From: Scruton, Cathleen
To: Horne, Christine
Subject: FW: RxE2
Date: Monday, October 10, 2022 2:58:45 PM
Attachments: image001.png
image006.png

Hello Christine,

Have you seen this email?

Thank you,
Cathy

If you have any questions or need additional assistance, please go to our website www.oplc.nh.gov or call 603-271-2152 to speak with one of our customer support representatives. Our office hours are Monday thru Friday, 8am-4pm (excluding holidays).

Thank you,

Cathleen

Licensing Bureau (or Customer Support)
NH Office of Professional Licensure and Certification
7 Eagle Square, Suite 300, Concord, NH 03301, 603.271.2152

From: Kim Moore <kim@gloetal.com>
Sent: Friday, October 7, 2022 11:11 AM
To: George Oestreich <george@gloetal.com>; OPLC: Pharmacy <pharmacy.licensing@oplc.nh.gov>
Subject: Re: RxE2

Dear Pharmacy Licensing and Board Administration,

Earlier this year G.L.O. & Associates contacted you introducing our client, RxE2, and their program to transition clinical drug trials to a more patient-focused, pharmacist-centric approach. We sent a second letter via Priority Mail on September 9th, as well as a follow-up email on September 26th to inform you of the program's continuing growth and expansion.

We want to maintain our connection with you, since our last outreach, in case there have been new developments, or you are considering changes that may be pertinent to this program. We continue to follow proposed state statutes and regulatory changes regarding pharmacist roles especially if they may affect investigational new drugs and their clinical trials. However, we want to ensure we have not missed a change or a concern of yours or another pertinent agency in this space.

Please let us know what your concerns are or if you have no concerns at this time. Thank you for your time and attention to our client's pharmacist-centric initiative regarding investigational new drugs and related clinical trials.

Kimberly B. Moore, Pharm.D., MS
Clinical Pharmacist

G.L.O. & Associates
A Division of Comprehensive Pharmaceutical Services, Inc.
3432 W. Truman Blvd., Suite 201
Jefferson City, MO 65109
C 314.791.1688 F 573.632.2411
kim@gloetal.com gloetal.com

From: George Oestreich <george@gloetal.com>
Date: Monday, September 26, 2022 at 1:31 PM
To: pharmacy.licensing@oplc.nh.gov <pharmacy.licensing@oplc.nh.gov>
Cc: Kim Moore <kim@gloetal.com>
Subject: RxE2

Dear Pharmacy Licensing and Board Administration,

Earlier this year G.L.O. & Associates contacted you introducing our client, RxE2, and their program to transition clinical drug trials to a more patient-focused, pharmacist-centric approach. We sent a second letter via Priority Mail on September 9th to inform you of the program's continuing growth and expansion. We are now reaching out via email in hopes this format will ease the burden of your response to our letter.

We want to maintain our connection with you, since our last outreach, in case there have been new developments, or you are considering changes that may be pertinent to this program. We continue to follow proposed state statutes and regulatory changes regarding pharmacist roles especially if they may affect investigational new drugs and their clinical trials. However, we want to ensure we have not missed a change or a concern of yours or another pertinent agency's in this space.

Thank you for your time and attention to our client's pharmacist-centric initiative regarding investigational new drugs and related clinical trials. If you can think of no issues, we would appreciate a quick response as well. Please read below for a copy of the most recent letter.

My Best, George

George L. Oestreich, Pharm.D., MPA
G.L.O. and Associates
A Division of Comprehensive Pharmaceutical Services, Inc.
3432 W. Truman Blvd., Suite 201
Jefferson City, Missouri 65109
T 573.632.2412 F 573.632.2411 C 573.230.7075
george@gloetal.com
www.gloetal.com

September 9, 2022

Pharmacy Licensing and Board Administration
New Hampshire Board of Pharmacy
7 Eagle Square
Concord, NH 03301

Dear Pharmacy Licensing and Board Administration,

Earlier this year G.L.O. & Associates contacted you introducing our client, RxE2, and their program to transition clinical drug trials to a more patient focused, pharmacist-centric approach. The purpose of this additional outreach is to inform you of the program's continuing growth and expansion.

We want to maintain our connection with you, since our last outreach, in case there have been new developments, or you are considering changes that may be pertinent to this program. We continue to follow proposed state statutes and regulatory changes regarding pharmacist roles especially if they may affect investigational new drugs and their clinical trials. However, we want to ensure we have not missed a change or a concern of yours or another pertinent agency's in this space.

We have attached RxE2's overview of services to refresh your memory of the program should it be necessary. If any issues come to mind, we would appreciate the opportunity to transparently discuss the topic or area of concern. If you see no additional issues other than previously noted, and do not anticipate any in the foreseeable future, a brief note or email would also be appreciated.

Thank you for your time and attention to our client's pharmacist-centric initiative regarding investigational new drugs and related clinical trials.

