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Buprenorphine Prior Authorization Removal: Low Hanging Fruit in the Opioid Epidemic Fight

Tamara Beetham

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The opioid epidemic in the United States is not abating. The most recently available data indicate that 2016 had more opioid fatalities than any other year on record, a 28% increase from 2015 (Centers for Disease Control and Prevention [CDC], 2018; CDC, 2017). The scope is daunting, but there is "low-hanging fruit" yet to be addressed. Though seldom mentioned in public debate, effective treatment is available, yet access to it is mired in red tape.

Buprenorphine is a life-saving treatment, most commonly known by the buprenorphine/naloxone combination drug, Suboxone. Buprenorphine reduces cravings, illicit opioid substance use, transmission of infectious diseases, criminal activity, and improves social functioning (Mattick, Breen, Kimber, & Davoli, 2014; Rinaldo & Rinaldo, 2013; Volkow, Frieden, Hyde, & Cha, 2014). Furthermore, it is positively associated with substantial reductions in both overdose and all-cause mortality (Sordo et al., 2017), and improves the likelihood of successful long-term recovery (Connery, 2015; Hser et al., 2016). The value of buprenorphine in curbing the ongoing epidemic is unequivocally established and unanimously supported by authorities on the issue including the director of the National Institute on Drug Abuse (Volkow, Frieden, Hyde, & Cha, 2014), the American Society of Addiction Medicine (American Society of Addiction Medicine, 2018), the Centers for Disease Control and Prevention (CDC, 2017), the World Health Organization (World Health Organization, 2009), and the American Medical Association (AMA), all of whom recommend that medication assisted treatment be first-line treatment for opioid use disorder (OUD) (American Medical Association [AMA], 2018). Buprenorphine and methadone are the most effective treatments for OUD (Sordo et al., 2017), though rather than being required to dose daily at a methadone clinic, buprenorphine can be accessed from the providers' offices. The scalability of buprenorphine is therefore promising and ought to be capitalized on, yet the growth in its use is slowing when it should be increasing to meet demand (Wakeman & Barnett, 2018).

Mitigating barriers to providing buprenorphine treatment is critical. One hurdle is a srt of regulations that require providers to become specially certified to prescribe buprenorphine, and also imposes patient capacity constraints on the amount of perscriptions (AMA, 2017c). Physicians frequently report concerns over time, bureaucracy, cumbersome regulations, diversion, lack of OUD education, and inadequate reimbursement (DeFlavio, Rolin, Nordstrom, & Kazal, 2015; Huhn & Dunn, 2017). State payers also report an insufficient number of physicians prescribing, and inadequate funds (Molfenter et al., 2015). A particular barrier that is rarely discussed can improve several of these hurdles if addressed and is not arduous too remedy.

Prior authorizations (PA) is a technique designed to minimize short term costs for the insurer by requiring the provider to obtain insurer approval prior to covering the cost of the treatment. Treatment can be delayed or payment denied as part of this process. Approvals may be based upon requirements set by the payer, even though rationing buprenorphine to save money or ensure safety is not supported by evidence (Clark, Samnaliev, Baxter, & Leung, 2011). PAs are frequently used to enforce restrictions imposed by the payer, the nature of which are often opaque and can differ by payer (Rinaldo & Rinaldo, 2013). Conditions may include "step therapy" which requires prescribing cheaper, less effective options first, quantity limits for patients' daily doses or lifetime limits, rigid tapering schedules, and ongoing detailed counseling documentation (Rinaldo & Rinaldo, 2013; Ruoff, 2016). Requirements are often more stringent for Medicaid patients than those who are privately insured, and non-existent for those who can afford to pay in cash which will set a patient back hundreds of dollars per prescription or office visit (Rinaldo & Rinaldo, 2013).

These PA policies can dissuade providers from prescribing. The approval process is time consuming and bureaucratic, with the vast majority of physicians reporting in an AMA survey that prior authorizations are a high or extremely high burden for providers and staff (AMA, 2017a). Almost 70% of Medicaid plans require prior authorizations for buprenorphine (Andrews et al., 2018), and prior authorizations are the highest rated barrier to perscription among buprenorphine providers treating Medicaid populations (Kermack, Flannery, Tofighi, McNeely, & Lee, 2017). In this context almost half of US counties lack buprenorphine-providing physicians (Andrilla, Coulthard, & Larson, 2017), and methadone clinics are operating at over 80% capacity (Jones, Campopiano, Baldwin, & McCance-Katz, 2015).Eighty percent of individuals with OUD are not receiving any treatment (Saloner & Karthikeyan, 2015). Thus, it is paramount to expand the number of buprenorphine providers and make it easier to treat patients.

