Plan in developing a future solicitation, should the Plan decide to proceed with a solicitation. Further, combinations of various responses from respondents may also become part of a solicitation, based on the needs of the Plan.

SignatureRx

1107 Wallace Dr Delray Beach FL

REQUEST FOR INFORMATION NO. 270-20240419GLP

Attn : Department of State Treasurer

NC State Health Plan for Teachers and State Employees

To whom it may concern:

We are honored and delighted to submit our following proposal as we fully understand the situation and challenges the State has experienced in regards to GLP-1 coverage and managing that expense while trying to do the best possibly can for your employees under the reality of current budget constraints.

SignatureRx is a FDA approved 503B outsourcing facility located in Delray Beach, FL focused on sterile drugs on the FDA short supply list, which obviously includes GLP-1s.

In addition to the ability to produce any and all GLP-1, GIP-GLP-1 agonists that are on the FDA shorty supply list which includes most if not all current big manufacturers brands, we have partner companies that can provide the pharmacy services required to provide to patients a unique refillable cartridge injector pen with metered doses similar to the branded products. This solution is not only significantly more cost efficient, but we can offer a consistent, reliable supply chain and it is more environmentally friendly due to the refillable cartridge model rather than disposable pens the big brands currently utilize.

Please see attached document enclosed with more details on the injector pen and SignatureRx in general.

With a current facility of over 10,000 square feet and robotic production lines, we can produce over 1 million units of monthly dose cartridges of GLP-1 drugs, with plans to expand this production capacity within the next 9 to 12 months to several million units per month with an additional facility of over 150,000 square feet in process.

Our simple yet effective proposal is to offer our GLP-1 solution at the cost of $400 for the first month supply which includes the reusable and refillable injector pen and subsequent monthly refill cartridges at only $200.

The Plan can decide whichever criteria and eligibility parameters see fit with no set restrictions imposed by us or our pharmacy service partners.

With the significantly lower cost to the Plan and the ability for the Plan to set and manage all eligible requirements that your team determines makes the most sense, we are confident it will enable the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss and accomplish the goal of managing the current budget for doing so.

We have no issues whatsoever with helping to achieve and accomplish the Plan goals:

1. Pay for varying percentages of the unit cost according to medical necessity considerations.

2. Receive the same effective net price if the Plan only choses to pay for a medication for an additional FDA indication without paying for it for all other indications.

3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.

We look forward to the opportunity of meeting with our team and the Plan's team to work out the further details, cover all concerns, and of course ensure all relevant compliance matters are fully addressed in order to achieve the Plan's objectives in providing a solution for GLP-1s for its employee members.

Please feel free to contact us anytime via email or call with contact information following below.

Thank you for the opportunity and your consideration in our proposal.

Sincerely,

David Hughes

CEO

SignatureRx

Hughes.david@signature-rx.com

Signature Rx: Auto Injector Pen

Affordable, Eco-Friendly, and Always Accurate

SIGNATURE RX

503A - 503B

Introducing the Signature-Rx Auto Injector Pen

To enhance the affordability of our 503B GLP-1 product line, Signature-Rx has developed an innovative solution. We manufacture a reusable glass cartridge that seamlessly fits into our Auto-Injector pen, providing users with a convenient one-month supply of four precisely metered doses. This glass cartridge is easily replaceable, ensuring a consistent supply for our customers.

As part of our commitment to sustainability, we include four sterile 23g BD needle tips with each monthly shipment. This approach not only reduces costs but also contributes to environmental conservation by significantly minimizing plastic waste, which is prevalent with disposable pens used by other branded GLP-1 products on the market today.