My best,

Dr. George L. Oestreich, PharmD, MPA
President, Principal
george@gloetal.com

3432 West Truman Boulevard, Suite 201
Jefferson City, Missouri 65109-0698
Telephone: 573.632.2412 Facsimile: 573.632.2411

RxE2®

Incorporating the Practice of Pharmacy into Clinical Research

Overview of Services

RxE2 is a new and innovative pharmaceutical services organization focused on incorporating the practice of pharmacy into clinical research. RxE2 utilizes a small staff of highly skilled experts to build simple, adaptive, and cost-effective solutions that pharmacies and pharmacists can use to create a new paradigm for conducting clinical research. This new paradigm capitalizes on the relationship the pharmacist has with his or her patients and addresses the time, cost, and quality issues faced by the pharmaceutical and biotech industry.

To date, the role of the pharmacist in clinical research is almost non-existent. RxE2's goal is to change this and ensure that the pharmacist, as the medication expert, is involved in clinical research. Having the pharmacist oversee the dispensing and patient counseling of investigational drug will improve patient safety, compliance and adherence, and outcomes. RxE2 will also work with pharmacies and pharmacists to oversee protocol design, patient recruit and other aspects that would benefit from the expertise of the pharmacist.

RxE2 believes by involving the pharmacist timelines and associated costs will be reduced through three key areas: clinical supplies (E2 Dispensing), medication counseling (E2 Counseling), and the recruitment and enrollment of patients (E2 Recruitment). Once these services are proven, RxE2 will then launch E2 Trials, incorporating all three services as one offering while adding the ability for patient data collection. Quality will be improved through all three services, but it will be RxE2's E2 Counseling services that will have the biggest impact on quality, specifically the quality of clinical trial outcomes which will directly impact the number of medications gaining approval by the FDA. This basic and simple service will revolutionize clinical research and have far-reaching implications for the industry.

E2 Dispensing is categorized as disruptive technology and will greatly reduce clinical supply timelines and costs by moving the packaging, labeling, and dispensing of clinical supplies to a central-fill pharmacy. The central-fill pharmacy dispenses the medication directly to the patient, healthcare provider, or local pharmacy, where allowed. This disruptive innovation eliminates the costs and waste associated with the packaging and labeling of clinical supplies at a GMP facility and the costs and waste due to the handling and dispensing of clinical supplies by clinical sites. Quality is improved as clinical supplies are labeled according to state pharmacy laws rather than GMP manufacturing regulations.

E2 Counseling will improve the quality and outcomes of clinical trials by using pharmacists - the medication experts - to counsel patients who received their medication through E2 Dispensing. Pharmacist counseling improves compliance and adherence as well as overall

patient retention. Outside of RxE2, patient counseling is currently non-existent in the clinical trial industry. E2 Counseling impacts the quality of medication compliance by the patients enrolled, the patient data collected, and subsequently the data filed in the New Drug Application (NDA). E2 Counseling ultimately affects the pharmaceutical industry's primary problem of medication failures which drives the ever-increasing cost of clinical trials.

E2 Recruitment will reduce timelines and costs through its unique pharmacy-focused model which engages the role of the pharmacist and his or her relationship with patients. Most importantly, the E2 Recruitment model decentralizes clinical research and brings the option of participating in a clinical trial to patients everywhere. Quality is improved by RxE2 centralizing and standardizing the recruitment process for all pharmacies, ensuring screened patients better meet protocol requirements.

E2 Trials incorporates all RxE2 services. E2 Trials will decrease timelines, decrease costs, and improve overall quality of clinical trials. Every aspect of pharmaceutical clinical research, including the way the industry views its resources, processes, and values will be impacted. The change brought about by RxE2 will be unprecedented and disruptive simply by incorporating the practice of pharmacy into clinical research.

Mission and Vision

Mission

RxE2 will make clinical trials a healthcare option for everyone everywhere by incorporating the practice of pharmacy and leveraging the expertise of the pharmacist.

Vision

RxE2 seeks to continually improve patient care and health outcomes by providing the education, training, and support for local pharmacies and pharmacists to participate in clinical trials. RxE2 will provide local pharmacies the opportunity to participate in a new revenue stream that does not disrupt their current practice, and in fact, will utilize their current practice and their long-term relationship with their patients. Patients trust their pharmacists and surveys show patients want to participate in clinical trials, but rarely do. RxE2, for the first time in the industry, will use the local pharmacist to reach a more diverse and dispersed patient population and address the concerns of the patients by providing them with the opportunity and assistance to take the next step and participate in clinical trials. Presently, pharmaceutical companies use clinical sites that are often only found in the big cities or large academic hospitals which focus only on their sub-populations. Our vision focuses on high-quality care for every patient everywhere, beginning with clinical trials in the US and North America and extending into the global setting, especially in those countries with a strong independent community pharmacy presence.

September 9, 2022

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New Hampshire Board of Pharmacy
7 Eagle Square
Concord, NH 03301

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