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To: U.S. Food and Drug Administration Docket No. FDA-2014-N-0233

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Developer of the Divert-X System

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Subject: New Controlled Substance management systems are severely needed

The Notice seeks information on **management systems** that could prevent patient harm by helping prescribers monitor for signs of abuse or diversion by facilitating effective patient management and follow-up. This is the core function of the Divert-X System that provides actionable real-time information to cause discovery and integrate follow-up.

Divert-X – the dispensing and behavioral monitoring system under development by VateX – tackles the prescription drug abuse crisis directly by seeking to separate authentic patients from those who are exaggerating the intensity and duration of symptoms. Those who subvert the system to feed an addiction or sell their medications are far less likely to demonstrate the spectrum of dosing behaviors exhibited by compliant, authentic patients. A healthcare insurer has permitted VateX to pilot Divert-X in a region it serves so that VateX can demonstrate the efficacy of the intervention via robust science.

The pilot of Divert-X includes an additional layer of management tools for prescribers, pharmacists, and payers that is termed “Active MTM.” Medication Therapy Management (MTM) is a well-regarded and proven drug safety approach that is used by all insurers that offer Medicare plans. The goal of MTM is to identify and intervene in complex poly-pharmacy cases so that patient safety and care efficiency (*e.g.*, spending) can be assured. These interventions are typically made by physicians and pharmacists who have the specialized training and practice focused on clinical pharmacology issues. The interventions are mandated, scheduled regularly, and comprised of written, patient-specific guidance and reporting. Unfortunately, MTM is uncommon for Controlled Substance safety enhancement because 1) prescribing of Controlled Substances is voluminous and 2) addiction, misuse, and diversion are deeply hidden behaviors – hence, MTM resources cannot be targeted with any efficiency.

Because MTM principles are not used to guide therapy with Controlled Substances, VateX employs a healthcare analytics approach, Active MTM, to nominate patients who appear to need help. The principles of Active MTM are depicted in Figure 1 below. Under the current system, there is a paucity of information surrounding the intent, motive, and medication-use idiosyncrasies of each patient. Pharmacies lack detailed clinical and diagnostic information and are essentially bystanders in the process. Clouding the clinical picture further, nearly all Controlled Substances treat diseases that lack objective measures for diagnosis and follow-up such as pain, anxiety, and ADHD. As a result, patient self-report – known to be unreliable when addiction or street sale is involved - drives spending for excessive clinical, diagnostic, and pharmacy services.

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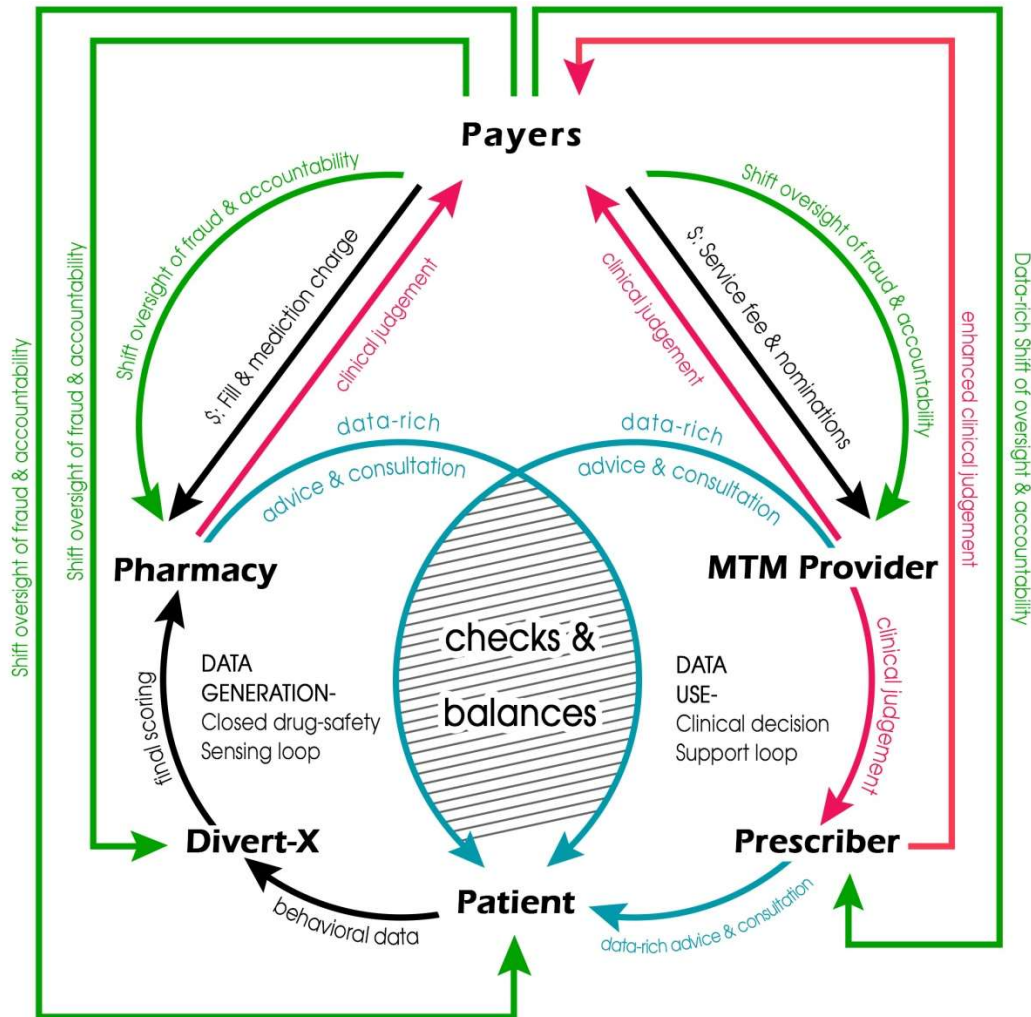