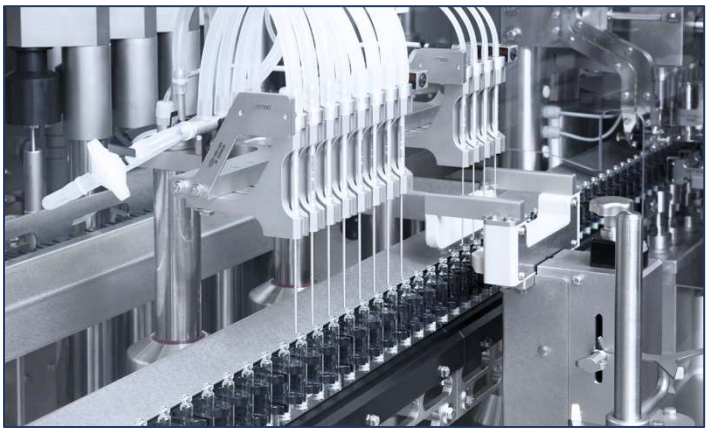
Our ingenious methodology is designed to make healthcare more accessible and environmentally friendly while offering substantial cost savings compared to competitors' products that rely on disposable plastic pens discarded after each use.

Background

Signature-Rx has leveraged an FDA-approved 510k Re-Usable metered dose auto injection pen, offering remarkable convenience and significant cost savings. This innovative device allows users to effortlessly replace the glass bullet-type cartridge with a fresh 503B Signature-Rx supplied cartridge, accompanied by four user-friendly, sterile screw-on 23g BD needle tips. As a result, patients can enjoy four precisely controlled metered doses per month at approximately one-third of the cost compared to current branded products.

Operating under the strict guidelines of the FDA's 503B regulations, Signature-Rx manufactures products of identical quality, utilizing formulations directly sourced from renowned drug manufacturers such as NovoNordisk and EliLilly.

These regulations compel manufacturers to collaborate with certified 503B cGMP facilities like Signature-Rx, ensuring the same stringent quality control standards and the use of USA-based ingredients found in branded drugs. This starkly contrasts with compound pharmacies that employ low-cost, China-derived ingredients with sodium bases intended solely for research purposes, not patient use.



Signature-Rx boasts state-of-the-art, German-made Bausch Systems fully robotic Glass Cartridge Filling lines, capable of producing an impressive 200 cartridges per minute. This technology guarantees an uninterrupted and robust supply chain, mitigating the risk of contamination prevalent in compound pharmacies that rely on manual labor in uncontrolled, non-cGMP environments when producing sterile subcutaneous drugs.

Strategic Partnerships

Signature-Rx is actively pursuing strategic alliances with insurance carriers to integrate our GLP-1 NDCs into their formulary with PBMs. This collaboration alleviates the financial burden borne by insurance carriers and TPAs. Current wholesale acquisition costs (WAC) stand at approximately $1400 per month, while Signature-Rx offers the same quality 503B manufactured product for under $400, with refills priced under $300. This remarkable cost-saving measure empowers insurance carriers to extend GLP-1 product accessibility to three times as many customers at a fraction of the current expenditure.

Addressing Healthcare Challenges

Studies have underscored the substantial threat posed by individuals predisposed to diabetes and those contending with obesity-related health challenges to insurance carriers' bottom lines. These conditions necessitate extensive medical interventions and costly medications, highlighting the pivotal role of cost-effective solutions.

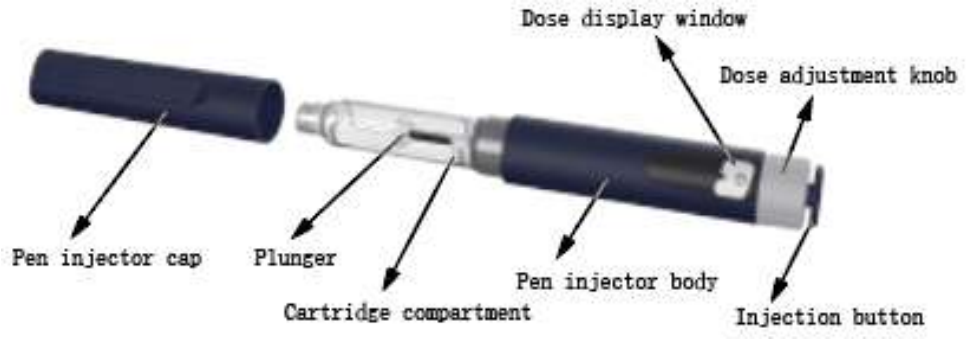
How It Works

Preface

Manufactured by Wuxi NEST Biotechnology Co., Ltd, the pen injector can be reused up to 3000 times for a full dose of 75 units. This product is suitable for standard 3mL cartridge pen refills and disposable injection needles. The injection dose can be adjusted between 1 and 75 units, with a scale value of 1 unit. This is intended for use by self-sufficient adult patients and professional caregivers according to medical advice.

