Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.tompkinscountyny.gov/hconsortium • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

Board of Directors Meeting
March 28, 2019 – 6:00 pm – Tompkins County Legislature Chambers

121 East Court Street, Ithaca, NY

1. Call to Order
2. Approval of December 13, 2018 Minutes **(VOTE)** (6:00)
3. Changes to the Agenda
4. Chair's Report: (6:05) — J. Drake
   a. Conflict of Interest Signatures
5. Report from Executive Director Interview Committee (6:10) — J. Drake
   a. **RESOLUTION:** Appointment of Executive Director
   b. **RESOLUTION**: Adoption of Personnel-Related Policies and Procedures – Consortium Employees
   c. **RESOLUTION:** Town of Ithaca Lease Agreement
6. Executive Director's Report (6:25) — D. Barber
   a. DFS Communications
   b. CanaRx
7. Wellness Consultant Report & Branding Work (6:35) — M. Courtney Berry
8. Financial Report (6:50)
   a. 2018 Overview and 2019 YTD Financial Update — S. Locey
   b. Treasurers Report: Investment and Cash Flow, JURAT and Audit Status — R. Snyder
9. Report from Audit and Finance Committee (7:05) — M. Cook
   a. **RESOLUTION:** Adoption of Cyber Security Policy
   b. **RESOLUTION:** 2019 Budget Amendment
10. Report from Governance Structure Committee (7:15) — C. Rankin
11. Report from Joint Committee (7:25) — O. Hershey
12. Report from Owning Your Own Health Committee (7:30) — K. Servoss
13. New Business (7:35)
14. Adjournment (7:40)

Next Meeting: June 27, 2019

Greater Tompkins County Municipal Health Insurance Consortium
Code of Ethics and Conflict of Interest Policy

(Adopted 2-27-2014; amended by Res. No. 008-2016, Res. No. 016-2018)

Employees and the Board of Directors of the **Greater Tompkins County Municipal Health Insurance Consortium** shall:

1. Be dedicated to the concepts of an effective Consortium and believe that professional general management is essential to the achievement of this objective.

2. Shall affirm the dignity and work of the services rendered by the Consortium and maintain a constructive, creative, and practical attitude toward Consortium affairs and a deep sense of responsibility as a trusted public servant.

3. Be dedicated to the highest ideals of honor and integrity in all public and personal relationships in order that the member may merit the respect and confidence of the elected officials, of other officials and employees, and of the public.

4. Conduct themselves so as to maintain public confidence in their profession, the Consortium, and in their performance of the public trust.

5. Conduct their official and personal affairs in such a manner as to give the clear impression that they cannot be improperly influenced in the performance of their official duties.

6. Recognize that the chief function of the Consortium at all times is to serve the interests of all members.

7. Shall not disclose **Confidential Information** to others or use to further their personal interest, confidential information acquired by them in the course of their official duties.

8. Shall not, except pursuant to such reasonable exceptions as are provided by regulation, solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.

9. Make no unauthorized commitment or promises of any kind purporting to bind the Consortium.

10. Shall act impartially and not give preferential treatment to any private organization or individual.

11. Shall not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official Consortium duties and responsibilities.

12. Shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards promulgated pursuant to this order.

13. Shall adhere to all laws and regulations that provide equal opportunity for all Americans regardless of race, color, religion, sex, national origin, age, or disability.

14. Shall not invest or hold any investment, directly or indirectly, in any financial business, commercial, or other private transaction that creates a conflict with their official duties.

15. **Reporting of Ethics Violations.** When becoming aware of a possible violation of the Consortium's Code of Ethics, employees, Board of Directors, employees of members, and the public may report the matter to the Consortium Attorney-in-fact, John Powers, Esq.. In reporting the matter, members may choose to go on record as the complainant or report the matter on a confidential basis. Resolution of the reported violation shall occur according to the alternative dispute resolution (ADR) process set forth in Article V of the 2015 Amended MCA, except as follows. In lieu of the ADR step set forth at MCA Article V.3.a.(i), the Attorney-In-Fact will collect all information presented regarding the matter and send that information to a neutral third party designated by the Board of Directors who shall attempt to resolve the matter informally through mediation. If unsuccessful, the mediator shall make a recommendation with respect to resolution of the dispute in writing to the Executive Committee, which shall present the recommendation to the Board as provided for in 2015 Amended MCA Article V.3.a.(i). The remainder of Article V shall remain in effect",

16. Employees and the Board of Directors should not discuss or divulge information with anyone about pending or completed ethics cases except as authorized by the Board of Directors.

17. No later than April 15th, and each successive year thereafter, individuals serving as officer, director and key employee shall certify they have read and agree to the terms stated within the Greater Tompkins County Municipal Health Insurance Consortium's Conflict of Interest and Code of Ethics Policy. The Board of Directors shall be made aware of any outstanding agreements at its next regularly scheduled meeting after the April 15 deadline. Should a successor be appointed to fill a position mid-year they shall be asked to sign the agreement at that time.

For purposes of this policy, (i) the terms "officer" and "director" shall have the same meaning as set forth in the Municipal Cooperative Agreement, dated October 1, 2010; and (ii) the term "key employee" shall mean any employee of the Consortium with executive or managerial capacity." These positions include:

- All Directors and Alternates designated by a Participant to have voting authority;
- Executive Director or Assistant Executive Director;
- Treasurer;
- Wellness Consultant;
- Plan Consultant;
- Administrative Clerk

CODE OF ETHICS AND CONFLICT OF INTEREST AGREEMENT

To be signed and submitted to the Consortium no later than April 15th of each year.

I have read and agree to the terms stated within the Greater Tompkins County Municipal Health Insurance Consortium's Conflict of Interest and Code of Ethics.

Signature	*Print Name*
Consortium Title/ Municipality	*Date*

CODE OF ETHICS AND CONFLICT OF INTEREST AGREEMENT

To be signed and submitted to the Consortium no later than April 15th of each year.

Year _____

I have read and agree to the terms stated within the Greater Tompkins County Municipal Health Insurance Consortium's Conflict of Interest and Code of Ethics.

_____ _____

Signature *Print Name*

_____ _____

Consortium Title/ Municipality *Date*

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

Board of Directors
December 13, 2018 – 6:00 p.m.
Tompkins Cortland Community College – Sprole Conference Room

Draft 12/22/2018

Municipal Representatives: 23

Mack Cook, City of Cortland
Judy Drake, Town of Ithaca
Charmagne Rumgay, Town of Lansing
Eric Snow, Town of Virgil
Gary Mutchler, Town of Scipio
Tom Adams, Town of Marathon
Sarah Thomas, Tompkins County
Nancy Niswender, Village of Groton
Nancy Zahler, Town of Ulysses
Terrance Baxter, Town of Moravia
Jim Doring, Town of Preble
Kristen Case, Village of Homer
Christine Laughlin, Town of Newfield *(excused at 7:25 p.m.)*
Kevin Williams, Town of Homer
Michael Murphy, Village of Dryden
Peter Salton, Village of Cayuga Heights *(arrived at 6:15 p.m.)*
Chuck Rankin, Town of Groton
Rordan Hart, Village of Trumansburg
Tom Brown, Town of Truxton *(arrived at 6:10 p.m.)*
Laura Shawley, Town of Danby
Bud Shattuck, Village of Union Springs
David Schenck, Town of Springport
Ann Rider, Town of Enfield

Via Skype: 2

John Fracchia, Town of Caroline *(arrived at 7:05 p.m.)*
Edward Wagner, Town of Owasco

Labor Representatives: 3

Jim Bower, 2nd Labor Representative
Tim Farrell, 5th Labor Representative
Zack Nelson, 3rd Labor Representative *(arrived at 6:18 p.m.)*

Excused: 7

Alvin Doty, Town of Willet
Olivia Hersey, 1st Labor Representative and Joint Comm. on Plan Structure & Design Chair
Steve Thayer, City of Ithaca
Alex Patterson, Town of Aurelius
Luann King Town of Cincinnatus
Kathrin Servoss, Town of Dryden
John Malenick, Town of Montezuma

Absent: 1

Doug Perine, 4th Labor Representative

Others in attendance:

Don Barber, Executive Director
Beth Miller, Excellus
Steve Locey, Locey & Cahill
Rick Snyder, Treasurer
Richard Nielens, Town of Mentz
Greg Pellicano, Seneca County
Sundae Earle, TC3
Mark Emerson, Town of Mentz
Ronny Hardaway, Village of Lansing
Ed Fairbrother, Town of Big Flats

Call to Order

Ms. Drake, Chair, called the meeting to order at 6:05 p.m.

Approval of September 27, 2018 Minutes

It was MOVED by Mr. Mutchler, seconded by Mr. Adams, and unanimously adopted by voice vote by members present, to approve the minutes of September 27, 2018 as corrected. MINUTES APPROVED.

Changes to the Agenda

The following changes to the agenda were announced:

A resolution was added to the agenda entitled "Delegating Authority and Responsibility for Developing Cybersecurity Policies and Procedures to the Audit and Finance Committee".

A revised resolution authorizing the purchase of Stop Loss insurance was distributed to Directors.

Chair's Report

Ms. Drake reported the Executive Committee has been reviewing reports received from Segal, the Consulting Firm that was hired to look at the Consortium's contracts for Prescription Benefit Management Services, Stop Loss, and Operations. The Committee has continued working on succession planning and the structure of the Consortium in addition to the Consortium's Stop Loss insurance.

Appointments

MOTION NO. 004-2018 – APPOINTMENTS TO OWNING YOUR OWN HEALTH COMMITTEE

MOVED by Mr. Rankin, seconded by Mr. Schenck, and unanimously adopted by voice vote by members present, to approve the following appointments to the Owning Your Own Health Committee:

Terms expire December 31, 2020
Sarah Thomas, Municipal representative
Judy Drake, Municipal representative

Terms expire December 31, 2021
Jackie Kippola, Municipal representative
Ted Schiele, Community Health and Wellness representative

****

MOTION NO. 005-2018 – APPOINTMENTS TO AUDIT AND FINANCE COMMITTEE

MOVED by Ms. Drake, seconded by Mr. Farrell, and unanimously adopted by voice vote by members present, to approve the following appointments to the Audit and Finance Committee:

Terms expire December 31, 2020
Peter Salton
Laura Shawley
Mack Cook
Bud Shattuck

****

RESOLUTION NO. 026 - 2018 – CREATION OF CONSORTIUM EMPLOYEE POSITION – EXECUTIVE DIRECTOR

Ms. Drake said the Executive Committee has been working with Mr. Barber on the subject of succession planning and after weighing several factors it is the Executive Committee's recommendation to hire a full-time Executive Director rather than to enter into a contract with an individual. She said the upon consultation with the Consortium's attorney on how to hire an employee it was recommended that one of the municipal partners be the host employer. She explained that discussions took place with Tompkins County; however, there would be obstacles due to it being a Chartered County.

Ms. Drake said the Town of Ithaca has experience with running a 5-G municipal entity and being an employer of record; the Town Board has been approached and expressed its willingness to take on this responsibility. She said the resolution creates an Executive Director position and establishes a subcommittee that would be responsible for the recruitment, interviewing, and recommending a candidate to the Board of Directors. That Committee would also be charged with setting the salary and benefits for the position and negotiating a Memorandum of Understanding with the Town of Ithaca.

