CSRO
Coalition of State Rheumatology Organizations

BOARD OF DIRECTORS

Officers

Madelaine A. Feldman, MD, FACR
President

Gary Feldman, MD
Vice President

Michael Saitta, MD, MBA
Treasurer

Michael S. Brooks, MD, FACP, FACR
Secretary

Directors

Kostas Botsoglou, MD
Director

Mark Box, MD
Director

Aaron Broadwell, MD
Director

Adrienne Burford Foggs, MD
Director

Sarah Doaty, MD
Director

Harry Gewanter, MD, FAAP, MACR
Director

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Amar Majjhoo, MD
Director

Gregory Schimizzi, MD
Director

Michael Schweitz, MD
Director

Joshua Stolow, MD
Director

Headquarter Office

Ann Marie Moss
Executive Director

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info

February 24, 2021

Pramod John, Ph.D.
CEO, VIVIO Health Inc.
1933 Davis Street Suite 274
San Leandro, CA 94577

Dear Dr. John,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country formed to advocate for excellence in rheumatologic disease care, and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our nationwide coalition serves practicing rheumatologists in charge of patient care for these illnesses. We have been one of the leading voices in the drug pricing arena, particularly when it comes to PBMs and formulary construction. We understand and lecture throughout the country on the perverse incentives that encourage higher list prices, and how that hurts employers and their employees who pay percentage co-insurances based on inflated list prices in particular.

We are writing to you concerning numerous complaints that CSRO has received from its members regarding Vivio's interference with their clinical decision-making, and concerning disregard for standard of care. While we all share concern for the rising cost of health care, a one-sided approach utilizing only cost cutting is not in the best interest of our patients nor their employers who may be reliant upon a certain level of uninterrupted productivity.

Circumvention of the Doctor-Patient Relationship
CSRO members have communicated that Vivio is requiring mandatory medication changes for its clients' beneficiaries. These changes are mandated in contravention of the treating physician's medical judgment, and solely for financial reasons. Such "non-medical switches" are below standard of care and, can result in serious adverse consequences for stable patients. These consequences include loss of effectiveness for the original treatment with the potential of irreversible changes in the joint structure, function and stability; increased comorbidities resulting in increased downstream medical costs, increased absenteeism, and loss of livelihood secondary to disability.

Many autoimmune and musculoskeletal conditions present in unpredictable fashions, requiring a high degree of individualized and tailored care. On average it takes 18 months to stabilize a rheumatoid arthritis patient and these capricious changes threaten the stability of disease suppression and control. Increased RA disease activity is associated with increased risk of cardiovascular disease and cancer due to prolonged inflammation. We hope that you would be transparent with your clients that their employees' livelihoods and health may be at risk with "non-medical

switches" that are not guided by best practices and standard of care but by "bottom-line" medicine.

Vivio's website indicates that its qVivio Clinicals model would replace "arbitrary formularies" and "PAs" with "individualized care planning." While we agree that the PBM formularies are based primarily on which manufacturer can generate the largest profit for the PBM, the evidence suggests that Vivio's approach is primarily dollar-driven, and seriously compromises appropriate individualized patient care. Indeed, CSRO has fielded reports from our members that Vivio *clinicians* have indicated that disputed medication changes ARE driven by cost to the employer, not an individualized plan of care developed in concert with the patient's treating physician. In fact, Vivio failed to furnish a clinical peer that could appropriately evaluate the treating physician's appeal. Again, these mandatory switches are not based in science and to the contrary may be extremely harmful to the patient, all to fulfill Vivio's promise to reduce costs.

Here are just 2 examples of harmful switches demanded by Vivio that threatened to endanger our members' rheumatology patients.

- Vivio mandated a change in medication for a patient in long-time remission on Humira, requiring a switch from the patient's self-injectable Humira to a completely different medication that had to be given intra-venously. Appeals were made and were subsequently denied. This was followed by 2 non-rheumatologist "peer to peer" reviews. The "clinician" suggested an off-label dosing interval for the Humira of every 3-4 weeks and admitted it was about the cost to the employer. After a letter threatening legal action, they approved the drug.
- Another egregious example was the Vivio mandate to switch a patient stable on IV Orencia for nearly 4 years to an entirely different infused medication.

Continued non-medical switching by Vivio is unacceptable and risks patient health. This is particularly true when the criteria used by Vivio lack transparency and leave no discernible role for physicians' clinical decision making. It is ironic that statements made by Vivio imply that physicians' decisions are based solely on financial gain and yet Vivio's existence is based completely on supply chain economics without any understanding of the complexity involved in the care of the chronically ill patient on a day-to-day basis. It appears that Vivio possesses a mistaken and erroneous belief that biologics are all the same and can be switched in patients haphazardly in order to save dollars. That is not the definition of "value-based care."

We are interested in **the names and credentials of the rheumatologist(s) who work with your Vivio PharmDs to** make these monetarily driven clinical decisions on our patients? In addition, CSRO has been told that there were pictures of rheumatologists placed on your website, implying that they agree with your practices. A few days later those same pictures disappeared after many of the rheumatologists reported being unaware that their photos were being used in that way. This suggests a lack of transparency and honesty in dealing with physicians.