Product Application

The pen injector consists of a body, a plunger, an injection button, a dose display window, a dose adjustment knob, a cartridge compartment, and a cap. The pen injector is used in conjunction with the cartridge and the disposable injection pen needle for subcutaneous injection of drugs.



Product Performance

When the dose adjustment knob rotates by one integer mark, a "click" sound should be heard, and the scale should not change when no external force is applied to the injection button. The accuracy of drug delivery dose should be within ±5% of the set injection dose. The product's service life is determined by whichever comes first between "3000 times of repetitive use" and "5 years".

Sustainable Cartridge System

Our Auto Injector Pen utilizes a replaceable glass cartridge, providing users with a one-month supply comprising 4 precise metered doses. This forward-thinking approach not only enhances patient convenience but also promotes environmental responsibility by drastically reducing plastic waste.

Our Company

Signature-Rx is supported by private equity, fortified by industry expertise, and operates from a cutting-edge 2023 facility spanning 11,000 square feet in Delray Beach, Florida. Our facility is equipped with state-of-the-art 2023 Bausch Systems Fully Robotic drug manufacturing production lines. We maintain stringent quality standards and adherence to 503B FDA guidelines and protocols through fully robotic Italy-based Anteris Vision inspection and QC lines.

Choose Signature-Rx for precision, cost-efficiency, and environmental stewardship in GLP-1 product delivery.

SIGNATURE RX

503A - 503B

REQUEST FOR INFORMATION NUMBER:270-20240419GLP
ADDENDUM NUMBER:1

REQUEST FOR INFORMATION (RFI) ADDENDUM

Issuing Agency:	North Carolina State Health Plan for Teachers and State Employees
RFI Number:	270-20240419GLP
RFI Description:	GLP-1 Solutions
RFI Opening Date and Time:	May 31, 2024, 2:00 PM ET
Addendum Number:	1
Addendum Date:	May 6, 2024
Purchasing Agent:	Kimberly Alston

FAILURE TO RETURN THIS ENTIRE ADDENDUM MAY SUBJECT YOUR RESPONSE TO REJECTION.

1. Addendum Number 1 is in response to questions submitted. Responses to questions begin on the next page.

2. Return one signed copy of this Addendum with your RFI response.

****

Execute Addendum Number 1, RFI Number 270-20240419GLP:

Respondent: Signature Rx

Authorized Signature: DocuSigned by: David Hughes 59D469BA5CFF43A...

Name and Title (Print): David Hughes

CEO

Date: May 29, 2024

REQUEST FOR INFORMATION:270- 20240419GLP
ADDENDUM NUMBER:1

Question #	Document Section	Respondent Question	State's Response
1	General	Since [Our Business] and the procedure of endoscopic sleeve gastroplasty (ESG) isn't a GLP-1 or manufacturer, what is your suggestion for us re: the RFI? We believe that ESG would be an excellent option for the NCSHP to consider.	Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan requests that you submit any information, potential solutions, or alternatives relevant to the matter of weight loss benefits/solutions, for the Plan's review and consideration as a response to the RFI.
2	General	What is the timeline for a potential decision? What is the desired go-live date?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.
3	General	Who is North Carolina State Health Plan for Teachers and State Employees pharmacy benefit manager? Is RX carved in or out of the health plan?	The Plan's Pharmacy Benefit Manager (PBM) is CVS Caremark. Pharmacy is carved out from the medical benefit. The Plan's current third-party administrator is Blue Cross Blue Shield of North Carolina.
4	Section 1.0, Page 2	Is there a current vendor providing these services? If so, how may I obtain copies of any incumbent contract documents?	The Plan discontinued coverage for GLP-1s, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss effective April 1, 2024. These benefits were provided through the Plan's PBM Contract. No current vendor provides services that includes these molecular entities as a covered benefit for weight loss. The Plan follows the provisions of the North Carolina Public Records Act for public documents with requests submitted to PublicRecords@nctreasurer.com.
5	Section 2.0, Page 2	Who/what type of physician was prescribing the majority weight loss drugs?	There were no limitations on the type of provider with prescribing authority that can prescribe these medications. That is true for all medications. The requirement is only that the member have a valid prescription and meet the utilization management requirements (if applicable).
6	Section 2.0, Page 2	If this RFI greenlights a solicitation, what is the estimated time frame for procurement?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.