Mr. Barber noted that he would remain a Consultant for the Consortium to provide assistance to the new Executive Director and to help with the transition as long as he is needed. Ms. Drake noted the job description still has to go through the County's Civil Service process and said a request will be made that the position be exempt and not a competitive-class position.

In response to a question as to what the salary of the position would be Ms. Drake said it would be approximately $76,000 which is a salary that compares with other Directors of non-profits in the County. Mr. Salton felt this is an extremely low salary for the duties being assigned to the position. Other Directors also expressed concern and a suggestion was put forth to have a salary range.

Ms. Drake said the Town of Ithaca has space for a couple of employees and noted that it is connected to the County's IT system which would be very helpful. She responded to questions about discussions that have taken place with regard to future growth and Consortium staffing. She said in addition to an Executive Director position there has been discussion of additional administrative, billing, and finance support.

Mr. Salton referred to the job description for the Executive Director and said he felt it contained two different jobs with two different and distinct skillsets, one person who would be responsible for administration of the Consortium and one who would be doing outreach. Mr. Barber said up to this point the discussion has included him doing the outreach and marketing work as a consultant and the Executive Director handling the administration of the Consortium that would include managing things such as contracts, consultants, and meeting preparation.

MOVED by Mr. Hart, seconded by Mr. Baxter, and unanimously adopted by voice vote by members present.

WHEREAS, the Consortium's growth in membership and covered lives as well as reporting requirements to the Department of Financial Service Services, the number of Consortium operations contracts, enrollment management, potential member contacts, and general operations tasks have all increased over the past few years to the point where the amount of time to accomplish the duties of the Executive Director has become full-time, and

WHEREAS, the Executive Committee has discussed the options for securing a person to be full-time Executive Director as a paid position of the Consortium instead of a contracted Independent Contractor relationship, and

WHEREAS, The Town of Ithaca has expressed a willingness to perform the payroll function should the Consortium desire to hire a full-time Executive Director and other potential staff and have negotiated a Memorandum of Understanding (MOU) for providing this payroll and benefit service, and

WHEREAS, the proposed MOU provides that the Consortium would maintain authority to hire and fire as well as set pay and benefit levels that would be administered through the Town's payroll system, now therefore be it

RESOLVED, on recommendation of the Executive Committee, That the Board of Directors hereby creates an Executive Director position as an employee for Consortium and approves of the job description for the position, and

RESOLVED, further, That the Board of Directors establishes a subcommittee to recruit and interview candidates for the Executive Director position, and to forward a recommendation of appointment to the Board including associated pay and benefits,

RESOLVED, further, That the Board of Directors gives the Executive Committee authority to complete negotiation of the MOU with The Town of Ithaca and establish pay and benefit levels that meet the Consortium's needs while working through the Civil Service process and complying with the Town's payroll system.

*** * * * * * * * * ***

MOTION NO. 006-2018 – CREATION OF SUBCOMMITTEE TO RECRUIT AND RECOMMEND EXECUTIVE DIRECTOR

MOVED by Ms. Drake, seconded by Ms. Rumgay, and unanimously adopted by voice vote by members present, to create and appoint the following individuals to a subcommittee to recruit and recommend an Executive Director:

Judy Drake
Rordan Hart
Steve Thayer
Chuck Rankin
Peter Salton
Mack Cook
Olivia Hersey
Kathy Servoss
Sarah Thomas

Staff support: Don Barber, Steve Locey, Rick Snyder, Michelle Cocco

*** * * * * * * * * ***

RESOLUTION NO. 027 - 2018 – ESTABLISH MEETING SCHEDULE – 2019

MOVED by Ms. Drake, seconded by Mr. Rankin, and unanimously adopted by voice vote by members present.

RESOLVED, on recommendation of the Executive Committee, That the Board of Directors hereby adopts the following meeting schedule:

BOARD OF DIRECTORS
2019 Meeting Schedule

March 28
June 27
August 22
September 26 – Annual Meeting (set rates)
December 19

Meeting time: 6:00 p.m. to 8:00 p.m.
TC3, Sprole Conference Room
170 North Street
Dryden, New York 13053

*** * * * * * * * * ***

RESOLUTION NO. 028 - 2018 – RE-ESTABLISHMENT OF GOVERNANCE STRUCTURE COMMITTEE

Ms. Drake said in 2017 a committee met to review the Consortium's structure as it was beginning to grow. That Committee came back with a recommendation that the structure not change but that the number of meetings be reduced by one. She said since the number of municipalities in the Consortium has grown to 39 the Executive Committee is recommending the Governance Structure Committee be re-established and charged with recommending an alternative governance model.

MOVED by Ms. Drake, seconded by Mr. Rankin, and unanimously adopted by voice vote by members present.

WHEREAS, NYS Insurance Law Section 4705(a)(8) requires the Cooperative to "establish a governing board to be responsible for the management, control and administration of the municipal cooperative health benefit plan...", and

WHEREAS, NYS Insurance Law Section 4705(c)(1) requires the MCA to include provisions "describing the composition, number, and procedure under which governing board members are chosen…" , and

WHEREAS, Resolution 009-2017 created a subcommittee to explore alternatives to governance structure of the GTCMHIC, and

WHEREAS, the Governance Structure Committee reported out its work to the Board but did not make a recommendation, and

WHEREAS, the Consortium has continued to grow in number of municipal partners to the MCA as well as covered lives, and

WHEREAS, the Executive Committee deems a review of the Consortium's governance structure is again of high importance to ensure both Director engagement and the Board's ability to conduct business efficiently, and

WHEREAS, any proposed changes recommended by this subcommittee would require approval by all municipal partners and the Department of Financial Services as stated in NYS Insurance Law Section 4705 (a), now therefore be it

RESOLVED, on recommendation of the Executive Committee, That the GTCMHIC Board of Directors re-establishes the Consortium Governance Structure Review Committee charged with developing an alternative governance model for the GTCMHIC subject to the direction of the Executive Committee.

****

MOTION NO. 007-2018 – APPOINTMENTS TO GOVERNANCE STRUCTURE COMMIMTTEE

MOVED by Ms. Drake, seconded by Mr. Hart, and unanimously adopted by voice vote by members present, to create and appoint the following individuals to the Governance Structure Committee:

Judy Drake
Chuck Rankin
Steve Thayer
John Fracchia
Lisa Holmes
Eric Snow
Kevin Williams
Greg Pelicano
Ed Fairborther
Bud Shattuck
Dave Schenck
Olivia Hersey
Jim Bower

****

Presentation of Resolution from Nominating Committee

MOTION NO. 008-2018 – ELECTION OF 2019 CONSORTIUM OFFICERS

MOVED by Mr. Mutchler, seconded by Ms. Rumgay, and unanimously adopted by voice vote by members present.

RESOLVED, on recommendation of the Nominating Committee, That the Board of Directors elects the following individuals to serve from January 1, 2019 through December 31, 2019 in the roles as follows:

Chairperson - Judith Drake
Vice Chairperson – Rordan Hart
Chief Fiscal Officer – Steve Thayer
Secretary – Peter Salton
Treasurer – Richard Snyder

****

Executive Director's Report

Mr. Barber reported on communications from the Department of Financial Services and said the Consortium is required to be compliant with New York State Cybersecurity regulations. Those

regulations allow for an exemption to be applied for certain sections which he has done and it was granted. The Consortium is still required to comply with certain other regulations to ensure it is in full compliance and also do a risk assessment. He noted that his communications with the Department of Financial Services several months before about cyber security compliance were never responded to but the Consortium must now take action. A resolution will be presented later in the meeting to contract with Tompkins County Information Technology Services to provide services that will include developing necessary policies that the Consortium and its benefit administrators will have to comply with. The Audit and Finance Committee will be tasked with oversight of this matter.

New Members

Mr. Barber reported after the last meeting the Town of Covert withdrew its interest in becoming a participant in the Consortium.

Wellness Consultant Report

Mr. Barber reviewed a report that was included in the agenda packet and said in addition to developing marketing information and brochures for flu clinics and benefit fairs Ms. Berry has been working on a wellness logo for the Consortium that will be presented at the educational retreat in the Spring. She has also been working on rollout of the Blue4U program that is a wellness component of all of the Metal Level Plans. He encouraged municipalities that offer a Metal Level Plan to look at this program and let him know if they would like assistance with introducing the program to employees as it should help to reduce large claims in the future.

Municipal Healthcare Financing Cooperative

Mr. Barber reported the Audit and Finance Committee has discussed the Municipal Healthcare Financing Cooperative for Stop Loss and is not recommending that the Consortium join in 2019 due to there being an increase from one to three individuals being lasered. The Committee will continue to explore this as an option for 2020.

The December newsletter has been published and distributed to municipalities.

Financial Report

Mr. Locey reported on financial results through October 31, 2019 and said the biggest difference between budgeted and actual revenue was in prescription drug rebates with over $.5 million more than expected ($1.3 million received versus budgeted amount of $750,000). On the expense side total claims were 3% more than budgeted (medical was 8.5% over budget and prescription drug 9% below budget). At the end of October there was a net income of $374,000; in November there was $400,000 in Stop Loss reimbursement received. Mr. Locey reviewed the expense distribution report and stated 94.6% goes towards paying the benefits of members, leaving only 5.4% being used to pay all other administrative expenses; this demonstrates that the Consortium is operating in an extremely efficient manner. Over the Consortium's eight years of operations it is 2½ % below what had been originally projected for claims expense.

Mr. Locey provided a historical report on the Consortium's high cost claims and said this year there has been an increase in claimants. The top five claimants have a total of $2.4 million in medical expense and only $15,000 in drug expense. He said more people insured through the Consortium have been identified as having potential high losses in the future. This is an area identified by the Stop Loss carriers and one of the reasons why there are additional lasers. He explained a laser is someone who has been identified as a high risk and that they will go over the deductible. He said it is likely that all three of the lasers that were identified will go beyond the $600,000 deductible level. He said this is something that is happening more frequently but noted it is not unique to the Consortium.

Mr. Brown questioned why there has been such a spike in high cost claims. Mr. Locey said the cases are predominantly related to medical claims and Mr. Barber said every two years the Consortium conducts an audit of claims and the high cost claims. He said the main drivers of cost are the high cost claimants and there needs to be some discussion with Cayuga Area Physicians and Cayuga Medical Center to see what may be causing this.

Presentation of Resolutions from the Audit and Finance Committee

RESOLUTION NO. 029 – 2018 - AUTHORIZE EXTENSION OF CONTRACT FOR PRESCRIPTION DRUG CLAIMS ADMINISTRATOR FOR 2019-2020 – PROACT

MOVED by Mr. Cook, seconded by Mr. Shattuck.

Mr. Fracchia arrived on video at this time.

Mr. Brown questioned the Committee's confidence in the rebate return continuing. Mr. Barber said the budget includes an aggressive figure for rebates and explained with the rise in the cost of pharmaceuticals the drug manufacturers have passed these proceeds on to prescription benefit managers as a way to get them to push their drugs forward. He called attention to the huge increase in prescription drug spend in recent years and now there is a counter to that in the form of rebates

The resolution was unanimously adopted by voice vote by members present.