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info

Mandatory Site of Service and Specialty Drug Acquisition Changes
CSRO members have reported that Vivio has mandated acquisition of provider administered drugs through a specialty pharmacy. This requirement to "white bag" specialty drugs threatens both patient access and safety. **Is Vivio purchasing these biologics directly? Is Vivio shipping these drugs to themselves? Is Vivio subcontracting the shipping and handling to the vendors? Who has oversight over Vivio's pharmacy activities?**

Under the white bagging model, practices do not have control over the handling, preparation, and storage conditions of the drug prior to its administration. Improper handling on the part of a specialty pharmacy can have serious consequences for patients, and white bagging removes practices' ability to prevent adverse events through internal oversight. While practices' responsibility for much of the pre-administration handling is removed under the white bagging model, their liability is not. Practices may still be held liable for adverse events that occur because of circumstances they no longer control under a white bagging model.

The likely outcome of this acquisition model will be decreased patient access to needed medication. The margins for practices engaged in buy and bill are thin. But these thin margins are what allows physicians to keep their infusion suites open. Reimbursement for administration of the drug alone does not sufficiently cover the overhead costs associated with infusing patients in private practices. Under a white bagging model, inventory control costs will increase dramatically and practices will still bear the costs of intake and storage, equipment, staff, facilities, spoilage insurance, and other overhead without compensation. Moving to a white bagging model threatens the viability of private practice rheumatologists continuing to infuse their own patients in their office.

CSRO is also concerned about other mandatory changes for site of service, including redirecting patient infusions to unsupervised infusion centers. The drugs infused for rheumatologic diseases have the potential for serious adverse reactions. Accordingly, they should be administered in settings that provide for appropriate supervision by qualified personnel.

There have been false accusations on Vivio's website regarding physicians who infuse medications in their office. Additionally, we have been told by some members that **Vivio is forcing their patients to change rheumatologists in order to find one that will follow Vivio's egregious recommendations**. Directing a patient away from their rheumatologist can be traumatic for a patient with a chronic autoimmune condition and disrupt the continuity of care. It damages the doctor-patient relationship potentially leading to patient drop out from care and consequent loss of disease control, increased morbidity, progressive disability, and additionally an increase in the cost of care in the short and long run.

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info

A key mission of CSRO is to advocate for continuity of care with the treating rheumatologists. Disrupting that continuity is shortsighted and is most certainly counterproductive.

Tapering Biologics

The author of the **most recent** study on tapering biologics in rheumatoid arthritis patients recently said, "The study indicates that in RA patients in sustained remission on TNF inhibitors, continued treatment should be the preferred choice," said lead author Siri Lilligraven, MD, MPH, PhD, of Diakonhjemmet Hospital in Oslo, Norway. This was presented at European E-Congress of Rheumatology in 2020, held virtually by the European League Against Rheumatism (EULAR).

Vivio appears to be willing to risk our patient's wellbeing with mandatory tapering of their biologic with no other concern except for cost and without peer reviewed studies and evidence-based data to support these changes. Benefit managers who have no concept of the difficulty in attaining and maintaining disease control for inflammatory arthritis patient should not be involved in these decisions capriciously. Decisions that utilize a" throw-of-the-dice" approach, hoping to win have no place in medical care. Unfortunately for our patients, Vivio's definition of winning does not include any patient health benefit but rather saving money. Vivio's website claims *not to follow population health but individual care programs* – the "biologic tapering" program is the antithesis to individualized care. In light of this, CSRO requests that Vivio provide the scientific evidence supporting your biologic tapering program and how it determines the medication tapering for each individual patient. For example, a "clinician" on a peer-to-peer discussion with a rheumatologist inappropriately suggested an arbitrary increase to the interval between Humira injections to 4 weeks does not appear to be based in science and is not an option listed in the FDA approved product information sheet.

Conclusion

It is troubling that your website, and other Vivio media comments, seem to belittle physicians' knowledge and ability to care for their patients, implying that even oncologists can be replaced by a primary care physician with the right algorithm in hand. Additionally, it has been stated to our members in letters from Vivio that FDA approval of a drug does not necessarily mean that it is effective or even safe. These statements are *a priori* antithetical and dangerous while attempting to subvert the doctor-patient relationship, promote distrust in the agency that approves medications for the US, and attempt to justify Vivio's cost cutting decisions.

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info

CSRO
COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Runaway pricing must be addressed along with our patient's health, safety, and quality of life. We are concerned that Vivio's policies, while paying lip service to the patient's conditions and 'individualized care' mantra, maintains a *cost-cutting, economics only* approach to patient care.

CSRO has been in communication regarding your policies with other organizations such as the American College of Rheumatology and the Community Oncology Alliance. We would be happy to take part in discussions regarding these issues and the growing concerns various organizations have with your policies.
Please contact Brian Henderson at bhenderson@hhs.com to schedule a meeting.

Sincerely,

Madelaine Feldman, MD, FACR
President – Coalition of State Rheumatology Organizations
MFeldmanCSRO@gmail.com

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202
P: (414) 918-9825 | F: (414) 276-3349
Email: info@csro.info | Website: www.csro.info