

STATE OF NORTH CAROLINA	REQUEST FOR INFORMATION NO. 270-20240419GLP
Department of State Treasurer NC State Health Plan for Teachers and State Employees	Due Date: May 31, 2024, 2:00 PM ET
Refer <u>ALL</u> 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 SHPCcontracting@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.

<u>DELIVERY ADDRESS</u>
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 SHPCcontracting@nctreasurer.com.

EXECUTION

RESPONDENT NAME: Sarah Wheeler	E-MAIL: sarah.wheeler@makorx.com	
STREET ADDRESS: 4901 Glenwood Ave Suite 300	P.O. BOX:	ZIP: 27612
CITY & STATE: Raleigh, North Carolina	TELEPHONE NUMBER:	TOLL FREE TEL. NO: 855-562-5679
TYPE OR PRINT NAME & TITLE OF PERSON SIGNING: Sarah Wheeler	FAX NUMBER:	
AUTHORIZED SIGNATURE: <i>Sarah Wheeler</i>	DATE: 7/25/2024	



NC BASED BUSINESSES JOINT RESPONSE TO REQUEST FOR INFORMATION

North Carolina State Health Plan for Teachers and State Employees

RFI Number: 270-20240419GLP

RESPONSE DATE: MAY 31, 2024 (REVISION ACCEPTED 7-25-2024)

SUBMITTED BY:

OneFul Health Inc.
3700 Regency Parkway, Ste 140
Cary, North Carolina 27518
www.oneful.health

MakoRx
4901 Glenwood Ave, Ste 300
Raleigh, North Carolina, 27612
www.makorx.com

dooable Health
1457 Kelly Road, Ste 112
Apex, North Carolina 27502
www.dooable.com

Please direct all questions to these individuals:

Edison T. Hudson, CEO
Email: edison@oneful.health

Phone: 1-919-215-9358

Sarah Wheeler, Head of Sales
Email: sarah.wheeler@makorx.com

Phone: 1-571-271-2451

Dr. Joe Jenkins, MD
Email: joe.jenkins@dooable.com

Phone: 1-910-273-2098

I. OVERVIEW

In response to the NC SHP RFI for GLP-1 coverage, dooable Health, MakoRx and Triangle Compounding Pharmacy, have created a joint solution comprised solely of NC based businesses that will lower the SHP expense to cover GLP-1 medications for weight loss and invest in local businesses ensuring NC tax payer dollars stay in state.

Solution Components:

dooable Health Coaching: Co-founded by Dr. Joe Jenkins, a former board chairman of the NC SHP, is an integral part of the solution to obesity treatment with GLP-1s for the SHP. Eligible weight loss members will participate in dooable health coaching services to ensure that they either qualify for GLP-1 coverage (based on a BMI lower than 35) or that they compliment their weight loss medication with lifestyle changes for lasting results.

MakoRx: For patients who prefer branded medications, MakoRx provides 340b pricing for these medications which lowers the price to the SHP and eliminates the rebate game completely with low upfront net costs. The full 340b discounted price is passed on to the SHP for this program, providing the lowest cost available to the plan for the medication. In addition, MakoRx will provide a network of independent pharmacies across the state where patients walk-in to collect the in-person data needed for plan participation. Pharmacy visits will provide a lower cost option to the plan in addition to traditional primary care provider visits and will eliminate the self-reporting issues currently faced by the SHP.

OneFul Health and its subsidiary Triangle Compounding Pharmacy (TCP) offers to supply patients who are comfortable using personalized compounded medications delivered in traditional insulin syringe/ vial solution with ingredients certified the same as FDA approved brands. If SHP prefers to utilize this traditional this solution Oneful

will provide the compounded versions of semaglutide (active ingredient in Wegovy) and tirzepatide (active ingredient in Zepbound) at these significantly lower price points. In conjunction with the dosage-based pricing model, the SHP can provide starting doses of these medications for as low as \$108 per month. The National Pharmacy Compounding Accreditation Board and the North Carolina Board of Pharmacy annually inspect and accredit their sterile and non-sterile facilities. TCP is an approved vendor to UNC healthcare, Duke Medical, and Veterans Administration.