WHEREAS, the Board of Directors by Resolution No. 028-2016 awarded a one-year contract with ProAct for Prescription Benefits Manager services with the Consortium having the option to extend the contract annually for each of the next two years, and

WHEREAS, the Audit and Finance Committee has discussed and desires to extend the Prescription Benefits Manager services with ProAct for an additional two years pursuant to the Contract Addendum proposed September 19, 2018, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the contract with ProAct for Prescription Benefits Manager services be extended per the terms outlined in the for the period January 1, 2019 through December 31, 2020,

RESOLVED, further, That the Chair of the Board of Directors is hereby authorized to execute said contract with ProAct, Inc.

* * * * * * * *

RESOLUTION NO. 030 - 2018 – AUTHORIZING FINANCIAL SERVICES AGREEMENT WITH TOMPKINS COUNTY – JANUARY 1, 2019 THRU DECEMBER 31, 2019

MOVED by Mr. Cook, seconded by Mr. Salton, and unanimously adopted by voice vote by members present. Ms. Drake commented and Mr. Cook agreed on behalf of the Audit and Finance Committee, that Mr. Snyder and his staff have been very responsive to the Consortium and have provided very good service.

WHEREAS, the Consortium initially formalized a contract with the Office of the Tompkins County Finance Director for the performing Consortium Treasurer functions on July 27, 2018, and

WHEREAS, the Consortium wishes to continue this contract arrangement, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the Board of Directors hereby authorizes the Chair of the Board to sign the Financial Services Agreement with Tompkins County for a term commencing January 1, 2019 through December 31, 2019,

RESOLVED, further, that the Financial Services Agreement will be kept on file in the Consortium's records.

* * * * * * * * *

RESOLUTION NO. 031 - 2018 – AUTHORIZING INFORMATION TECHNOLOGY SERVICES AGREEMENT WITH TOMPKINS COUNTY – JANUARY 1, 2019 THRU DECEMBER 31, 2019

MOVED by Mr. Cook, seconded by Ms. Rider, and unanimously adopted by voice vote by members present. Ms. Drake said the County has helped the Consortium for several years at no cost and it is appropriate to reimburse the County for services provided.

WHEREAS, the Consortium has received technical assistance at no charge from the Tompkins County Information Technology Services Department (ITS) since beginning operations in 2011, and

WHEREAS, technical support has included website hosting and assistance, e-mail account technical support, audio and visual assistance, development of a secure online enrollment program, and general computer support, and

WHEREAS, the frequency of requests and time involved has increased as the Consortium has grown, and

WHEREAS, the Executive Committee has recommended that the Consortium provide compensation for work done by the Department on behalf of the Consortium,

WHEREAS, the Audit and Finance Committee review the Memorandum of Understanding (MOU) for Information Technology Services and has recommend that the Board of Directors authorize the Board Chairperson to sign this MOU, and

WHEREAS, since initially approved by the Audit and Finance Committee, the need was identified for additional Information Technology Services to be added to the MOU for assistance with the Consortium's compliance with NYCRR 500 Cybersecurity requirements, now therefore be it

RESOLVED, on recommendation of the Audit and Finance and Executive Committees, That the Board of Directors approves an agreement with Tompkins County Information Technology Services for 2019 based on a rate for an average of seven (7) hours per month at $60 per hour for ITS support provided to the Consortium from January 1, 2019 thru December 31, 2019 for a total of $5,040,

RESOLVED, that the amount of $5,040 will be submitted as a single invoice by ITS in January, 2019, and

RESOLVED, that ITS will invoice annually for the direct cost of the assigned Consortium Microsoft Office 365 licenses as procured under the Tompkins County Microsoft Office 365 tenant, and

RESOLVED, further, That this rate and hours associated with ITS support shall be reviewed annually to ensure that as the Consortium grows that it supports the assistance provided by the Department,

RESOLVED, further, That the Chair of the Board is hereby authorized to execute this contract on behalf of the Consortium,

RESOLVED, further, that the TC Information Technology Services Agreement will be kept on file in the Consortium's records.

* * * * * * * * *

RESOLUTION NO. 032 - 2018 – DELEGATING AUTHORITY AND RESPONSIBILITY FOR DEVELOPING CYBER SECURITY POLICIES AND PROCEDURES TO THE AUDIT AND FINANCE COMMITTEE

MOVED by Mr. Cook, seconded by Mr. Farrell, and unanimously adopted by voice vote by members present.

WHEREAS, the Consortium has been notified by the Department of Financial Services to be in compliance with NYCRR 500 Cyber Security and this notice advised the Consortium that the Consortium had not filed proper forms for compliance, and

WHEREAS, the Consortium has filed for exemption from this Regulation, and

WHEREAS, the exemption has been accepted, but this exemption does not exempt the Consortium from compliance with a few subsections of this regulation, now therefore be it

RESOLVED, That the Board of Directors, due to the requested timing of the cyber security compliance filing, gives to the Audit and Finance Committee the authority and responsibility for developing cyber security policies and procedures, conduct a risk assessment and file all of these documents as soon as practical,

RESOLVED, further, That the Audit and Finance Committee is directed to bring these policies and procedures back to the full Board for adoption.

*** * * * * * * * ***

RESOLUTION NO. 033 - 2018 – APPROVAL OF CONTRACT FOR INVESTMENT MANAGEMENT SERVICES – WILMINGTON TRUST – 2019

MOVED by Mr. Cook, seconded by Mr. Rankin. Mr. Cook this is the result of the Consortium going through a very competitive Request for Proposals process. The 2019 budget includes an estimated revenue of $200,000 and will maintain $6 million in operating cash in a local bank. Mr. Barber said the Consortium will be have three accounts with Wilmington Trust, one for the surplus reserve, one for the IBNR reserve, and each will be gaining interest. A third will be a fund balance of other reserves that will be available that will have some maturities within a week. He also noted the contract with Wilmington is for one year.

Mr. Hart said because the Consortium is made up of municipalities it is limited by General Municipal Law and State Finance Law as to what it can invest in so that restricted all of the firms that responded to the RFP to work with treasuries. He thinks the Consortium should be looking to get 2½ to 3% in future years and would like to see the interest income higher than $200,000 next year.

The resolution was unanimously adopted by voice vote by members present.

WHEREAS, the Consortium conducted a Request for Proposal process that netted six responses, and

WHEREAS, the Consortium appointed an Investment Management RFP Review Committee that interviewed three (3) highly qualified firms, and

WHEREAS, the Investment Management RFP Review Committee found that Wilmington Trust, a subsidiary of M&T Bank, had by far the largest volume of fixed income assets under management, and Wilmington offered a complete package of investment management and custodial services, and

WHEREAS, Wilmington Trust will deliver month updates, quarterly and annual reports and expressed willingness to attend meetings and educational retreats to raise our awareness of the investment management business, and Wilmington Trust agreed to complete Schedule B of our quarterly and annual JURAT financial filings with DFS (Department of Financial Services) which these investments would now require the Consortium to file as part of their services, and

WHEREAS, the Investment Management RFP Review Committee unanimously recommends the Consortium enter into a one-year contract Wilmington Trust for Investment Management Services, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the Board of Directors authorizes the Consortium to enter into a contract with Wilmington Trust for investment management services for a one-year term period January 1, 2019 through December 31, 2019,

RESOLVED, further, That the Chair of the Board of Directors is hereby authorized to execute said contract on behalf of the Consortium.

*** * * * * * * * * ***

RESOLUTION NO. 034 - 2018 - AMENDMENT TO RESOLUTON NO. 008-2013 - DESIGNATION OF BANKING INSTITUTIONS

MOVED by Mr. Cook, seconded by Ms. Rider, and unanimously adopted by voice vote by members present.

WHEREAS, Consortium Treasurer must choices of approved banking institutions to conduct financial transactions on behalf of the Consortium, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That Resolution No. 008-2013 be amended to include M&T Bank as a designated banking institution for the Consortium.

*** * * * * * * * ***

Ms. Laughlin was excused at this time.

RESOLUTION NO. 035 - 2018 – EXTENSION OF CONTRACT FOR PLAN CONSULTANT – LOCEY & CAHILL, LLC – 2019

MOVED by Mr. Cook, seconded by Ms. Niswender, and unanimously adopted by voice vote by members present. Ms. Drake agreed with Mr. Cook that the Consortium is appreciative and very fortunate to have Locey and Cahill as it's Consultant.

WHEREAS, the Consortium requires ongoing Plan consulting services to continue its operations, and

WHEREAS, the Plan consulting services needed include: strategic planning, financial analysis, recommending a budget, producing and filing benefit plan documents, calculating premium equivalents, preparing a variety of internal reports and requests for proposals, attending Board and Committee meetings, claims trends and large loss analysis, assisting municipal partner with benefit and premium questions, and interfacing with third party administrators and ancillary benefit providers, and

WHEREAS, the Consortium by Resolution No. 17 of 2013 awarded a contract for Plan consultant services on December 19, 2013 to Locey & Cahill, LLC of Syracuse for the period January 1, 2014 through December 31, 2015 with the option to renew for three additional one-year terms, and

WHEREAS, the Executive Committee has discussed the need and scope of Benefit Plan Consultant Services and recommends that the Consortium retain Locey and Cahill, LLC for those services, and

WHEREAS, the Audit and Finance Committee has reviewed and discussed the terms of the Consortium's contract with Locey and Cahill, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the Board of Directors hereby extends its contract with Locey & Cahill, LLC for an additional one-year term for the period January 1, 2019 through December 31, 2019.

****

RESOLUTION NO. 036 - 2018 - APPROVAL OF RENEWAL OF ADMINISTRATIVE SERVICES CONTRACT WITH EXCELLUS BLUECROSS BLUE SHIELD FOR MEDICAL CLAIMS ADMINISTRATION

MOVED by Mr. Cook, seconded by Mr. Shattuck, and unanimously adopted by voice vote by members present.

WHEREAS, the Greater Tompkins County Municipal Health Insurance Consortium (GTCMHIC) is a self-insured municipal cooperative health benefit plan operating pursuant to a Certificate of Authority issued by the New York State Department of Financial Services pursuant to Article 47 of the New York State Insurance Law, and

WHEREAS, Section E Paragraph 11 of the current GTCMHIC Municipal Cooperative Agreement defines the actions to be taken by the GTCMHIC Board of Directors to include the approval of contracts with third parties for the furnishing of goods and services, and

WHEREAS, the Audit and Finance Committee has determined that it is in the Consortium's best interest to continue its relationship with Excellus Blue Cross Blue Shield for the administration of the Consortium's medical claims, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee That the Board of Directors approvals renewal of the Administrative Services Contract with Excellus BlueCross BlueShield for Medical Claims Administration with fees of $36.87 PMPM for 2019 (3.5%), and $38.17 PMPM for 2020 (3.5%),

RESOLVED, further, That the Chair of the Board is authorized to execute said contract on behalf of the Consortium

****

RESOLUTION NO. 037 - 2018 - AUTHORIZATION TO PURCHASE INSURANCE POLICIES: ERRORS AND OMISSIONS, DIRECTORS AND OFFICERS LIABILITY, AND EMPLOYMENT PROTCTION COVERAGE

MOVED by Mr. Cook, seconded by Mr. Mutchler.