PAs also delay and deter access for patients. Over 90% of physicians report that prior authorizations delay access to necessary care and that issues related to prior authorizations have led to patients abandoning treatment (AMA, 2017a). Delaying medication for a patient in opioid withdrawal is a deadly gamble, yet patients with OUD experience delays that would not be acceptable for patients with other high mortality medical conditions, such as a cardiac patient reporting chest pain.

Supporters of these restrictions often cite valid diversion concerns, as buprenorphine can be abused and is subject to dependency. It can elicit euphoria when misused (though less so than methadone or oxycodone), and can contribute to overdoses particularly when taken with sedatives, though deaths are rare (Kintz, 2001; Substance Abuse and Mental Health Services Administration [SAMHSA], 2016a). Buprenorphine is safer than other opioids because its effects (including respiratory depression) plateau at moderate doses (SAMHSA, 2016b). The most frequently used formulation has an additional abuse deterrent built in; naloxone will throw a patient into withdrawal if injected. Importantly, a majority of those using buprenorphine without medical supervision report doing so to prevent cravings and withdrawals, or because they cannot afford formal treatment (Bazazi, Yokell, Fu, Rich, & Zaller, 2011; Monte, Mandell, Wilford, Tennyson, & Boyer, 2009; Schuman-Olivier et al., 2010). That said, legitimate diversion concerns remain. Improving the functioning and utilization of prescription drug monitoring programs and increasing treatment accessibility are alternative methods to address diversion issues without impeding access to care.

A persistent stigma associated with substance dependence and negative myths surrounding buprenorphine underlie these barriers (Wakeman & Barnett, 2018).. The widespread falsehood that buprenorphine treatment is "trading one addiction for another" engenders a hostile environment for treatment and needs to be dispelled. There is additionally a deep inequity underlying these PA access barriers, because patients who can afford cash-pay treatment are not subject to these contingencies, bypassing unnecessary delays, treatment interruptions, time-consuming additional offices visits, and the burden of initiating and coordinating authorization requests.

Some of the inequity experienced by those with OUD was intended to be addressed by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Act Equity Act passed in 2008. This prohibits insurers from imposing more restrictive limits on addiction treatment than on other medical services, such as requiring PA more often for behavioral health than other health services. However, states often take a passive approach to this parity verification (Ruoff, 2016). Parity violation complaints[1] can be useful to this end; the New York Attorney General (AG) opened an investigation in 2016 in response to hundreds of complaints. This resulted in two large insurance companies removing their buprenorphine PAs in a matter of months (Anthem, Inc. & Empire BlueCross BlueShield, 2017; Cigna, 2016), and the AMA soon followed with a letter imploring all AGs to take similar action (AMA, 2017b). Filing parity complaints and encouraging state AGs to open parity violation investigations can both bring awareness to violations, as well as arm the AGs with stronger grounds for inquiry to enforce parity. Though this is a crucial strategy to enforce fairness and mitigate treatment access barriers, further action is needed.

The nature of this epidemic requires emergency measures, and an exception needs to be made for buprenorphine prior authorizations. Private and public insurers should remove administrative barriers, state and local jurisdictions can lift their requirements, and policymakers and regulators can increase oversight and enforce parity laws. Law makers should pass, legislation on the state and federal levels to remove prior authorizations, which some governors have begun to do (*Governor's Working Group on Opioids Update*, 2016; Press Release of Gov Tom Wolf, 2018). Removing prior authorizations should be a critical component of a broader set of policies aimed at increasing treatment access by getting more providers to prescribe. Though there are reasonable concerns by proponents of prior authorizations, many of those concerns can be better addressed through a well-functioning prescription drug monitoring program. Any diversion or buprenorphine misuse risk pales in comparison to the magnitude of the current problem, and buprenorphine needs to be more accessible

than heroin or fentanyl. Emergency measures are needed, and with 115 opioid deaths daily, the urgency cannot be understated. Though the opioid epidemic is a high-salience issue frequently discussed in the public domain, the accompanying PAs and restrictions are rarely mentioned. Mitigating barriers to accessing an effective, life-saving medication for a population at high risk of mortality needs to be a top priority to curb this public emergency.

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