Conclusion:

Investing in NC: By choosing to work with NC businesses to provide access to GLP-1 medications for weight loss, the State is investing in multiple ways. First in the health of the SHP members with improved access to a holistic solution supporting them in a healthier lifestyle which will save the SHP in long term medical related costs. Secondly, the money spent by the SHP will remain in local NC communities fueling jobs and local growth. Finally, by involving local pharmacies across the state, small businesses will gain a valuable new revenue stream and provide members convenient expanded access to services for SHP members in rural areas with healthcare deserts.

This alliance of NC businesses will provide the NC SHP with the optimal solution to meet the needs of the SHP members who were using or will use GLP-1 medications for weight loss, implementing the appropriate requirements for participants, ongoing data collection and holistic approach to obesity management.

We look forward to the opportunity to work with the Plan to improve the health and well-being of its members.

Thank you for considering our response to the RFI.

II. BACKGROUND

dooable Health, MakoRx and OneFul health have joined forces to create a North Carolina based business solution in response to the NC SHP RFI for GLP-1 and GLP-1 agonist support for Obesity. The basic components of the response involve, behavioral coaching and support through dooable Health a local NC based health coaching organization co-founded by Dr. Joe Jenkins. It is our belief that health coaching is imperative to the success of weight loss through GLP-1 medications and that the overall health of NC SHP employees who participate in the program will greatly benefit from the lifestyle changes and educational support that dooable Health coaches provide.

The purpose of this RFI is to provide a sustainable approach for the state to provide access to the expensive GLP-1 medications. MakoRx, a local North Carolina based business has a unique program to provide the SHP members with access to the 340b price of the branded medications. Unlike typical 340b programs, MakoRx will pass the full savings of 340b pricing through to the plan. The pricing model is cost-plus pricing which entails the 340b cost of the medication plus a program fee to cover the cost of the provider visit and dispensing of the medication, shipped straight to the member's home. In addition, MakoRx maintains a state-wide network of local independent pharmacies which can serve SHP members as a location to capture in-person data for program participation, further stimulating the local NC economy.

As the current branded weight loss GLP-1 medications are on FDA shortage, compounded versions are legally available and can provide the SHP with an affordable option for patients during the shortage. Oneful Health a North Carolina based business has been committed to developing and commercializing affordable and highly effective treatments for cardio-metabolic health for over ten years. OneFul has invented and patented systems to affordably personalize nutritional and pharmaceutical treatments to address the highest personal and public

healthcare costs and the greatest cause of death globally. Using novel regulatory strategies, current Good Manufacturing Practices (cGMP), digital formulation, and robotic automation. OneFul ensures traceable quality by using blockchain tracking of ingredients and processes. Our product strategy is to bring highly effective personalized therapies scaled to mass markets at price points typically a fifth of the cost of treating chronic diseases with traditional medicines.

We are participating in the GLP-1 agonist revolution directly by investing in the lab-certified bulk inventory of the **FDA-approved form of semaglutide and tirzepatide**, the active ingredient of popular drugs Ozempic®/Wegovy® and Mounjaro®/Zepbound®. We are making personalized and affordable forms of these GLP-1 and GIP-GLP-1 injectable pharmaceuticals in our wholly owned accredited sterile pharmaceutical facility in Cary, NC, Triangle Compounding Pharmacy ("TCP"). TCP was the first in North Carolina and one of the earliest nationally to implement a 503B Human Drug Outsourcing Facility and is an approved vendor to UNC Healthcare, Duke Medical, Veterans Administration, and over 7,000 individuals and physicians in nine Southeastern states. The National Pharmacy Compounding Accreditation Board and the North Carolina Board of Pharmacy annually inspect and accredit our sterile and non-sterile facilities.

III. RFI SPECIFIC RESPONSES

In accordance with the Plan's RFI Number: 270-20240419GLP, to the topics enumerated (in red) our responses are presented (in black):

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 weight loss.

The response contained within allows the Plan to provide benefit coverage for GLP-1 and similar new molecular entities for weight loss by providing a framework to combine medication support with in-person data verification and collection along with lifestyle education and support to ensure the best outcomes for participating members. [REDACTED]

[REDACTED] [REDACTED] premised on success rather than failure also protects the Plan against medication usage as a first line of treatment.