The resolution was unanimously adopted by voice vote by members present.

WHEREAS, it is the desire of the Board of Directors to ensure liability coverage for the Consortium, the Board of Directors personally and professionally, and the participating municipalities, now therefore be it

RESOLVED, on recommendation of the Plan Consultant, Locey & Cahill, LLC, the Tompkins County Risk Manager, and the Audit and Finance Committee, That the Consortium shall purchase coverage for these policies from the following for the period January 1, 2019 thru December 31, 2019:

- Errors and Omissions Insurance with the Darwin Group at $1,000,000 limit with $25,000 retention (placed by insurance agent Haylor, Freyer and Coon);
- Directors and Officers Liability Insurance with the Darwin Group at $1,000,000 limit with $25,000 retention and Employment Protection Liability at $1,000,000 limit (placed by insurance agent Haylor, Freyer and Coon)

RESOLVED, further, That the Plan Consultant is directed to provide the Administrative Clerk of the Consortium with a copy of each policy.

* * * * * * * * *

RESOLUTION NO. 038 - 2018 - AUTHORIZE PURCHASE OF STOP LOSS INSURANCE FOR 2019 WITH EXCELLUS AND INCREASE CATASTROPHIC CLAIMS RESERVE

Mr. Locey said they have been trying to get the Stop Loss quote finalized for the last couple of months. He said the Board should be aware that Stop Loss carriers do not like to set final rates until they have information for the year. In the receipt of the final quotes there was a major change in the policy provisions associated with Berkley. He explained that their first quote contained the same lasers as the Excellus quote; however, their final quote included a third laser that created $1.3 million more in exposure to the Consortium that what the Excellus presented. After weighing this additional risk the Committee recommended Excellus to be the Stop Loss carrier for 2019.

MOVED by Mr. Cook, seconded by Ms. Rumgay, and unanimously adopted by voice vote by members present.

WHEREAS, the Consortium must purchase stop loss insurance, as required by Section 4707 of New York State Insurance Law, and

WHEREAS, the Audit and Finance Committee has received four (4) proposals for 2019 Stop-Loss insurance and has considered the variations of Stop Loss insurance models and level of deductible, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the Board of Directors authorizes the purchase of Stop Loss insurance policy with a deductible of $600,000 from Excellus,

RESOLVED, further, That the Board of Directors hereby approves an increase in the Catastrophic Claims Reserve from $2 million to $2.8 million,

RESOLVED, further, That the Plan Consultant is directed to provide the Administrative Clerk of the Consortium with a copy of said policy.

* * * * * * * * *

Telemedicine Overview

Ms. Miller provided a demonstration on the new Telemedicine benefit that will become available on January 1, 2019 to all individuals covered under a Consortium plan. This user-friendly benefit that expands access to care by use of a mobile device, computer, or telephone for care in urgent situations that are not life threatening. Ms. Miller said information will be provided to benefit clerks and webinars will be offered to assist members in signing up. She noted regardless of what plan a member is in it will be a claim charged to the Consortium as an office visit with a cost of $40 less a member's copay. Mr. Brown said he hopes there will be tracking of prescriptions that are written. Mr. Locey agreed and said there will need to an analysis done to look closely at savings and to also see if members still visited physician.

New Business

There was no new business.

Adjournment

The meeting adjourned at 7:50 p.m.

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

RESOLUTION NO. - 2019 – APPOINTMENT OF EXECUTIVE DIRECTOR

WHEREAS, the Board of Directors adopted resolution No. 026-2018 which created the position of Executive Director, approved the position's job description, and formed a subcommittee to interview and recommend a candidate for the new position of Executive Director as the first employee of the Consortium, and

WHEREAS, the subcommittee, over the past three months has developed a pay and benefit structure, recruited, and interviewed seven candidates for the position, and

WHEREAS, the subcommittee has determined that _____ possesses the necessary knowledge and skills to fill the duties of Executive Director, and hereby recommends their appointment, and

WHEREAS, this appointment is a provisional appointment pending Civil Service classification of the position in the Exempt classification, now therefore be it

RESOLVED, That the Board of Directors hereby approves the provisional appointment of _____ to the position of Executive Director effective April xxx, 2019,

RESOLVED, further, That this position is classified as a salaried position exempt from overtime, at the salary of $xx,xxx, with full time benefits,

RESOLVED, further, That a minimum twenty-six week probationary period applies, in which the Executive Committee is charged with developing the position's performance review criteria and conducting said review.

****

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

RESOLUTION NO. - 2019 – ADOPTION OF PERSONNEL-RELATED POLICIES AND PROCEDURES – CONSORTIUM EMPLOYEES

WHEREAS, as the Consortium is now hiring employees there is the need to establish Personnel related policies, procedures and a benefit structure, and

WHEREAS, with the Town of Ithaca as the designated "Employer of Record", the Executive Director Employment Committee recommends utilizing the established policies, procedures and benefit structure of the Town of Ithaca, now therefore be it

RESOLVED, That the Board of Directors hereby adopts the Personnel-related Policies and Procedures and established benefit structure of the Town of Ithaca for the Consortium employees.

****

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

RESOLUTION NO. - 2019 – AUTHORIZING OFFICE SPACE LEASE AGREEMENT WITH THE TOWN OF ITHACA

WHEREAS, the Executive Committee has negotiated a lease agreement with The Town of Ithaca for office space for its employee and future employees, and

WHEREAS, the Consortium's legal counsel has reviewed and approves the language of the lease agreement, and

WHEREAS, the term of the lease is for one year with the ability to extend annually and all utilities are the responsibility of the landlord, now therefore be it

RESOLVED, That the Board of Directors authorizes the Vice Chair to sign said lease agreement with the Town of Ithaca for office space.

* * * * * * * *

CanaRx Services Inc 2/26/19

10903 New Hampshire Avenue
Silver Spring, MD 20993

TO: Mr. Gregory Anthony Howard
FROM: The United States Food and Drug Administration
RE: Causing the Introduction of Unapproved and Misbranded Drugs into Interstate Commerce
DATE: February 26, 2019

WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your websites listed at the bottom of this letter and determined that you and your affiliates cause the introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]. While this letter refers to CanaRx Services Inc/CRX Intl (hereinafter CanaRx), the violations discussed apply to all entities conducting business by or on behalf of CanaRx. FDA requests that you immediately cease causing the distribution of violative drugs to U.S. consumers.

UNAPPROVED NEW DRUGS

CanaRx operates as a prescription drug provider that engages in activities to cause the introduction of unapproved new drugs from foreign sources into the United States in violation of the FD&C Act. Because these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or affect the structure or function of the body, these products are drugs within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. These products are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No FDA-approved applications pursuant to section 505 of the FD&C Act [21 U.S.C. § 355] are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)].

Specifically, CanaRx contracts with public and private sector employers throughout the U.S. to provide select prescription drugs to employees. CanaRx acts as a broker between foreign pharmacies and the employer-sponsored health insurance plan to provide enrolled employees with prescription drugs. CanaRx accepts the employee's U.S. prescription and facilitates its reissue under the direction of a foreign physician. The reissued prescription is subsequently filled by a pharmacy contracted by CanaRx in that foreign physician's jurisdiction. The foreign pharmacy then ships the drug directly to the employee in the U.S. For each shipment, CanaRx uses the same templated invoice, which contains the standard disclaimer, "[d]epending on your country, our medications may appear to be different in size, shape or color." Having this disclaimer in each invoice demonstrates that CanaRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs. This distribution scheme is particularly concerning, as employees are likely inclined to trust that they will receive safe and effective drugs through their employer's "insurance" plan and may not question their legitimacy.

The substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers. For example, CanaRx offers certain drugs on its medication lists for which the FDA-approved version is subject to a Risk Evaluation and Mitigation Strategy (REMS) program, has a narrow therapeutic index, and/or is indicated to treat serious conditions such as HIV, cancer, or hepatitis. CanaRx also offers numerous maintenance medications that are indicated for conditions such as high blood pressure, high cholesterol, and acid reflux. Furthermore, the FDA-approved versions of several drugs listed on CanaRx's medication lists have been subject to one or more recalls in the U.S. FDA has established processes to recall unsafe, substandard, and poor quality drugs within the legitimate U.S. drug supply chain. No such safeguards exist for unapproved drugs illegally distributed in the U.S. from foreign sources such as those provided through CanaRx. Therefore, many of the foreign versions of FDA-approved drugs substituted by CanaRx may also have been subject to recalls that were not carried out in the U.S. CanaRx's operation does not appear to provide U.S. consumers with any protection or recourse should they receive or be harmed by drugs that may have been recalled in a foreign country.

In addition, several of the unapproved versions of FDA-approved drugs offered by CanaRx have different trade names and/or dosage amounts in their labeling than their FDA-approved counterparts. Such differences can cause patient confusion and lead to medication errors. Moreover, the substitution of FDA-approved prescription drugs with unapproved versions that may have substantially different risk profiles can pose serious health risks to consumers, especially in vulnerable patient populations that suffer from serious conditions such as HIV, cancer, or hepatitis. Unapproved drugs do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown active ingredients. Treatment with drugs that may be subpotent, superpotent, or adulterated in such vulnerable patient populations can lead to drug resistance and/or therapeutic failures, and jeopardize the effectiveness of alternative drug therapies on patient outcomes.

Examples of drugs offered on CanaRx's medication lists and a general description of their respective indications are depicted in the table below. These include drugs that are for vulnerable patient populations with serious medical conditions. Such vulnerable patient populations may have received drugs subject to a recall or may have experienced medication errors due to receiving drugs with different dosages or risk profiles, which can lead to side effects that are life-threatening.

Baraclude (hepatitis)	Norvir (HIV)
CellCept (organ rejection)	Reyataz (HIV)
Foradil (asthma, COPD)	Stivarga (cancer)
Gilotrif (cancer)	Tegretol (epilepsy, nerve pain)
Gleevec (cancer)	Tracleer (pulmonary arterial hypertension)
Inlyta (cancer)	Truvada (HIV)
Invirase (HIV)	Zortress (organ rejection)

MISBRANDED DRUGS

Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a practitioner licensed by law to administer such drugs. Because CanaRx advises consumers that their U.S. prescriptions are being filled with less expensive, foreign approved drugs, CanaRx intends for these drugs to be used as prescription drugs. This is especially concerning considering that CanaRx offers drugs that have a narrow therapeutic index (NTI) on its medication lists. One such drug currently offered by CanaRx is Tegretol. Substituting an NTI drug without the U.S. prescriber's direction poses significant health risks to patients. In particular, small differences in dose or blood concentration for NTI drugs may lead to serious therapeutic failures or adverse drug reactions that are life-threatening, or result in persistent or significant disability or incapacity.