Figure 1: *The Active MTM Management System for Controlled Substances: Checks & Balances Lower Fraud Costs, Improve Clinical Outcomes, and Create a New Paradigm of Accountability Among Providers and Beneficiaries. The presence of detailed data and multi-party scrutiny discourage providers and beneficiaries from unsafe activities and relieve the current over-concentration of regulatory and law enforcement burden on the prescriber.*

Active MTM is the Vatec approach to uncovering hidden fraud and to identifying and helping patients who are misusing their medications. Active MTM uses real-time, objective data collected from Divert-X devices, combined with state PMP data and insurer records, to afford rapid nominations for MTM intervention. As shown in Figure 1, all parties have access to patient-specific objective information and scoring and so, they are aware that significant checks & balances exist. The current islands of autonomy (see Figure 2) that now exist will be disrupted, and this should cause each act of prescribing and dispensing to be more thoughtful. For example, repetitive prescribing or dispensing in the face of external red flags will be more quickly noticed by other participants on the healthcare team because of broadly dispersed data.

Prescribers take direct clinical responsibility for the care of patients but, unique to the Controlled Substance arena, they must also shoulder significant regulatory and law enforcement burdens. Hence, patient care and access suffer because of overburdening, fear, and lack of training and interest in law enforcement techniques. The addition of objective data beyond patient self-report allows for a broad shift of risk and responsibilities that can be easily adopted by any system and any payer. Active MTM is scalable and transferrable among healthcare systems, all of which are afflicted by the prescription drug abuse crisis. Comparison of Figure 1 (Active MTM) with Figure 2 (current system) shows the additional risk shifting and checks-and-balances that are afforded by Active MTM. By adding Divert-X monitoring, patients showing addictive or diversionary behaviors can be objectively nominated for intervention by an MTM Provider, specifically trained to address substance abuse issues, who can assist and share responsibilities.

Active MTM should cause a major shift in risk and accountability and should improve care quality and access to care. Figure 2 below shows the structure of the current management system for Controlled Substances. Comparing the green arrows in Figures 1 and 2, it becomes clear that checks & balances are introduced. Currently prescribers are entirely responsible for the disposition and use of Controlled Substances by their patients. Given the grave climate surrounding prescription drug abuse, pressure from DEA and state medical boards is intense. For honest prescribers, this concentration of risk (without corresponding objective information or reimbursement) has become onerous, leading to diminished access for patients in need. Under Active MTM risks and accountability are shared by six entities. Checks & balances among these providers will identify problems early and actively, and new liabilities will develop for ignoring data flow. Active MTM promotes active discovery of safety issues and information sharing. As a single example, patients who have been nominated for MTM intervention will have access to the shared wisdom and mutual oversight of their MTM Provider and their prescriber. In addition to enhanced care quality, a web of shared accountability and scrutiny should increase trust for patients who are truly in need, increasing care access.