[REDACTED]

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:

[REDACTED]

[REDACTED]

[REDACTED]

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

One of the benefits of working with MakoRx and OneFul and doable Health is that there are no stipulations or regulations on the Plan in terms of decision making for benefits or coverage.

[REDACTED]

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

i. [REDACTED]

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.

[REDACTED]

[REDACTED]

2. Develop step therapies involving lower cost medications.

[REDACTED]

3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.

In person data collection prior to program approval is important and will eliminate prescriptions from online providers who do not have an in person relationship with the member. In addition, if desired MakoRx can provide a centralized provider network for obesity program participants that will ensure all prescriptions are from practitioners with appropriate levels of expertise. [REDACTED]

[REDACTED]

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.

MakoRx proposes that the Plan utilize our network of local NC based independent pharmacies to collect in person data for the program participants. This solution not only ensure access in the rural areas of the state with existing healthcare deserts, but also support and stimulates local economies with a novel revenue stream for these pharmacies. We propose the data collected include: in-person BMI calculations, A1C testing, blood pressure and pulse ox data.

[REDACTED]

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:

We propose to measure this in person on regular 90 day intervals for program participants

2. Current weight:

We propose to measure this in person on regular 90 day intervals for program participants

3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity:

Dooable health™ is incredibly unique. We have built a platform established on the holistic approach to helping SHP employees not only believe change is possible, but also to reach goals that allow life to feel less burdensome and more joyous. Through this shift process, less weight loss medication is needed. Centered around its three pillars Eat Well, Move Well, and Live Well, dooable health™ pairs its technology with national board-certified health coaching. The result is to help members lose weight, normalize blood pressures, and reverse pre-diabetes. Most importantly, it allows for individuals to finally feel free from medications. They move towards confidence, motivation, consistency and experience results that once felt out of reach. Almost universally individuals will “fall off of the wagon.” Understanding the “dooable way” is paramount to getting back on track. For Tier 1 and 2 members Individuals use the dooable app as their portal to engagement. They will enter their baseline health measurements and lab results obtained by their primary care provider. They then fill out a dooable health assessment. Next is a consultation with the assigned Health Coach. Working with their coach, they will establish manageable goals.

4. Documented enrollment and measurable participation in other nutritional or dietary programs:

Employees will be invited to the program's multiple components. These offerings include lessons, webinars, recipes, and a live group curriculum that builds community. All of these opportunities are related to weight loss, physical, and mental health. Dooable health's™ unique program keeps stress, emotional well-being, and sleep at the core of its process. Everyone is valued and unique, and we believe that no one should feel categorically dismissed.

Nutritional Coaching:

Participants will learn about real foods versus fake foods and how to navigate our complex food system without overspending. Through coaching, participants will understand why certain choices contribute to illness and inflammation, while others increase energy and vitality. When members understand cravings on a deeper level, they can work with their bodies instead of against them, freeing themselves from any shame. Recipes and the basics of meal preparation are a fun component of the program. Insulin-reducing tips are important for all participants. Education on metabolic syndrome and managing blood sugar through lifestyle choices are key. These lifestyle modifications will be documented through participation with dooable Health and can be tracked and documented in their program app.

Exercise Program:

Health coaches will work with the members to establish healthy movement programs to improve stamina and maintain muscle mass. One of the main side effects of GLP-1 weight loss can be a loss of overall muscle. It's imperative that participants include strength training exercises to maintain muscle mass during GLP-1 usage. There are many ways to engage with healthy movement that don't require long days at the gym.

5. Consideration of evidence for one or more comorbid conditions or other obesity-related medical conditions;

Obesity often occurs with comorbid conditions and those conditions will be addressed through monitoring of A1C levels for diabetes risk, blood pressure and pulse ox for cardiovascular risk and nutritional counselling to support liver and cholesterol levels. A full metabolic panel of labs will be required to initiate the program participation and that will ensure the providers and coaches are aware of any comorbid conditions to be aware of and address during the program.