A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). The drugs obtained through CanaRx are intended to treat conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. Therefore, adequate directions for use cannot be written for these drugs, and they must qualify for one of the exemptions to section 502(f)(1) to avoid being misbranded. The exemption to section 502(f)(1) found at 21 CFR § 201.100 does not apply to unapproved new drugs because that exemption requires that such drugs bear "the labeling authorized by the approved new drug application." Furthermore, unapproved new prescription drugs also do not qualify for the exemption set forth at 21 CFR 201.115, which also requires an approved new drug application (NDA) or active investigational new drug application (IND). Consequently, a prescription drug that is a new drug and has not been approved by FDA, or is not subject to an exemption from the premarketing approval requirements under the FD&C Act, cannot qualify for the exemptions to section 502(f)(1). Because none of the exemptions to section 502(f)(1) apply, these drugs are misbranded under section 502(f)(1).

These drugs are also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] because they fail to bear "adequate warnings against use…where [their] use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application...." This is particularly concerning because certain drugs offered by CanaRx are subject to REMS programs (e.g., Tracleer and CellCept). Specifically, the REMS program for Tracleer restricts distribution to minimize: the risk of fetal exposure and serious birth defects in female patients who are exposed to Tracleer and the risk of liver damage in patients who are exposed to Tracleer. Prescribers must order and review pregnancy tests prior to the initiation of treatment, monthly during treatment, and for one month after stopping treatment. In addition, prescribers must order and review liver function tests prior to the initiation of treatment and monthly during treatment. Furthermore, to comply with the REMS program for Tracleer, this drug must be mailed to patients from pharmacies certified in the REMS program. Pharmacies are also restricted from dispensing more than a 30-day supply and must verify the required testing prior to dispensing. The REMS for CellCept requires healthcare providers to report pregnancies to a registry and has an educational component regarding fetal toxicity. CanaRx is causing important safety measures that are put in place for the FDA-approved versions of these drugs to be bypassed.

By causing these products to be shipped to U.S. consumers, CanaRx is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

* * *

FDA is taking this action against CanaRx because of the risks posed by its conduct in facilitating the importation of unapproved new drugs and misbranded drugs to U.S. consumers. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling

review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Unapproved new drugs and misbranded drugs do not have the same assurance of safety and effectiveness as drugs subject to FDA oversight, and may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

Substituting an unapproved drug for the FDA-approved drug prescribed by a patient's healthcare practitioner can negatively affect patient outcomes because the health care practitioner may unknowingly make subsequent treatment decisions based on the patient's response to the unapproved drug. This can also cause potentially dangerous drug interactions with the patient's other medications. In addition, sourcing drugs from uninspected, unregulated, and/or unknown supply chains can result in serious health consequences, especially in vulnerable patient populations, which may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the distribution of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. Failure to do so immediately may result in further regulatory action, including seizure or injunction without further notice.

Please notify this office in writing within 10 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence. If the corrective action(s) cannot be completed within 10 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response, and any other inquiries concerning this letter, should be sent to FDA's Internet Pharmacy Task Force at **FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov (mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov)**.

Table of Websites Affiliated with CanaRx
Connecting URL
http://abacushealth.biz
http://abacushealth.com
http://abcscripts.com
http://adirondackhealthcanarx.com
http://albanymedsintl.com
http://amherstmeds.com
http://amsterdammeds.com
http://ashleywardrx.com
http://aspireindianacanarx.com
http://auburnmeds.com
http://averillparkmeds.com
http://bayarearooferscrx.com
http://bethlehemmeds.com
http://brandscripts.com
http://burlingtonmeds.com
http://burlingtonscripts.com
http://burlingtonscripts.com/BCBS
http://burlingtonscripts.com/BCE
http://burlingtonscripts.com/HP
http://canarx.com
http://canarxalbco.com

http://capitalotbmeds.com
http://ccmhg.com/mymedicationadvisor
http://cityofgreensburgrx.com
http://cityofschenectadymeds.com
http://columbiacountymeds.com
http://crownpointrx.com
http://crxdirect.com
http://crxintl.com
http://crxmeds.com
http://crxmeds.com/CCC.html
http://crxmeds.com/TC.html
http://csdameds.com
http://dcsmeds.com
http://delameds.com
http://dickinsoncrx.com
http://dphrx.com
http://enterprisemeds.com
http://entrustscripts.com
http://etmwmeds.com
http://everettmeds.com
http://everettmeds.com/BCE
http://everettmeds.com/HP
http://fallrivermeds.com
http://franklinmeds.com
http://greateramsterdammeds.com
http://guilderlandmeds.com
http://hardwoodmeds.com
http://hcgitmeds.com
http://herrsscripts.com
http://hudsonfallsmeds.com
http://iscrx.com
http://jaynescrx.com
http://jcccanarx.com
http://jsfscripts.com
http://knauzrx.com
http://leemasonryrx.com
http://madisonmeds.com
http://mainesensemeds.com
http://mainesensemeds.com/CORE-HRA
http://mainesensemeds.com/HSA
http://mansfieldmeds.com
http://mcsmeds.com
http://mmhcanarx.com
http://mohonasenmeds.com
http://montgomerymeds.com
http://munciemeds.com
http://mygloberx.com/GlobeAR

http://mygloberx.com/GlobeCMG
http://mygloberx.com/GlobeMetallurgical
http://mygloberx.com/GlobeNiagara
http://mygloberx.com/GlobeSelma
http://mygloberx.com/GlobeWVA
http://mymedadvisor.com
http://mymedicationadvisor.com
http://mymodernmeds.com
http://myyocscripts.com
http://newcastlemeds.com
http://niskayunacsdmeds.com
http://otsegomeds.com
http://pagechesterrx.com
http://panostoncrx.com
http://pbvrx.com
http://phbrx.com
http://plattsburghmeds.com
http://pogominemeds.com
http://portlandmeds.com
http://pramcrx.com
http://pramcrx.com/Pram-TC
http://ptdc36meds.com
http://reveremeds.com
http://richmondrx.com
http://romemeds.com
http://saratogacanarx.com
http://sbtmeds.com
http://sbtmeds.com/CC.html
http://scottsburgrx.com
http://selectmailmeds.com
http://shenendehowameds.com
http://slcmeds.com
http://slumeds.com
http://spartanscripts.com
http://ssehpmeds.com
http://stangersurveyingrx.com
http://steubenmeds.com
http://stickleycanarx.com
http://suarezmeds.com
http://theabacusgroup.com
http://tnameds.com
http://townofclarksvillerx.com
http://troymeds.com
http://ualocal467crx.com
http://ulsterscripts.com
http://vineyardsrx.com
http://voorheesvillemeds.com

http://wbameds.com
http://westminstercanterburymeds.com
http://westsuburbanhealth.com/wellness/mymedicationadvisor
http://witrx.com
http://www.canarx.com/AdirondackHealthCanaRx
http://www.canarx.com/AmherstMeds
http://www.canarx.com/AmsterdamMeds
http://www.canarx.com/AuburnMeds
http://www.canarx.com/AverillParkMeds
http://www.canarx.com/Burlington
http://www.canarx.com/CrownPointRx
http://www.canarx.com/CRXMeds
http://www.canarx.com/DELAMeds
http://www.canarx.com/EntrustScripts
http://www.canarx.com/EverettMeds
http://www.canarx.com/GreaterAmsterdamMeds
http://www.canarx.com/GuilderlandMeds
http://www.canarx.com/HaverhillMeds
http://www.canarx.com/HenCoMeds
http://www.canarx.com/HighlandsCountyRx
http://www.canarx.com/LeeMasonryRx
http://www.canarx.com/LewisMeds
http://www.canarx.com/MaineSenseMeds
http://www.canarx.com/MohonasenMeds
http://www.canarx.com/MontgomeryMeds
http://www.canarx.com/MuncieMeds
http://www.canarx.com/NewCastleMeds
http://www.canarx.com/OtsegoMeds
http://www.canarx.com/PLATTSBURGHMeds
http://www.canarx.com/PortlandMeds
http://www.canarx.com/REVEREMeds
http://www.canarx.com/REVEREMeds/BCBS.html
http://www.canarx.com/REVEREMeds/HP.html
http://www.canarx.com/ROMEMeds
http://www.canarx.com/SLCMeds
http://www.cseameds.com
http://www.goodhealthgateway.com
http://www.mainesense.org/?page_id=461
http://www.minuteman-nashoba.org/employees-retirees/mymedicationadvisor
http://www.pnwmeds.com
http://www.rcscsdmeds.com
http://www.scantichealth.org/prescription-plans.html
http://www.schenectadymeds.com
http://www.schenectadymeds.com/MVP_General.htm
http://www.schenectadymeds.com/NonMedicare1.htm
http://www.somervillema.gov/sites/default/files/documents/MMA-OrderingInstructions.pdf
http://www.wayland.k12.ma.us/administration/human_resources/benefits

http://www.webster-ma.gov/index.php?option=com_content&view=article&id=141&Itemid=705
http://www3.newton.k12.ma.us/hr/medflexinfo
http://youngcrx.com

Table of Business Entities Affiliated with CanaRx
(b)(4)

Sincerely,
/s/
Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research

More in Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)

MORRIS & DE LA ROSA
LAW OFFICES
6171 NORTH SHERIDAN ROAD
No. 312
CHICAGO, ILLINOIS 60660

Writer's Direct Telephone: (312) 927-4680
Writer's Direct E-Mail Address: MDLRusuk@aol.com

March 11, 2019

Dear Mr. Christl:

I am counsel in the United States for CanaRx Services, Inc. ("CanaRx"), of Windsor, Ontario, Canada. I write in response to your Warning Letter of February 26, 2019, to G. Anthony Howard, the Chief Executive Officer of CanaRx.

Permit me to state, at the outset, that CanaRx views itself as an ally of the U.S. Food and Drug Administration ("FDA") in efforts to ensure that the medicines that American consumers receive are safe and conform to their doctors' orders.

We have carefully reviewed your letter and respectfully submit that you are mistaken as to the facts regarding CanaRx and its activities. As will be seen below, CanaRx is not an internet pharmacy or a pharmacy of any kind. Rather, CanaRx is a service agency that guides American consumers who wish to exercise their rights of personal importation of doctor-prescribed medicines to trade with licensed and regulated pharmacies in three nations — Canada, the United Kingdom, and Australia — that are precisely of the kind of reputable "brick-and-mortar" pharmacies in countries whose regulatory regimes are on a par with that of the FDA that FDA Commissioner Scott Gottlieb praised in the agency's public announcement of the issuance of your warning letter.

CanaRx does its work from its service offices in Windsor, Ontario. It does not maintain any stores or ordering offices in the United States. To engage the services of CanaRx, an individual American must initiate contact with CanaRx in Canada and then engage, with CanaRx, in an individual enrollment process that includes entry into an individual agency agreement, the voluntary grant to CanaRx of authority to receive and use personal and health information from and about the patient, and the voluntary disclosure to CanaRx of the patient's relevant health history.

Mr. Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, Maryland 20910

By Mail and by E-Mail to FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov

Throughout the entire life of CanaRx and all its programs, these key facts have applied to every single transaction in which CanaRx has been involved:

- In each case CanaRx has served an individual American patient under an individual written agreement with that patient under which the patient furnishes to CanaRx a pertinent health history and the necessary authorities to act as the patient's agent in helping the patient shop for prescription medicine and in helping the patient present a claim for benefits to the appropriate health plan.