Active MTM will not disrupt or reduce beneficiary choice because pharmacies have strong incentives to participate (the subject of a separate Memorandum submitted to this Docket – search for “System Incentives and Workflow Issues”) and because most MTM Providers are pharmacists. Although Active MTM will reduce dispensing by uncovering fraud and misuse, the system is strongly positive for the profession of pharmacy because it utilizes and leverages a key expertise of the profession. Evidence-based assistance of patients in the safe use of Controlled Substances builds another mechanism by which pharmacies can compete for status and broaden their business.

Active MTM is an active quality feedback system. Because Active MTM data and checks & balances bring more clarity to clinical, diagnostic, and pharmacy spending related to Controlled Substances, the payer can more easily assess the quality of individual clinical judgment and outcomes. As an example, dispersed accountability will uncover well-hidden complicit providers (some schemes cannot be identified by current utilization monitoring) by identifying and highlighting clinical judgment that is incompatible with red flags – aberrant data shared widely are more likely to be noticed.

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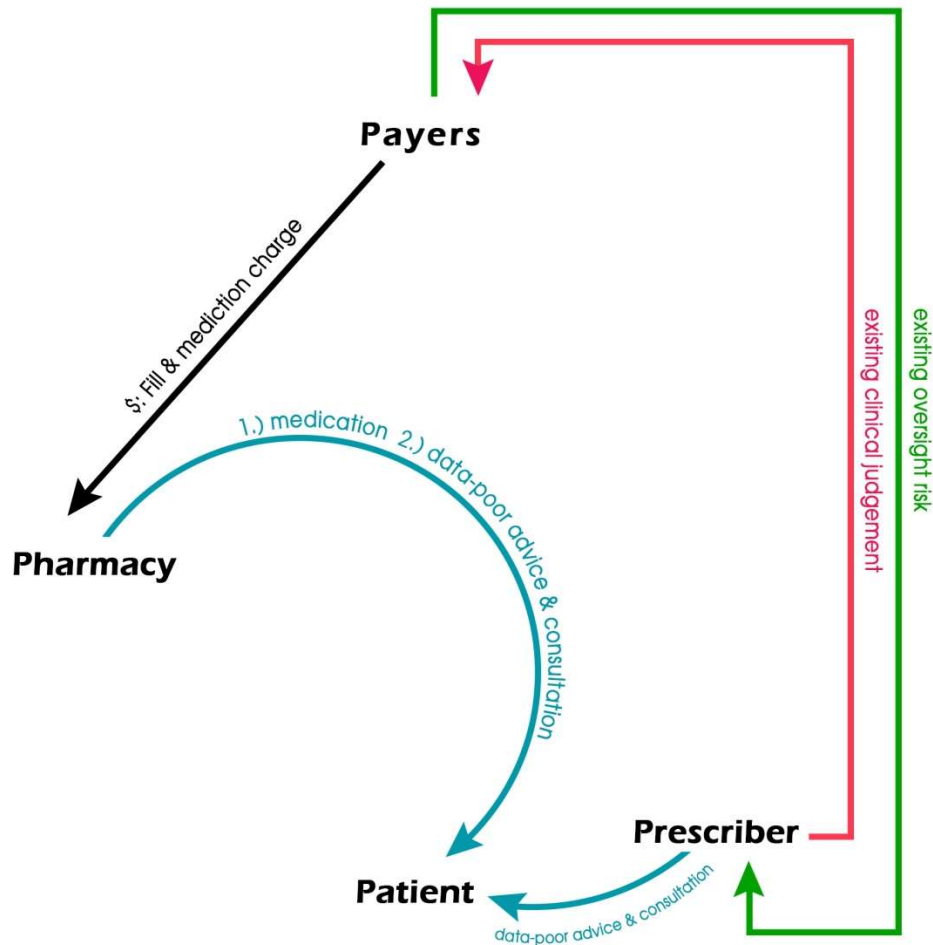


Figure 2: *Current Controlled Substance Management System: Stakeholders Are Islands, With Most Decisions Based on Patient Self-Report. Patient self-report is less reliable when patients are a) addicted to the medication, b) selling the medication, or c) participating in a fraud ring. Criminals understand how to avoid detection by PMPs and utilization review. Liability for diversion and misuse is currently concentrated on the prescriber due to a lack of objective data dispersed among the care team.*

The current model for Controlled Substance dispensing and management shown in Figure 2 is incompatible with the safety and societal risks posed by Controlled Substances and has led to massive mortality and excess healthcare spending. Figure 2 shows the current climate in which most participants are isolated and bereft of detailed information. For example, pharmacies and payers lack detailed clinical and diagnostic information and are essentially bystanders in the process. MTM is not shown in Figure 2 because no evidence-based tools exist for nominating any but the most egregious cases for follow-up – the variety of fraud types detailed in federal prosecutions shows that organized diverters know and exploit current gaps.