REQUEST FOR INFORMATION:270- 20240419GLP
ADDENDUM NUMBER:1

Question #	Document Section	Respondent Question	State's Response
7	Section 2.0, Page 2	What is the anticipated contract value?	This is a request for information only, and not a request for services. We do not have an anticipated contract value at this time.
8	Section 2.0, Page 2	What is the number of patients who were taking GLP-1 and GIPs for weight loss in 2023? What is the estimated growth year over year? Goals for the program for the next 5 years?	There were approximately 24,750 utilizers in calendar year 2023. The estimated growth year over year is 51.2% in 2024; 28.6% in 2025 and 14.8% in 2026. The Plan's goal is to have a solution in place that permits benefit coverage for Plan Members in a financially sustainable manner.
9	Section 2.0 B.1., Page 2	B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to: 1. Pay for varying percentages of the unit cost according to medical necessity considerations. Can you please elaborate on what this is referring to (i.e., GLP-1)?	Under this cost model, the member's cost share for the medication would vary based on need. For example, a member with a lower BMI and no chronic conditions would have a higher cost share than someone with a BMI of 40 and multiple comorbidities.
10	Section 2.0 B., Page 2	Is there a list of medications that ideally would be included for weight loss? Will the state consider "off-label" prescriptions i.e., Ozempic for weight loss instead of Wegovy or Moujaro instead of Zepbound? Is the state open to alternative options such as sterile compounding for these medications while they're on the FDA shortage list?	The specific brand names may expand over time but currently include Saxenda, Wegovy, and Zepbound. The Plan is aware of the possibility for off label use by prescribers and have put specific utilization management guidelines in place to avoid this. The Plan is not interested in off labeled use of a GLP-1, GIP-GLP-1 agonist FDA approved for diabetes (Ozempic, Mounjaro, etc) within our current PBM framework. Consequently, any off labeled use would have to be fully separate from the existing pharmacy benefit administrative processes. The Plan is open to reviewing all legal, feasible, and fiscally sound solutions. Any solution would have to be structured such that it would be administratively feasible.

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ADDENDUM NUMBER:1

Question #	Document Section	Respondent Question	State's Response
11	Section 2.0 C., Page 2	What were the specific parameters for coverage for GLP-1 and GIPs for weight loss before they were removed from the plan? Is there any data from when the meds were covered on efficacy of certain programs or requirements?	The Plan was using the standard utilization management guidelines for the GLP-1 and GIP-GLP-1s for weight loss provided by our PBM (CVS Caremark). This included a prior authorization in line with FDA approved BMI criteria, participation in a comprehensive weight management program for at least 6 months prior to using drug therapy, and quantity limits. Prior to 1/1/2024 this prior authorization permitted attestation from providers and did not require documentation. CVS Caremark updated the standard UM beginning 1/1/2024. This update requires documentation of BMI and comorbid conditions (if applicable). However, the update does not require documentation for participation in a weight management program - CVS permits an attestation. Grandfathered members eligible after 1/1/2024 that had prior authorizations due between 1/1/2024-4/1/2024 were subject to these new guidelines.
12	Section 2.0 C.1., Pages 2 and 3	Would group sessions, virtual coaching or webinar format be allowable for lifestyle coaching options? Will you allow any health coaches who are not certified NBC-HW? (National board-certified health wellness)	Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan is open to reviewing all alternatives and potential solutions.
13	Section 2.0 C.4., Page 3	Please explain the prohibition on BMI measurements via telehealth. Given the rural nature of North Carolina, in person measurement requirement is likely a very large barrier to care.	The Plan begins within a frame of reference that a provider should meet with the patient to assess BMI and clinical necessity. However, solutions that meet the objective of ensuring an accurate and medically appropriate diagnosis and include components to subsequently ensure correct measurements that maintain accountability for continuation of therapy would be welcomed.
14	Section 2.0 D.1., Page 3	Is a waist to height or waist to hip ratio acceptable in lieu of BMI for program qualification?	The Plan prefers to use BMI for program qualifications if for no other reason than it is used by the FDA for indication, but the Plan would be open to multiple measures that represent alternative thinking.