- CanaRx will assist patients in shopping only for approved brand-name drugs that have been prescribed by the patient's U.S. physician and that the patient will take under the supervision of the patient's U.S. physician.

- CanaRx programs do *not* involve prescriptions for generic drugs, controlled substances, opioids, "lifestyle drugs", drugs that do not travel well, and drugs that are needed for acute care rather than for long-term maintenance. When the patient's physician prescribes a medicine in one of those categories, CanaRx declines to assist the patient and, instead, suggests that the patient proceed to a local pharmacy.

- CanaRx never assists a patient seeking a drug without a doctor's prescription, and every prescription that is presented to CanaRx is verified and is subjected to a utilization review by pharmacists engaged by CanaRx before the prescription is placed for processing by a pharmacy.

- The only pharmacies to which CanaRx will refer a patient are those in countries whose health regulatory regimes are recognized by the United States Government as comparable in rigorousness and substantive standards to those which prevail under the FDA and State regulators in the United States: Currently in Canada, the United Kingdom, and Australia.

- It is not possible to obtain medicine through a CanaRx program anonymously; without a doctor's prescription; or through a website. Although CanaRx maintains various websites for the convenience of patients and program participants, the websites are informational only, and do not include ordering portals.

As will be seen, some of the street addresses and websites that you associate with CanaRx are actually completely unconnected with CanaRx, leading us to believe that, perhaps, there have been mistakes of identity made in some of the inquiries undertaken by your staff.

Your letter does not mention a crucial fact, acknowledged by the Commissioner and your colleagues in media interviews in announcing the warning letter: That the FDA has not received *any* complaints about medicine dispensed by a pharmacy to a patient through a CanaRx program. That's important because, when carefully analyzed, your warnings turn out to be speculation and conjecture based on hypotheses that are at variance to the facts of what CanaRx is and does. In serving its clients, who are individual Americans seeking affordable ways of obtaining the

medicines that their doctors have prescribed for them and that they will be taking under the direct supervision of their own physicians, CanaRx follows a rigorous set of safety protocols that we believe are a model that the FDA should welcome as part of its essential work of protecting the lives and health of American patients. When the facts are on the table, we would hope that the FDA would acknowledge that CanaRx is not part of the problem regarding the flow of counterfeit, substandard, and other dangerous drugs that imperil Americans but, rather, is a legitimate part of the solution to that problem.

CanaRx has always sought to be cooperative with the FDA and transparent in its dealing with the FDA and other regulatory agencies. Thus, for example, when in 2003 the FDA warned CanaRx about the dangers involved in assisting Americans as they imported insulin — not because of questions about the quality of the medicine or about the reputability of the legitimate pharmacies that were dispensing it, but because of concerns that it was difficult in shipment to maintain necessary conditions for product safety in transit — CanaRx promptly yielded to the FDA's expertise and ceased assisting Americans in shopping for insulin. Thus, to this day, CanaRx declines to assist American patients in shopping outside the United States for medicines that do not travel well, and such drugs will not be found in any current lists of medicines that can be sought through a CanaRx program.

The intervening years have passed without any further warning letters or other adverse communication until CanaRx received your letter of February 26, 2019. During those years there have been a handful of occasions on which CanaRx has learned that the FDA had contacted a CanaRx client, a client's physician, or a client's plan sponsor about a particular matter. On each of those occasions CanaRx has proactively reached out to the FDA office or official in question to offer assistance and information if and as desired. Not once has any of those contacts resulted in any adverse action or complaint of any kind, and none involved any instance of a bad drug or patient harm.

In this spirit and practice of taking FDA guidance seriously, CanaRx takes due note of the discussion in your warning letter regarding certain drugs that have appeared on CanaRx lists for which the FDA-approved version is subject to a Risk Evaluation and Mitigation Strategy ("REMS") program. In each instance in which CanaRx has assisted an American in obtaining a REMS drug, the drug has been prescribed by the patient's U.S. doctor and its administration has been supervised by the patient's U.S. doctor. Although there have been no reports of any defects in the medicines or the program, CanaRx takes the point that the time and distance involved between prescription and dispensing and then between dispensing and administration may affect the physician's supervisory routines, which understandably require delicate calibrations in REMS cases. For that reason CanaRx is immediately yielding to the FDA's guidance and will no longer assist Americans in obtaining REMS drugs. Similarly, although there have been no reports of any problems with any of the other drugs to which your warning letter specifically refers, out of deference to the FDA and to show that CanaRx views itself as the FDA's ally in the right for drug safety, CanaRx will immediately discontinue its programs with respect to all 14 drugs that you have listed.

With those preliminary statements, I turn now to a consideration of each of the points raised in your letter, paragraph by paragraph.

> The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your websites listed at the bottom of this letter and determined that you and your affiliates cause the introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug , and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 331(a), 331(d), and 355(a)]. While this letter refers to CanaRx Services Inc / CRX Intl (hereinafter CanaRx), the violations discussed apply to all entities conducting business by or on behalf of CanaRx. FDA requests that you immediately cease causing the distribution of violative drugs to U.S. consumers.

Only two CanaRx entities, CanaRx Services, Inc., and CRX International, Inc., serve American clients, and both conduct their operations in Windsor. Services for clients of both agencies are furnished by CanaRx Services, Inc., in Windsor. There are no other "affiliates". Your letter lists a total of 165 websites. Of these, 1 is the main CanaRx website; 92 are websites that are associated with particular plans whose beneficiaries CanaRx serves (and of those 92, aside from duplicates, 6 are dead links and 1 is a pass-through link that merely connects a visitor with the main CanaRx website); 28 are websites that are associated with particular plans whose beneficiaries CRX serves; 18 are for programs whose beneficiaries CanaRx no longer serves; 10 are for programs whose beneficiaries CRX no longer serves; and 15 are websites not owned by CanaRx, are dead links, or are otherwise irrelevant to any matter at hand. (Similarly, your letter lists many old and outdated addresses for CanaRx, some of which have been inapplicable for years. The only correct address for CanaRx is the first one stated at 235 Eugenie Street West in Windsor, Ontario. CanaRx maintains no offices or business operations in the United States, including in Florida; other businesses you name — Abacus Health Care Solutions, GBS Insurance Agency, Inc., and Prescription Benefit Services, Inc. — are not CanaRx companies but are independent entities having no cross-ownership or other CanaRx ties; the several Florida addresses you list are residential properties formerly owned by Mr. Howard or family members, all of whom are Canadian citizens; the Manitoba address you list formerly belonged to a completely unrelated, and now defunct, pharmacy with a vaguely similar name.) In any event, no drug can be ordered via a CanaRx website; all orders must be tendered off-line and accompanied by a verifiable prescription written by a licensed U.S. physician.

> CanaRx operates as a prescription drug provider that engages in activities to cause the introduction of unapproved new drugs from foreign sources into the United States in violation of the FD&C Act. Because these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and / or affect the structure or function of the body, these products are drugs within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. These products are also new drugs as defined by Section 201(p) of the FD&C [21 U.S.C. § 321(p)] as they are not generally recognized as safe and effective for their labeled uses. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No FDA-approved applications pursuant to Section 505 of the FD&C Act [21 U.S.C. § 355] are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)].

CanaRx is not a "provider" of prescription or other drugs. Rather, in each instance when a drug is dispensed, a licensed and regulated pharmacist and pharmacy are the providers. The name, address, and contact information of the

dispensing pharmacy are fully disclosed to the patient receiving the medicine, and the same information is accessible to postal, customs, and FDA inspectors as the patient's shipment enters the country. No drug is new or unapproved, and each is produced by government-approved manufacturers. No drug is introduced into commerce; rather, each prescription is dispensed directly to an individual patient solely for that patient's personal use under the supervision of that patient's U.S. physician.

> Specifically, CanaRx contracts with public and private sector employers throughout the U.S. to provide select prescription drugs to employees. CanaRx acts as a broker between foreign pharmacies and the employer-sponsored health insurance plan to provide enrolled employees with prescription drugs. CanaRx accepts the employee's U.S. prescription and facilitates its reissue under the direction of a foreign physician. The reissued prescription is subsequently filled by a pharmacy contracted by CanaRx in that foreign physician's jurisdiction. The foreign pharmacy then ships the drug directly to the employee in the U.S. For each shipment, CanaRx uses the same templated invoice, which contains the disclaimer, "[d]epending on your country, our medications may appear to be different in size, shape or color." Having this disclaimer in each invoice demonstrates that CanaRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs. This distribution scheme is particularly concerning, as employees are likely inclined to trust that they will receive safe and effective drugs through their employer's "insurance" plan and may not question their legitimacy.

CanaRx does not contract with public and private employers and does not "provide" any drugs to anyone. Rather, CanaRx contracts with individual patients to connect them with Canadian, British, and Australian physicians and pharmacies who serve those patients individually. CanaRx accepts referrals from public and private employers, but does not contract with them, and when CanaRx presents benefits claims to health plans it does so expressly as the individually-appointed agent of a plan's beneficiary. The instruction that CanaRx gives to the foreign physician and pharmacy is to dispense in accordance with the U.S. physician's prescription using the approved brand-name version of the medication that the prescriber has ordered, sourcing exclusively to approved manufacturers in the dispensing jurisdiction. The outcome is exactly the same as if the U.S. patient physically visited a brick-and-mortar drugstore in London, Toronto, or Sydney and presented his prescription and health history there, but without having to go to the expense of physical international travel. The drugs in question are not new and are not substitutions; they are precisely what the FDA's counterpart regulators in Canada, Britain, and Australia have authorized under conditions of art and science that the FDA recognizes as being on a par with itself. More to the point, the medicines that are supplied are not generics, are not compounded to order, and have not been mysteriously sourced; they are well-identified and are obtained in a transparent, documented, and regulated supply-chain. CanaRx can never be the sole agency to whom a plan refers a patient for medicines, as, for example, CanaRx does not supply generic drugs (which, in any event, are often less expensive than brand-name drugs even if obtained through a CanaRx program) or drugs needed for acute care. A patient who can trust a brick-and-mortar pharmacy around the corner from his house ought to be able, as Commissioner Gottlieb has said, to trust a brick-and-mortar pharmacy in Canada — or, for that matter, one in Britain, or Australia.

> The substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers. For example, CanaRx offers certain drugs on its medication lists for which the FDA-approved version is subject to a Risk Evaluation and Mitigation Strategy (REMS) program, has a narrow therapeutic index, and / or is indicated

> to treat serious conditions such as HIV, cancer, or hepatitis. CanaRx also offers numerous maintenance medications that are indicated for conditions such as high blood pressure, high cholesterol, and acid reflux. Furthermore, the FDA-approved versions of several drugs listed on CanaRx's medication lists have been subject to one or more recalls in the U.S. FDA has established processes to recall unsafe, substandard, and poor quality drugs within the legitimate U.S. drug supply chain. No such safeguards exist for unapproved drugs illegally distributed in the U.S. from foreign sources such as those provided through CanaRx. Therefore, many of the foreign versions of FDA-approved drugs substituted by CanaRx may have been subject to recalls that were not carried out in the U.S. CanaRx's operation does not appear to provide U.S. consumers with any protection or recourse should they receive or be harmed by drugs that may have been recalled in a foreign country.

