

August 21, 2018

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Subject: CMS-1693-P

Dear Madam/Sir,

Covectra would like to acknowledge the Centers for Medicare and Medicaid Services (CMS) foresight and efforts to modernize Medicare and restore the doctor-patient relationship. Creating an efficient, value-based healthcare system for the 21st century is an enormous challenge that impacts many Americans, and thus is a top priority for our country.

Covectra is a developer of Technology-based Compliance Tracking Solutions that are patient-centered, cloud-based, and facilitate near real-time data generation for the physician and patient that lead to enhanced outcomes. While creating these tools, Covectra acquired a broad and deep understanding of the diverse stakeholders across the healthcare spectrum and the barriers that exist that are preventing the adoption of new technologies, the very modernization CMS is seeking to expedite.

In 2016, the Health and Human Services (HHS) Interagency Pain Research Coordinating Committee (IPRCC) published the National Pain Strategy, A Comprehensive Population High-Level Strategy for Pain, and found:

*Insurance policies have been shown to affect consumer choices of treatments and their adherence to treatment regimens. Payment policies also can affect the clinical strategies adopted by health care providers. Payment policies for different procedures and products, formulary placement of drugs, and managed care arrangements all can affect the choices made by patients and physicians about managing chronic pain. **The structure of payment and coverage arrangements can therefore exert powerful effects on how pain is managed.***
(Service & Delivery, Page 34)

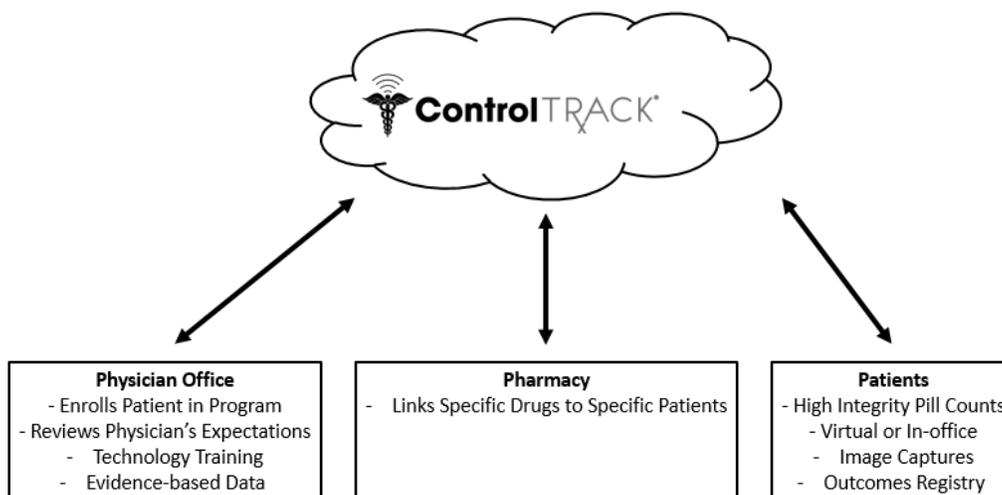
While our comment will primarily focus on Covectra's experience and solutions in the areas of pain and addiction, we maintain that many of the barriers and challenges are addressable and endured in other disease states. Consequently, the benefits and gains to patient outcomes through the application of Technology-based Compliance Tracking can also be realized in other therapeutic areas.

Comment: A fundamental barrier to the adoption of technology-based solutions that can modernize healthcare, improve patient outcomes, and lower costs is the lack of economic and administrative incentives for physicians, pharmacies and other practitioners for new services required to integrate technology into treatment.

Therefore, it is crucial CMS take into consideration the wide range of support services practitioners will be providing to execute modernization, ensure the Relative Value Units (RVUs) and payments are commensurate with the effort required, and that the appropriate Billing Codes are established and well understood across the healthcare treatment landscape.

ControlTrack® – Technology-based Compliance Tracking Model

As an example, Covectra’s ControlTrack® Patient Compliance Solution enables physicians to extend the reach of their practice beyond its four walls and introduces new technologies that create an enhanced level of transparency and communication while preserving the vital physician-patient relationship.



Covectra is commencing a ControlTrack® study with Brigham & Women’s Hospital Pain Management Center in 4Q18 relative to opioids. Leveraging the model above, specific patients will be linked to specific opioids dispensed to them by integrating various ControlTrack® technologies and utilized in conjunction with the Pain Center’s Patient Engagement Tool. ControlTrack® will enable the Pain Center to conduct high integrity pill counts both in-office or virtually using communication technologies such as Apple FaceTime or Skype along with the ControlTrack® Patient Phone App. Today, two patients taking the same opioid can share the pills in order to deceive the physician because pills are dispensed in vials. ControlTrack® not only helps prevent this behavior, but also

tracks that the patients are adhering to the physician's expectations. The physician's office can also monitor the patient's activity without directly engaging them by reviewing images the patient uploads into their patient profile in the cloud. The patient profile can also be configured to send the physician's office notifications if the patient is taking doses too soon, or taking too much, based on the prescription details. These new capabilities are also beneficial for contentious patients who are trying to adhere to their physician's directions, but may have trusted family members or associates who are stealing opioids from them without their knowledge or consent.