REQUEST FOR INFORMATION:270- 20240419GLP
ADDENDUM NUMBER:1

Question #	Document Section	Respondent Question	State's Response
15	Section 2.0 D.3., Page 3	Are there any specific qualifications or components required for the weight loss lifestyle management?	There are on specific requirements, but documentation of participation and completion will be required. Attestations will not be sufficient.
16	Section 2.0 E., Page 3	What are the determinants of the program decision in terms of weighted value? -Price -Patient experience -Overall value -Small business/Local NC business	There are no set determinants for making program decisions at this time. The Plan will review all submissions for feasibility and achieving the Plan's fiscal goals solutions.

David Hughes, PharmD, R.Ph., ABAAHP, PAHM

Pharmaceutical Compounding/Manufacturing • cGMP • Specialty / Infusion • Operations • PBM

Multifaceted Healthcare Executive with a unique mix of strategic business experience, clinical background, Ivy League Medical School faculty appointment, and exceptional educational credentials. Experienced in all areas of pharmaceuticals, healthcare management, DEA/State regulatory and compliance. Experienced in building, maintaining, and leveraging relationships with key opinion leaders.

Areas of Expertise

P&L • Strategic Planning • cGMP Compliance • Operations Director • Health Informatics • Healthcare Marketing • Product Development & Launch • Business Development • Vendor and KOL Management • Project Management • Contracts • Training and Teambuilding • Publications • Regulatory Compliance • Pharmaceutical Sales • Account Management

PROFESSIONAL EXPERIENCE

Insight Hospital and Medical Center – Chicago and Michigan Operations 2022 - Present
VP, Chief Pharmacy Officer

- C-Suite executive overseeing all Insight pharmacy operations
    - Operations, business development, and oversight for health-system pharmacy operations across Chicago and Detroit area delivery networks including inpatient pharmacy, specialty pharmacy (outpatient), and HOPD infusion sites.
    - Care Signature implementation across all medical and pharmacy service lines throughout the health-system including ER, Oncology, Neurology, Surgery, OBGYN, Allergy and Immunology, Pediatrics, etc.
    - Business planning and strategy for rapid expansion of Insight Hospital and Medical Center's 340b program initiatives including specialty pharmacy and home infusion

Yale New Haven Health System, New Haven, CT 2019 - 2022
Director, Home Infusion Therapy and IV & Sterile Compounding
Pharmacy Executive Leadership (PEL)

- Pharmacy Executive Leadership lead on health-system wide home infusion pharmacy initiative
    - Strategic operations and business development of Yale New Haven Health System's home infusion pharmacy service line
    - $200M business plan to offer continuity of care throughout the six hospital system (3,000 beds) covering Connecticut, New York, and Rhode Island.
    - Expanding the Advanced Care at Home initiative for post-acute-care initiatives and offering continuity of care with an internal service line for specialty infusion therapy (site-of-care restrictions)

- Responsible for the management of all operations of facilities and divisions related to outpatient infusion therapies including post-acute-care therapies and specialty infusion therapies. Responsibilities include but are not limited to:
    - Pharmacy operations, business development, marketing, network contracting, pharma contracting, procurement, HIT billing**,** Leadership, registered/non-registered staff selection, hiring, management
    - Quality improvement implementation and supervision, accreditation, licensing, and regulatory oversight.
    - USP<797>, <800> sterile compounding oversight and clean room oversight/compliance.