Most of the relationships and information access shown in Figure 1 do not exist now and cannot exist without a source of objective medication-use data such as that afforded by the Divert-X device. Because so many new relationships are created by Active MTM, the impact of the new system has been summarized in Figure 3 below.

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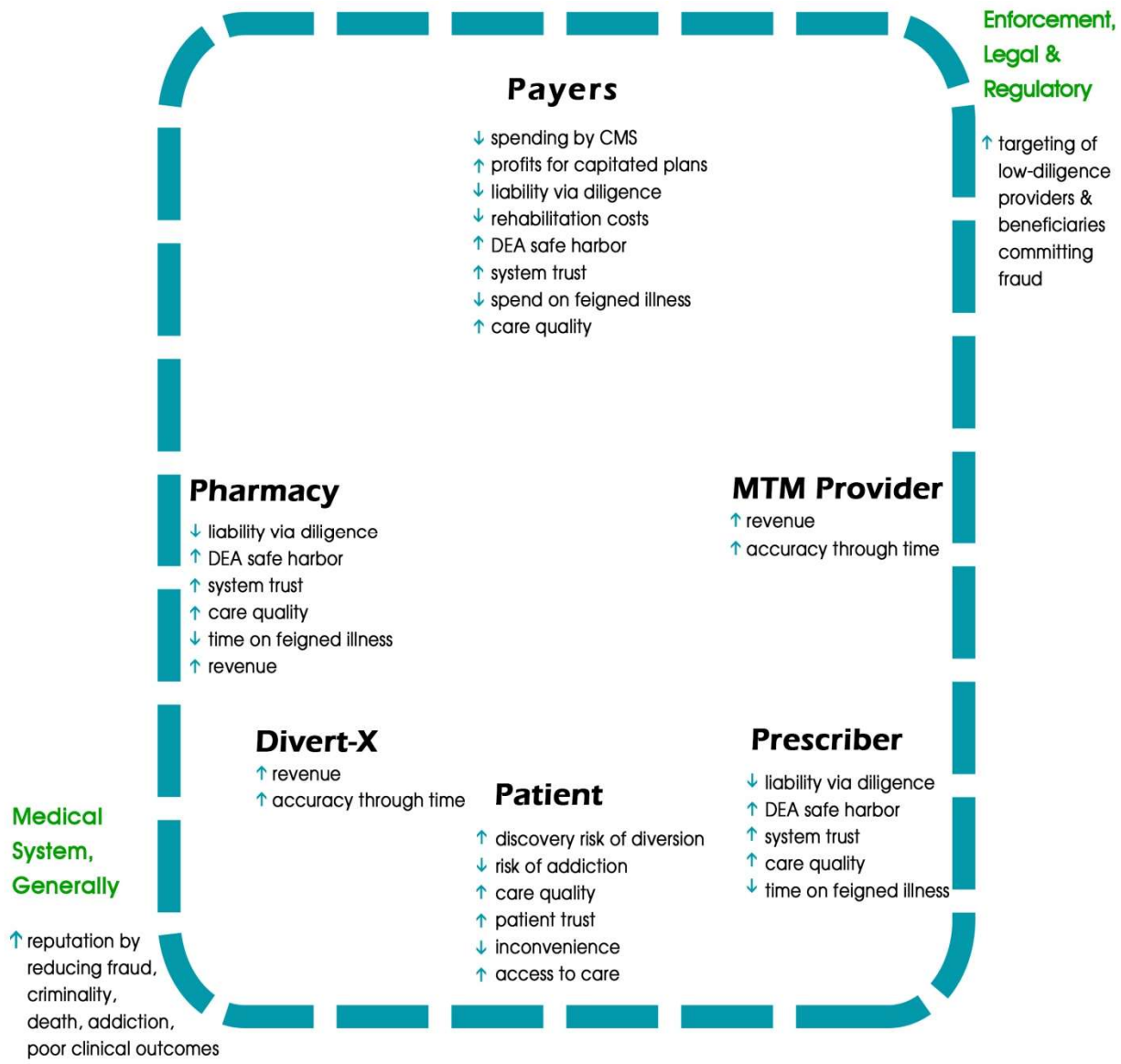


Figure 3: All Stakeholders Benefit From Adoption of the Vortex System for Controlled Substance Management.