This paragraph is troubling and unfair because is consists entirely of speculation (*e.g.*, "may have been subject...") and is lacking of any specific examples. In fact, because every CanaRx transaction is fully documented from start to finish, contacting patients in the events of recalls is eminently doable and standard practice, and, in fact, a recall can readily be accomplished with the dispensing pharmacy replacing a recalled drug shipment without expenses to the patient. Each of the regulators in the sourcing countries — Canada, Britain, and Australia — has recall procedures and the FDA itself has announced from time to time that they are coordinated with each other and with the FDA. CanaRx is satisfied that the non-U.S. physicians and pharmacies (all of whom are fully licensed and regulated) to which it refers American patients are capable of, and diligent about, keeping current with the relevant states of the art and with use, recall, and other notices issued from time to time by the FDA and their own local regulators. It should also be noted that some prescription drugs that are subject to REMS programs for some patients are not subject to such programs for others (because of the varying natures of their conditions and other factors). Nonetheless, CanaRx wishes to leave the FDA in no doubt about the willingness of CanaRx to heed the guidance of the FDA when it is clear and specific and, if only for that reason alone, CanaRx has promptly ceased assisting its clients in obtaining any of the 14 drugs that are expressly mentioned in your letter.

> In addition, several of the unapproved versions of FDA-approved drugs offered by CanaRx have different trade-names and / or dosage amounts in their labeling than their FDA-approved counterparts. Such differences can cause patient confusion and lead to medication errors. Moreover, the substitution of FDA-approved prescription drugs with unapproved versions that may have substantially different risk profiles can pose serious health risks to consumers, especially in vulnerable patient populations that suffer from serious conditions such as HIV, cancer, or hepatitis. Unapproved drugs do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown active ingredients. Treatment with drugs that may be subpotent, superpotent, or adulterated in such vulnerable patient populations can lead to drug resistance and / or therapeutic failures, and jeopardize the effectiveness of alternative drug therapies on patient outcomes.

Again we are at the disadvantage of responding to speculation without specific examples. CanaRx is unaware of any instance in which a subpotent, superpotent, or adulterated drug was dispensed to one of CanaRx's clients. The instructions given to dispensing pharmacies are to dispense in accordance with the directions, including as to active ingredients and dosages, of the patient's U.S. prescriber. My client's experience is that the regulatory regimes of the United States, Canada, Britain, and Australia are highly and successfully harmonized in the field of pharmaceuticals and particularly with regard to the relatively narrow field of brand-name drugs in which CanaRx assists its clients.

> Examples of drugs offered on CanaRx's medication lists and a general description of their respective indications are depicted in the table below. These include drugs that are for vulnerable patient populations with serious medical conditions. Such vulnerable patient populations may have received drugs subject to a recall or may have experienced medication errors due to receiving drugs with different dosages or risk profiles, which can lead to side effects that are life-threatening.

Yet again your letter insists on speculating on events that "may" have happened but did not, and again it fails to supply specific facts regarding any specific case of a medicine actually dispensed by a pharmacy to a client of CanaRx. We are grateful, however, that you have identified specific drugs that are of concern to the FDA under these circumstances, most of which have, in any event, previously been discontinued from inclusion in any CanaRx program. Of the 14 drugs, all are sourced from approved manufacturers (which may include a firm's parent, subsidiary, sister, and affiliated companies and licensees which, located inside and outside the United States, variously structure their operations including as to the locations of where they own intellectual property and conduct their manufacturing and distribution operations, all as disclosed to the FDA and Canadian, British, and Australian regulators); 3 are REMS drugs, one of which was previously discontinued by CanaRx; and 11 are non-REMS drugs, of which 6 were previously discontinued. Thus, only Baraclude, CellCept, Foradil, Gleevec, Norvir, Tegretol, and Truvada were available to a U.S. consumer through the CanaRx program at the time of your warning letter, and all are made by approved manufacturers. As previously stated, out of deference to the FDA, CanaRx will no longer assist American consumers in obtaining any of the 14 drugs you specified.

> MISBRANDED DRUGS.
>
> Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a practitioner licensed by law to administer such drugs. Because CanaRx advises consumers that their U.S. prescriptions are being filled with less expensive, foreign approved drugs, CanaRx intends for these drugs to be used as prescription drugs. This is especially concerning considering that CanaRx offers drugs that have a narrow therapeutic index (NTI) on its medication lists. One such drug currently offered by CanaRx is Tegretol. Substituting an NTI drug without the U.S. prescriber's direction poses significant health risks to patients. In particular, small differences in dose or blood concentration for NTI drugs may lead to serious therapeutic failures or adverse drug reactions that are life-threatening, or result in persistent or significant disability or incapacity.

In every case a drug dispensed through a CanaRx program has been prescribed by a U.S. physician as part of a course of treatment that the U.S. physician is directly supervising. Foreign prescribers engaged by CanaRx on behalf of American consumers are instructed to confer with the American prescriber if there is any doubt about active or other ingredients, dosage, or any other concern, and to ensure that the American treater's directions are observed. CanaRx has never received a complaint from a patient or a physician about the quality or conforming characteristics of a dispensed prescription for Tegretol and has never received a report of a therapeutic failure or adverse drug reaction in connection with any medicine dispensed through a CanaRx program. Even so, CanaRx will respect the FDA's caution and, effective immediately, no longer assists American patients in ordering Tegretol.

> A drug is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). The drugs obtained through CanaRx are intended to treat conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. Therefore, adequate directions for use cannot be written for these drugs, and they must qualify for one of the exemptions to section 502(f)(1) to avoid being misbranded. The exemption to section 502(f)(1) found at 21 CFR 201.100 does not apply to unapproved new drugs because that exemption requires that such drugs bear "the labeling authorized by the approved new drug application." Furthermore, unapproved new prescription drugs also do not qualify for the exemption set forth at 21 CFR 201.115, which also requires an approved new drug application (NDA) or active investigational new drug application (IND). Consequently, a prescription drug that is a new drug and has not been approved by FDA, or is not subject to an exemption from the premarketing approval requirements of the FD&C Act, cannot qualify for the exemptions to section 502(f)(1). Because none of the exemptions to section 502(f)(1) apply, these drugs are misbranded under section 502(f)(1).

We are handicapped in responding to this paragraph because your letter does not specify what "these drugs" that are allegedly misbranded are. You seem to be laboring under the misapprehension that drugs are obtained through a CanaRx program on the basis of "self-diagnosis" without prescription of the medicine and supervision of treatment by a licensed medical practitioner. All medicines involved in a CanaRx program must be prescribed by a physician who is treating the patient and who will supervise the administration of the medicine. Prescriptions are accepted for placement only when they prescribe name-brand drugs that the FDA has already approved.

> The drugs are also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] because they fail to bear "adequate warnings against use ... where [their] use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application...." This is particularly concerning because certain drugs offered by CanaRx are subject to REMS programs (e.g., Tracleer and CellCept). Specifically, the REMS program for Tracleer restricts distribution to minimize: the risk of fetal exposure and serious birth defects in female patients who are exposed to Tracleer and the risk of liver damage to patients who are exposed to Tracleer. Prescribers must order and review pregnancy tests prior to the initiation of treatment, monthly during treatment, and for one month after stopping treatment. In addition, prescribers must order and review liver function tests prior to the initiation of treatment and monthly during treatment. Furthermore, to comply with the REMS program for Tracleer, this drug must be mailed to patients from pharmacies certified in the REMS program. Pharmacies are also restricted from dispensing more than a 30-day supply and must verify the required testing prior to dispensing. The REMS for CellCept requires healthcare providers to report pregnancies to a registry and has an educational component regarding fetal toxicity. CanaRx is causing important safety measures that are put in place for the FDA-approved versions of these drugs to be bypassed.

CanaRx is confident that the prescribers, treaters, and dispensers of the patients whom CanaRx serves conscientiously discharge their professional responsibilities, including as to observing necessary therapeutic protocols and practicing at the state of the art with respect to pre-prescription testing and monitoring during and after the course of administration of medicines. CanaRx is persuaded, however, that, given the intensity of the REMS programs, their efficacy is more likely ensured with shorter lines of communication. CanaRx therefore accepts the guidance of the FDA

and, as has been reported above, has immediately ceased to assist patients in obtaining Tracleer and CellCept.

> By causing these products to be shipped to U.S. consumers, CanaRx is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

CanaRx respectfully rejects the contentions that any drugs ordered by patients through a CanaRx program are misbranded; and that CanaRx causes any drugs to be introduced into interstate commerce. Every prescription ordered through a CanaRx program is imported into the United States by the individual patient for his or her personal use.

I have already addressed the lists of street addresses, "affiliated" businesses, and websites included in your letter. Visits to the websites actually operated by CanaRx will show that they are not ordering sites and do not include ordering portals.

CanaRx agrees with the FDA on the principles that undergird patient safety, and strongly concurs that obtaining drugs from licensed and regulated pharmacies supported by well-documented chains of supply from approved manufacturers is a crucial element in achieving the goal of safely delivering to each patient the medicine that the patient's doctor has ordered.

CanaRx takes seriously your cautions regarding medicines that require special attention from prescribers, dispensers, and patients, and has therefore immediately ceased to furnish assistance to consumers in ordering any of the 14 drugs specified in your warning letter.

I trust that we have satisfactorily addressed your concerns.

Sincerely yours,

Joseph A. Morris

Mr. G. Anthony Howard
Chief Executive Officer
CanaRx Services, Inc.