ControlTrack® also includes a Patient Registry that enables the physician to not only track opioid compliance, but also any alternative pain treatments such as physical therapy, acupuncture, psychosocial counseling, etc. All of this data is linked with patient feedback enabling the physician to monitor and determine what treatment regimens are leading to the best patient outcomes. ControlTrack® aggregates this evidence-based data at the patient and practice levels, and can also be shared in a regulatory compliant manner across practices, raising the awareness level of all participating physicians in support of fact-based treatment decisions and improved patient outcomes.

Technology-based Compliance Tracking Solutions are also aligned with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain:

1. Establish treatment goals with patients that include realistic pain and function objectives
2. Ensure patients understand the risks and realistic benefits of opioid therapy and the responsibilities of both patient and clinician for managing therapy
3. Conduct a harm/benefit analysis with the patient within 1-4 weeks of starting treatment or dose escalation and at least every 3 months
4. Regularly evaluate the patient's overdose risk and incorporate strategies to mitigate risks in the patient's pain management plan

As CMS develops the new Physician Fee Schedule (PFS), modernization may be accelerated if Evaluation and Management (E&M) visits and Billing Codes include new required services, such as:

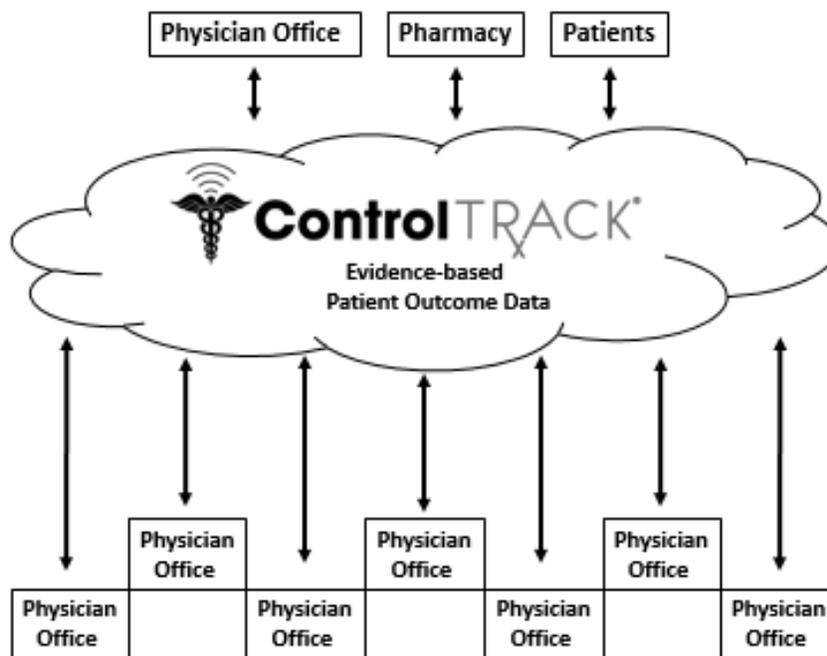
- 1. Enrolling patients and configuring patient data into technology-based systems**
- 2. Training patients on how to utilize new tools, such as patient phone applications**
- 3. Monitoring patients directly (pill counts) or indirectly (reviewing patient uploaded information), in-office or virtually**
- 4. Creating Dispensing Fees for pharmacies that have an essential role in linking specific drugs to specific patients**

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Multi-Layered Brand Protection

Comment: Technology-based Compliance Tracking Solutions can improve the quality of treatment, reduce costs, enhance physician-patient communication, and be utilized by multiple physicians treating a specific patient. While ControlTrack® is currently being used to address the most difficult compliance/utilization issue surrounding opioid use, this technology can easily be transferred to other therapeutic areas where compliance and adherence is an issue.

Therefore, CMS should include the utilization of such technologies as a qualifying factor for eligibility into the Quality Payment Program (QPP) and a consideration for reducing the physician’s program administrative reporting requirements.



Technology-based Compliance Tracking Solutions create vast repositories of evidence-based, meaningful patient outcome data. The data value is maximized through the engineering of intuitive user interfaces and reporting capabilities configured to demonstrate the significant factors impacting the patient’s health. Reports that not only can be utilized by the practitioner(s), but also shared with the patient, further enriching the physician-patient relationship and proactively engaging the patient in their own care.

Critical mass is developed as this evidence-based data is shared with other physicians who may be treating the same patient, as well as aggregating the data across practices to determine what treatment regimens are most effective and leading to the best patient outcomes.

Additional value can be garnered and physician burden minimized by creating reports that generate data relevant to the CMS QPP, which demonstrate the physician's efforts towards:

1. Improving beneficiary population health
2. Improving the care received by beneficiaries
3. Lowering costs through improvement of care and health
4. Advancing the use of healthcare information between allied providers and patients
5. Educating, engaging and empowering patients as members of their care team
6. Extending the reach of the practice

These benefits are particularly meaningful in the treatment of pain, the use of opioids, and efforts to address the addiction epidemic. While many of the recent recommendations and regulations have constrained physician treatment options and reduced patient access in an effort to "screen-out" risk, improving transparency of patient use and the communication between the physician and patient will enable physicians to "screen-in" legitimate Medicare beneficiaries and lead them down a path to successful outcomes.

Thank you for affording the public the opportunity to comment on your plans to modernize Medicare and restore the physician-patient relationship. There are many significant technological opportunities evolving that can improve the quality of care for Medicare beneficiaries; however, establishing effective economic/administrative incentives across the healthcare landscape will be critical to facilitate the new treatments being adopted.