Yale New Haven Health / Yale Medicine Committee Memberships:
Home Infusion Therapy Multidisciplinary Committee - Chair
Post-Acute Care Executive Committee – member
High Cost Drug Infusion Committee – Co-Chair/Sponsor
Chief Operation Officer Executive Operations Committee – member

National Committee Memberships:
CarePathRx – Home Infusion Executive Advisory Board
Vizient – Home Infusion Subcommittee
Excelera Rx – Home Infusion Subcommittee

Tri-Unity Infusion Services, New Buffalo, MI & Chicago, IL 2018 - 2019
PCAB®/ACHC Specialty/ACHC Infusion Rx Accredited
Senior Director, Pharmacy Operations

- Responsible for the management of all operations of pharmacy facilities and divisions. Responsibilities include but are not limited to:
    - Pharmacy operations, business development, marketing, network contracting, HIT billing ○ Leadership, registered/non-registered staff selection, hiring, management
    - Quality improvement implementation and supervision ○ Goal setting and attainment

- Accreditation lead for specialty, infusion Rx, and PCAB® sterile/non-sterile compounding ○ ACHC Specialty Pharmacy – successfully achieved accreditation ○ ACHC Infusion Rx – successfully achieved accreditation ○ ACHC Infusion Nursing – successfully achieved accreditation ○ PCAB® Sterile/non-sterile – successfully achieved accreditation

Coral Pharmaceuticals, Nassau, Bahamas
cGMP and Facility Design Consultant 2015 - Present

- 503b Facility Consultant
- Responsible for formulation development including but not limited to IV, oral, sublingual, transdermal, and inhaled dosage forms.
- Head of quality assurance for product development/manufacturing assuring cGMP compliance.
- Clinical liaison to key opinion leaders (KOLs), patients, and vendors.
- Marketing and sales of pharmaceutical products developed and distributed by Coral.

Phusion Rx, PCAB® Accredited Specialty Pharmacy, Coventry, RI 2011 – 2018
Founder, CEO & President, Director of Business Development and Pharmacy

- Founder and lead on entrepreneurial endeavor to develop a unique pharmaceutical and health care operation utilizing the latest health care and pharmaceutical innovations to develop and deliver quality products.
- Integrating health care and pharmacy to provide a continuum of care from patient to physician to pharmacist.
- Responsible for the management of all operations of Phusion Rx and its divisions. Responsibilities include but are not limited to:
    - Pharmacy operations, business development, marketing, clinical trial management, network contracting, healthcare provider education, and all other aspects of pharmacy operations.
    - Quality Assurance and USP and cGMP Compliance.
- Grew the business from the ground up to over $11 million in sales.
- Provided scientifically and clinically rigorous presentations to KOLs, product advocates, and managed care organizations.
- Establish/maintained relationships with KOLs, customers and medical specialty societies.
- Successfully launched products and established logistics and limited distribution contracts for products requiring REMS

HEB RxTRA Advantage PBM, San Antonio, TX, 2010-2011
Clinical Account Executive-
Business Development Director (BDD)-

- Clinical Lead on the launch of a new pharmacy benefit management (PBM) product with MedImpact and H-E-B Pharmacy.
- Responsible for management of all operations of the PBM and wellness services offered under the H-EB RxTRA Advantage product portfolio.
- Responsibilities include but are not limited to: o formulary development, clinical program management, contracting with pharmaceutical companies for product rebates and formulary inclusion, sales support, plan design, clinical consultation, pharmacy network contracting, utilization and trend analysis, and all other aspects of client support and PBM operations.
- Spearheaded launch of co-branded PBM powered by MedImpact®
- Successfully grew the business from inception to over one million lives.
- Lectured groups of over 400 physicians and other healthcare providers on pharmaceuticals and appropriate therapeutic utilization.

- Successfully negotiated contracts with pharmaceutical companies to obtain competitive rates and rebate programs.