Greater Tompkins County Municipal Health Insurance Consortium (GTCMHIC)

2018 Budget Performance Analysis

Results as of: ***12/31/2018***
# of Months: ***12***

		2018 Adopted Budget	*2018 Year-to-Date*	*2018 Actual Results*	*Variance*	*% Difference*
Income						
	Medical Plan Premiums	$42,527,371.07	$42,527,371.07	$42,401,705.53	-$125,665.54	-0.30%
9000	Ancillary Benefit Plan Premiums	$156,750.00	$156,750.00	$150,959.06	-$5,790.94	-3.69%
	Interest	$16,000.00	$16,000.00	$21,937.59	$5,937.59	37.11%
9010	Rx Rebates	$1,000,000.00	$750,000.00	$1,308,285.17	$558,285.17	74.44%
9040	Stop-Loss Claim Reimbursements	$0.00	$0.00	$446,891.08	$446,891.08	n/a
9030	Other	$4,120.00	$4,120.00	$5,400.26	$1,280.26	31.07%
Total Income		***$43,704,241.07***	***$43,454,241.07***	***$44,335,178.69***	***$880,937.62***	***2.03%***
Expenses						
8090	Medical Paid Claims	$27,872,149.95	$27,872,149.95	$29,703,463.95	$1,831,314.00	6.57%
8120	Rx Paid Claims - ProAct	$12,014,156.34	$12,014,156.34	$10,863,475.35	-$1,150,680.99	-9.58%
8121	Rx Paid Claims - CanaRx	$300,000.00	$300,000.00	$164,063.30	-$135,936.70	-45.31%
8050	Medical Admin Fees	$1,044,357.36	$1,044,357.36	$1,082,657.64	$38,300.28	3.67%
	Rx Admin Fees	$85,555.95	$85,555.95	$85,978.61	$422.66	0.49%
8084	Flu Clinic Fees	$10,000.00	$10,000.00	$600.00	-$9,400.00	n/a
8091	NYS Graduate Medical Exp.	$264,075.00	$264,075.00	$237,553.45	-$26,521.55	-10.04%
9060	ACA PCORI Fee	$12,259.93	$12,259.93	$12,361.08	$101.15	0.83%
8115	ACA Transitional Reins. Program Fees	$0.00	$0.00	$0.00	n/a	n/a
8110	Stop-Loss Aggregate and Specific	$888,633.32	$888,633.32	$442,185.54	-$446,447.78	-50.24%
	Advance Deposit / Pre-Paid Claims	$100,000.00	$100,000.00	$0.00	-$100,000.00	-100.00%
8070	Legal Fees	$10,609.00	$10,609.00	$13,862.50	$3,253.50	30.67%
8055	Executive Director Fees	$33,990.00	$33,990.00	$49,900.62	$15,910.62	46.81%
8030	Consultant Fees	$59,410.40	$59,410.40	$87,097.03	$27,686.63	46.60%
8000	Accounting Fees	$30,900.00	$30,900.00	$25,811.25	-$5,088.75	-16.47%
8010	Actuarial Fees	$11,404.68	$11,404.68	$16,800.00	$5,395.33	47.31%
8020	Audit Fees	$63,785.45	$56,650.00	$34,325.00	-$22,325.00	-39.41%
8060	Insurances (D&O / Prof. Liability)	$36,453.01	$36,453.01	$33,139.11	-$3,313.90	-9.09%
8041	Internal Coordination (Finance)	$65,400.00	$65,400.00	$51,541.31	-$13,858.69	-21.19%
8042	Internal Coordination (Support)	$20,600.00	$20,600.00	$22,464.30	$1,864.30	9.05%
	Surety Bond Fee / Loan Interest	n/a	n/a	$0.00	n/a	n/a
	Payment Refund	n/a	n/a	$0.00	n/a	n/a
9050	Ancillary Benefit Premiums	$156,750.00	$156,750.00	$149,173.19	-$7,576.81	-4.83%
9060	Other Expenses / Supplies	$6,180.00	$6,180.00	$20,937.11	$14,757.11	238.79%
Total Expenses		***$43,086,670.40***	***$43,079,534.95***	***$43,097,390.34***	***$17,855.39***	***0.04%***
Net Income		$617,570.67	$374,706.12	$1,237,788.35		
Ending Balance		$25,802,131.21	$25,559,266.66	$26,422,348.89		
Liabilities and Reserves						
	IBNR Claims Liability	$4,720,595.05	$4,720,595.05	$4,720,595.05	12% of Incurred Claims	
5010	Surplus Account Per §4706(a)(5)	$2,017,487.57	$2,017,487.57	$2,017,487.57	5% of Premium Income	
	Rate Stabilization Reserve	$1,966,914.60	$1,966,914.60	$1,966,914.60	5% of Paid Claims	
5012	Catastrophic Claims Reserve	$2,000,000.00	$2,000,000.00	$2,000,000.00	Established by Board Policy	
Total Liabilities and Reserves		$10,704,997.23	$10,704,997.23	$10,704,997.23		
Unencumbered Fund Balance		***$15,097,133.98***	***$14,854,269.43***	***$15,717,351.66***		

Medical Premiums = 6000 + 6010
Interest Income = 9021 + 9022
Rx Admins Fees = 8081 + 8082 + 8083
Advance Deposit = 4020 + 4021

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

RESOLUTION NO. - 2019 – ADOPTION OF CYBER SECURITY POLICY

WHEREAS, the Department of Financial Services (DFS) has promulgated Part 500 of Title 23 of the Official Compilation of Codes, Rules, and Regulations (NYCRR) of the State of New York, and requires Article 47 Municipal Cooperative Health Benefit Plans to comply, and

WHEREAS, Part 500 Cyber Security allows for agencies to seek exemption from some portions of this Part, and

WHEREAS, the Executive Director has filed and received exemption under the conditions of: 1) fewer than 10 employees, and 2) does not control any information systems, and

WHEREAS, these exemptions still require the Consortium to comply with sections 500.09 Risk Assessment, 500.11 Third Party Service Provider Security Policy, 500.13 Limitations on Data Retention, and sections 500.17 through 500.23, with only sections 9,11, and 13 requiring action by the Consortium's Board of Directors to establish a policy and perform risk assessments, and

WHEREAS, the Consortium has entered into a contract with the Tompkins County Information Technology Services Department for developing such policy and to perform the stated risk assessment thereafter, and

WHEREAS, the Tompkins County Information Technology Services Department has developed and presented the attached policy proposal for review by the Audit and Finance Committee, and

WHEREAS, the Audit and Finance Committee has reviewed said Cyber Security Policy and found it to be in compliance with NYCRR Part 500 sections 09,11, and 13, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the GTCMHIC Board of Directors hereby adopts said policy,

RESOLVED, further That the Board of Directors directs the Executive Director to conduct an assessment for operations compliance with this Cyber Security Policy, and

RESOLVED, further, That the Board of Directors hereby delegates the authority to approve the any amendments to this policy to the Audit and Finance Committee.

****

Greater Tompkins County Municipal Health Insurance Consortium

125 East Court Street • Ithaca, New York 14850 • (607)274-5590
www.healthconsortium.net • consortium@tompkins-co.org

"Individually and collectively we invest in realizing high quality, affordable, dependable health insurance."

RESOLUTION NO. - 2019 – 2019 BUDGET AMENDMENT – CONSORTIUM EMPLOYEE EXPENSES

WHEREAS, the position of Executive Director has expenses associated with the position not anticipated in the adopted 2019 Consortium budget, and

WHEREAS, the Consortium will be entering into a lease with the Town of Ithaca for office space and will be acquiring additional equipment for its staff, now therefore be it

RESOLVED, on recommendation of the Audit and Finance Committee, That the following budget amendment be hereby approved by the Board of Directors:

Account No.		Amount
66002	Fringes	$20,333
66001	Executive Director Salary	_____
8805	Executive Director Fees	(to remain open for Consultant charges)
8151	Computer Equipment	$5,602
8152	Lease Expense/Parking	$4,500 ($900 parking + $3,600 lease)
8044	Compensation – County ITS Support	$10,131

****

Meeting Notes and ITS Response for Health Insurance Consortium (2/28/19)

1. New POE Switch and Professional Services
   Need to purchase, configure and install new switch to manage new office location at the Town of Ithaca on the County network. If approved, ITS would manage this office location with the same service level of any other County facility. The attached quote totals **$5,090.81** which includes the Cisco 24 Port network switch and three-year service plan; and the professional services from FirstLight is based on engineering labor costs to configure this switch and complete all configuration changes on existing County network equipment under the existing 2019 ITS/FirstLight Professional Services contract.

2. Relocation of existing single County Shoretel Phone
   ITS will relocate the existing Shoretel phone with the same extension (274-5590) to the new Town of Ithaca office location. **No cost change or additional Shortel charges.**

3. Add three new Office 365 G3 licenses and reconfigure existing accounts
   This would result in a total of five Office 365 accounts assigned to the Health Care
   a) Add G3 license and title: HCConsulting@tompkins-co.org (*asap*)
      est. **$212** for 2020
   b) Add G3 license and title: HCWellness@tompkins-co.org
      est. **$212** for 2020
   c) Add G3 license and title: HCInfo@tompkins-co.org
      est. **$212** for 2020
   d) Change existing G3 EDconsortium@tompkins-co.org to HCDirector@tompkins-co.org
      $206.13 for 2019 (paid)
   e) Change existing G5 Consortium@tompkins-co.org to HCAdmin@tompkins-co.org
      $360.75 for 2019 (paid)

   *All Office 365 licensing costs are annual subscriptions. ITS will prorate expense based on implementation date of each new license.

4. Ricoh Mulitfunction Color (8.5x11, Legal)
   Need to purchase, configure and install new color Multifunction (print/copy/fax/scan) at the new office location at the Town of Ithaca on the County network. If approved, ITS would manage this device with the same service level of any other County units under the current RICOH contract. The attached unit description would cost a total **$1,544.06** for one-time purchase, ***plus*** support/maintenance service fees of .0046 per click for black and white, and .045 per click for color billed monthly by ITS. These fees are the direct cost we are charged under the existing Ricoh service contract with the County. In addition the monthly per click service fees cover toner and maintenance.

5. VPN (remote access), Encryption, Data Management for Michelle Cocco Laptop
   ITS will coordinate these items with Michelle. It would be best to implement these changes at the same time Michelle migrates to a new laptop as discussed at the meeting. Sophos encryption and anti-virus at **$28** per year, per device; or **$84** per year for three laptops.

6. New Latitude Series Dell Laptops
   It was discussed that three new laptops, two docking stations, and four monitors would be required. Below are the costs for Dell equipment standardized on the County network as procured from the NYS OGS contract.

   Large laptop (15.6") with number pad: **$1,200** ea.
   Small laptop (14") without number pad: **$900** ea.

   Docking stations: **$125** ea.

   Monitors: **$150** ea.

7. Tompkins County ITS Implementation Charge Estimations (**$1,380**)
   Under the existing MOU between Tompkins County ITS and the Health Insurance Consortium a charge of $60 per hour. The following are *estimates* (actuals to be billed directly) for each itemized section above:
   1. Switch – 6 hours **$360**
   2. Phone - 1 hour **$60**
   3. Microsoft Office 365 – 4 hours **$240**
   4. Ricoh MFD – 2 hours **$120**
   5. VPN etc. – 4 hours **$240**
   6. Laptop setup - 6 hours **$360**

MEMORANDUM OF AGREEMENT
GREATER TOMPKINS COUNTY MUNICIPAL HEALTH INSURANCE CONSORTIUM AND TOMPKINS COUNTY INFORMATION TECHNOLOGY SERVICES DEPARTMENT

This is municipal cooperation agreement pursuant to General Municipal Law 119-o between the Greater Tompkins County Municipal Health Insurance Consortium and the Tompkins County Information Technology Services Department for the provision of technology services provided to the Consortium including support in compliance with 23 NYCRR 500.

A) This shall be an annual agreement, effective January 1, 2019 thru December 31, 2019.

B) The Consortium shall be billed annually based on a rate of 7 hours per month at $60 per hour for ITS support provided to the Consortium during the calendar year for a total of $5,040.

C) The Consortium shall be billed annually for the direct cost of the assigned Consortium Microsoft Office 365 licenses as procured under the Tompkins County Microsoft Office 365 tenant.

D) This rate is based on an estimate of services and will be reviewed each year prior to renewal.

E) Either party may terminate this agreement with or without cause upon 30 days written notice.
TOMPKINS COUNTY INFORMATION TECHNOLOGY SERVICES

_____	_____
Name Chair, Board of Directors	Name
_____	_____
Title	Title
_____	_____
Date	Date