6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;

[REDACTED]

7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or

To minimize the cost to the plan based on the large amount of potential program participants, in-person treatment will be required for data collection in participating local pharmacies but we will not require a cadence of in-person medical visits as our recommended hybrid solution arms the providers with in-person data while leveraging the cost savings of telehealth providers.

8. Any other considerations or parameters that would support a program in achieving the Plan's objectives of serving the members who need these medications the most?

Because NC has so many recognized healthcare deserts along with exercise access deserts, this program which utilizes established, trusted local pharmacies as the in-person brick and mortar locations for program participants, will provide consistent and equitable access to all SHP members who participate regardless of their location in the State. In addition, by supporting all local NC based businesses, the investments that the Plan makes in this program will remain local and stimulate the local economies across the State.



June 6, 2024

Re: RFI Number: 270-20240419GLP, NC State Health Plan for Teachers and State Employees, OneFul Health Inc.

Dear Secretary Folwell and others administering the State Health Plan:

Thank you for your efforts on behalf of the people of the state of North Carolina. I am writing to you as a diabetes/obesity physician, researcher, and customer in support of the OneFul Health proposal to provide semaglutide and tirzepatide to the State Health Plan.

First, my background. I came to the University of North Carolina School of Medicine in July 1994 to start a diabetes center to provide clinical care, research, and training. I am especially proud of the impact our program has had on training an entire generation of providers in NC. We have provided excellent care for tens of thousands of patients with diabetes. We have also been centrally involved in the development of the GLP-1 receptor agonist (GLP-1RA) class of drugs since 1997 for both diabetes and weight management indications. UNC was the site of the first study of GLP-1RA in patients with diabetes way back in 1998.

I have been a consultant and investigator for all the companies that develop GLP-1RA. I am a former president of the American Diabetes Association and have received national awards from them for my success as a researcher in 2019 and as a clinician this year. Having worked in the GLP-1RA field for more than 20 years and as someone with a BMI of 32 with associated problems (hypertension, dyslipidemia, elevated liver enzymes, insulin resistance), I asked my primary care doctor to prescribe Wegovy as soon as it was FDA approved. I lost sixty pounds and all my metabolic problems resolved. My BMI is now twenty-two.

The GLP-1RA have the promise to revolutionize care of people with obesity who face terrible health outcomes, early death/disability, stigma, and psychological burden. They have been shown to not only reduce weight but reduce cardiovascular events in high-risk patients. The concern you have raised about their cost is completely appropriate. Their value is great, but cost effectiveness analysis is driven by cost. A number of studies suggest that at a cost of \$200-\$400 a month, semaglutide for instance would be cost effective for managing people with overweight/obesity and established metabolic disease (stage 2) as conceived of by the American Heart Association in 2023.

But what I really want to tell you is that when the SHP stopped paying for my Wegovy and with the difficulty in getting Wegovy or Zepbound at any cost, I did my due diligence about the compounding pharmacy marketplace. Through my primary care doctor, I became aware of OneFul and the Triangle Compounding Pharmacy in Cary. I have been taking tirzepatide 7.5 mg a week since April 29. My weight and metabolic parameters have held steady. Their service is outstanding. As perhaps one of the best-informed consumers and prescribers of GLP-1RA on the planet, I give them my strong endorsement. I understand that they have made a proposal to you. (Though I have lots of conflicts of interest with the pharma industry, I have none with OneFul.)

If I can help with your deliberations, please feel free to reach out. Best wishes for a successful negotiation to get GLP-1RA for weight management to our State Health Plan members at a cost-effective price. Again, thank you.

Sincerely,

A handwritten signature in black ink that reads "Buse". The signature is written over a circular stamp or watermark.

John B. Buse, MD, PhD
Verne S. Caviness Distinguished Professor
Director, Diabetes Care Center
Director, NC Translational and Clinical Sciences Institute

University of North Carolina School of Medicine
8027 Burnett-Womack Building, 160 Dental Circle
Chapel Hill, NC 27599-7172
Telephone: 919-966-0134/ Fax: 919-966-6025

UNC Hospitals Diabetes and Endocrine Clinic
100 Eastowne Drive, 3rd floor
Chapel Hill, NC 27514
Telephone: 984-974-2950/ Fax: 984-974-2924

E-mail address: jbuse@med.unc.edu