CVS HEALTH, Woonsocket, RI, 2006 – 2010

Senior Manager, eBusiness and Technology

- Promoted to lead all pharmacy and health services business for online properties.
- Directed all pharmacy and health operations for flagship consumer website, CVS.com, with over 7M unique visitors/month and over 5M pharmacy prescription transactions representing $300M in sales.
- Supported PBM web portal, caremark.com, and worked cross-functionally to develop new programs to increase generic substitution, therapeutic alternatives for single-source brands, and lowest cost channel.
- Spearheaded digital strategy for enterprise core marketing campaigns.
- Liaised with Pharmacy and Store Operations to dovetail processes with eBusiness.
- Ensured regulatory compliance, accreditation, and licensing for website and brick and mortar facilities.
- Directed multiple technology and content vendor relationships that included negotiations/contracts.
- Led a team of 10 with 3 direct reports, and managed online pharmacy marketing budget.
- Spearheaded pharmacy and health services business unit for 2+ year and completed a relaunch of CVS.com. Tasks included but weren't limited to:
    - Managed a team of 100+ offshore developers in development of all healthcare service products, including consumer electronic health record (EHR) that enables patients to view, print, and refill CVS/pharmacy prescription records utilizing HIPAA compliant web application.
    - Successfully launched new CVS.com, for 100% growth in web traffic and revenue, increased patient retention, and better prescription adherence with online multi-channel customers. ○ Grew revenues from retention and incremental prescriptions by $360M.
    - Serving as CVS Caremark digital strategy lead on H1N1 enterprise Flu Task Force, developed requirements for CVS.com flu shot locator and flu center. Spearheaded email marketing campaign. Contributed directly to operational plan for US wide administration of flu vaccines.
    - Successfully implemented CVS.com flu locator on CVS.com and integrated pharmacy and Minute Clinic flu vaccine availability with Google Flu Shot locator.
    - Email and online marketing campaign drove 2M+ users to search for/locate season and H1N1 flu vaccines.
    - Exceeded target and administered 2M seasonal flu and H1N1 vaccinations.
    - Challenged to completely rethink pharmacy operations for CVS.com Online Pharmacy and returned business unit to profitability after rapid loss of sales, with no adverse impact on CVS retail sales.
    - Developed business model utilizing nationwide distribution capabilities and 3rd-party network to distribute prescription products that might otherwise have limited distribution due to orphan drug status or buy-and-bill market.
    - Successfully implemented 4 major Pharma programs to grow slipping facility pharmacy sales of $6M annually to $13M in 2009 with projected $25M million in 2010.
    - Packaged new business model to support patient-assistance-programs (PAP) for Pharma companies.
    - Spearheaded submission of multiple RFPs winning a majority of contracts.
    - Served on enterprise core teams including Privacy Committee, Digital Strategy Team, and Private Label Pharmacist Recommended Panel.
    - Ensured regulatory compliance with Ryan Height Online Pharmacy Act and VIPPS accreditation. ○ Ensured seamless transition of registered users to CVS.com. ○ Led enterprise digital integration strategy for all Longs Drugs consumer web properties including flagship website longs.com with 1M+ registered users, and total sales impact of conversion of $10 M for the longs.com pharmacy

operations and $100M+ in pharmacy transactions initiated on website for brick-and-mortar stores.
- Achieved all retention goals.
- Successfully converted longs.com mail order and specialty pharmacy facilities to CVS.com home delivery and specialty pharmacy in Indianapolis.

MSL Experience included:

- **Accordia Therapeutic Life Science; Medical Science Liaison through cross-functional program with CVS Health (4 years)**
  - Key stakeholder on the launch of Qutenza® 8% Patch (capsaicin)
  - Developed medical literature and conducted research for physicians and other healthcare providers on Accordia products
  - Developed a limited distribution program for Qutenza® to ensure compliance with the FDA required REMS program.

- **Bayer Pharmaceuticals**; **Medical Science Liaison through cross-function program with CVS Health (3 years)**
  - Educated physicians and other healthcare professionals on Mirena.
  - Developed a limited distribution program for Bayer Pharmaceutical's Mirena® intrauterine device.
  - Implemented Program to allow direct shipment to OB/GYN offices for patients with third parties that required billing on the pharmacy benefit versus the medical benefit.
  - Grew program to over $60 million of product being shipped through the CVS limited distribution program.

CVS/pharmacy Osco/Sav-On Pharmacy Integration Team, Phoenix, AZ 2005-2006
Pharmacy Integration Manager-

- Led integration of Osco and Albertsons pharmacies in Phoenix and Las Vegas markets with total sales volume of $300M.
- Led a team of 160 and trained former Osco and Albertsons pharmacists and technicians on CVS/pharmacy policies and procedures.
- Assembled conversion leaders, and managed model store.
- Successfully completed integration on time/on budget.

CVS Pharmacy, Woonsocket RI 2004-2005
District Pharmacy Supervisor

- Directed all pharmacy operations with full P&L for 26 pharmacies/$130M in sales throughout NH and Northern MA.
- Led a team of 90+ pharmacists. Ensured full regulatory compliance.
- Spearheaded recruiting efforts in struggling district.
- Successfully filled 7-8 full time vacancies and built 'bench strength' to effectively support business growth.
- Consistently overachieved sales targets through streamlining of processes, increased team alignment, and improved customer service and satisfaction.

WAL*MART PHARMACY, Sanford, ME 2003-2004
Pharmacy Manager

- Directed pharmacy and OTC department with full P&L.

- Exceeded sales targets.
- Selected as member of "Rising Star" fast track leadership program.

CVS/PHARMACY, Coventry, RI 2001-2003
Pharmacy Manager

- Rapidly promoted from intern, to staff pharmacist and pharmacy manager for a store that ranked #3 out of more than 7K total locations.
- Managed operations improving efficiency and customer service.

RXINSIDER.COM, East Greenwich, RI 2000-2001
Web Copywriter/Developer

- Worked closely with CEO of startup organization to build business concept and strategy and develop web content
- Contributed to building one of the largest pharmacies recruiting site in the US.

HONORS AND AWARDS

CVS/Pharmacy Paragon Award (2005)

CVS Caremark Achievement award for eCVS Project (2007)

E-Healthcare Platinum Leadership award (2008)

POST GRADUATE CERTIFICATIONS

Certificate in Pain Management and Palliative Care
University of Southern Illinois School of Nursing 2010

Certificate in Women's Health
University of Florida College of Pharmacy 2011

Certified in High, Low, and Medium Risk Sterile Compounding
American College of Apothecaries 2011

ACADEMIC APPOINTMENTS

Brown University, Alpert Medical School
2012 – 2018
Adjunct Assistant Professor of Pediatric Medicine

University of the Incarnate Word School of Pharmacy
2010 - 2018
Adjunct Professor Pharmacotherapeutics

FELLOWSHIPS and HONORS

Faulty American Board of Anti-Aging Health Practitioners (ABAAHP)
Professional, Academy of Healthcare Management (PAHM)
Diplomat Academy of Managed Care Pharmacy (DAMCP)

VOLUNTEER

FEMA Deployments 2021 and 2022
COVID-19 MAB Infusion Clinic Setup Training and Operations
Norfolk, VA and Flagstaff, AZ

LICENSURE

Registered Pharmacist:
AZ, CT, FL, IL, MA, ME, RI, TX, VA, MD, MI, OK, TN

EDUCATION

Louisiana State University Shreveport, LA – MBA (*in progress)*

University of Arkansas for Medical Sciences Little Rock, AR Doctor of Pharmacy (2007)
(GPA 3.79)

University of Rhode Island Kingston, RI Bachelor of Science, Pharmacy, cum laude (2001)
(GPA 3.34)

Massachusetts School of Law
Attended 2007 - 2010

Tulane University New Orleans, LA
Master Certificate Business Management – Professional Development Program (2005)

AFFILIATIONS

International Academy of Compounding Pharmacists • American Academy of Anti-Aging Medicine American Society of Health-System Pharmacists • American Society of Consultant Pharmacists • Academy of Managed Care Pharmacy • Academy of Healthcare Management • RI Medical Reserve Corps • FL Department of Health Emergency Response Team • TX Department of Health Emergency Response Team