

# Opioid Agreement Ethics Challenged

Nancy A. Melville | September 25, 2015

NATIONAL HARBOR, MD — One of strongest testaments to the effect of the prescription drug abuse epidemic on clinical practice is the increase in state mandates for opioid or controlled substance agreements that clinicians are required to have patients sign when receiving opioid prescriptions.

But such agreements are not without significant controversy, raising a host of ethical issues, said bioethicist Richard Payne, MD, MPH, the Esther Colliflower Professor of Medicine and Divinity at Duke University, Durham, North Carolina.

Dr Payne discussed the issue in a keynote address at the recent American Academy of Pain Management (AAPM) 2015 Annual Meeting.

"The original clinical objectives for these treatment agreements were laudable goals — to be used as tools to educate patients about their treatment plan, to inform about risk and benefits of treatment, clarify treatment goals and to promote adherence to treatment," said Dr Payne, who is also the John B. Francis Chair in Bioethics at the Center for Practical Bioethics in Kansas City, Missouri.

"But with the opioid overdose epidemic, the agreements over the years have taken on layers of regulatory and legal objectives favoring the clinician's legal risk objectives."

As a result, concerns are that the agreements have evolved to include more punitive language conveying a paternalistic air, with the suggestion of mistrust of the patient and corrupting the practitioner-patient relationship, he said.

Agreements that imply a power differential between the provider and patient "would appear to be the antithesis of promoting a patient-centered relationship of shared decision making," Dr Payne asserted.

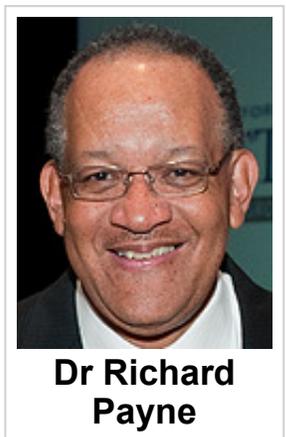
He cited comments once made by bioethicist Robert Fine, MD, from Baylor University, on the issue, arguing that the very notion of a physician 'contract' with patients was in fact alien to medical ethics.

"If anything, we should be talking more about a covenantal, trusting relationship instead of using these agreements as sledgehammers to highlight power differentials over patients," Dr Payne said.

## Clouded Intent, Questionable Efficacy

While the use of such agreements dates back to the 1980s, their primary purpose appears to have become clouded, as indicated in [a survey](#) published 2014 in the *Journal of Opioid Management* showing that primary care physicians commonly believed a basic goal for the contracts was in fact physician self-protection.

Importantly, few who took the survey said they believed that the opioid agreements even



accomplished the clear goal of preventing opioid misuse — and the evidence appears to support that belief.

Dr Payne cited a [systemic review](#) of opioid agreement studies from 1966 to 2009 with and without urine testing, published in the *Annals of Internal Medicine*, which concluded that of 102 studies with and without urine testing identified, only 11 met strict inclusion criteria.

Four of the studies showed the agreements were linked to a reduction of opioid misuse by 7% to 23%, and the other seven, which included urine analysis, showed reductions in misuse ranging from 3% to 43%, prompting the authors of the review to conclude that "relatively weak evidence supports the use of opioid agreements in reducing opioid misuse in chronic pain patients."

With the efficacy of the agreements in helping patients uncertain, the potential for unintended consequences raises the question of whether they may in fact do more harm than good.

Among the biggest concerns is the possibly disastrous fallout of a highly vulnerable patient being let go, or "fired," from a practice as the result of breaking the stipulations in the agreement and facing the shame of having much-needed care forfeited.

"There are anecdotal stories of patients having trouble finding other practices or even some horrendous examples of patients harming or even killing themselves in the context of being 'dismissed' from a practice," Dr Payne said.

### **Letting the Agreement Say It All**

Yet another concern with the agreements is the potential of letting the agreement — and not the clinician — do the talking, Dr Payne noted.

"There is some evidence in the literature that the opioid contracts can become a way of noncommunicating with patients; rather than talking an issue out with the patient, the discussion is reduced to a matter of 'well, you broke the contract so we're tapering your medication,' so the contract becomes a means of avoiding communication."

An especially problematic issue with that scenario is [evidence](#) that many high-risk patients may not even realize they have signed agreements, much less fully comprehend their content.

Dr Payne noted that progress has been made, however. In response to the concerns about the agreements, the US Food and Drug Administration convened a multidisciplinary group of outside experts to draft a user-friendly patient-provider opioid agreement, and [a survey](#) of FDA employees with the Center for Drug Evaluation and Research with 209 respondents showed 67.5% felt the agreement was neutral in tone and 90.4% felt it was easy to understand.

The Department of Veteran's Affairs National Center for Ethics in Health Care meanwhile has published [useful materials](#), including draft agreements, regarding informed consent for long-term opioid therapy for pain.

Dr Payne and his colleagues at the Center for Practical Bioethics are meanwhile continuing to work toward agreements that more closely follow the model of informed consent, with more patient-centered intent and language.

In a policy brief issued in 2014, the team called for key language elements in opioid treatment agreements, including the rationale for therapy, such as clarification of the medical diagnosis and goals for therapy; discussion of the potential adverse effects of the therapy, including the

risk for opioid tolerance and misuse; and behavioral expectations, including patient responsibilities and the consequences of "contractual violation" on the part of the patient.

### **Clinician Experts Chime in: Pro and Con**

While noting the validity of the issues Dr Payne concerned, AAPM incoming president Joanna G. Katzman, MD, said her experience with such agreements has generally been favorable.

"I have seen agreements that do exactly what Dr Payne described. My experience, however, is that controlled substances agreements are only as effective as the clinician presenting the information to the patient," she said.

"In other words, the most important aspect of the agreement is how they are used, how they are written, and how they are presented, rather than being a function of having an agreement per se."

In addition, well-written agreements can extend to benefiting the entire health care team, she added.

"The agreements can align all members of the clinic team, including clinician, nurse, medical assistant, et cetera, by educating medical practices to the safety risks of these medications."

In terms of perhaps the most controversial elements of dismissing a noncompliant patient from the practice, Dr Katzman noted that language can indeed be tailored to provide less severe alternatives.

"We prefer to see agreements that specify that deviations will trigger a re-evaluation of the terms under which controlled substance treatment is provided," she said.

Effective measures might include tightening the controls by, for instance, giving prescriptions a week at a time, rather than a month at a time, or, in some cases, it might include dismissing the patient from the practice, Dr Katzman said.

"But we should make every effort to help the patient use the medication safely and appropriately, or find alternative nonopioid medications and nonpharmacologic therapy that can help the patient's pain rather than just dismissing the patient from the practice."

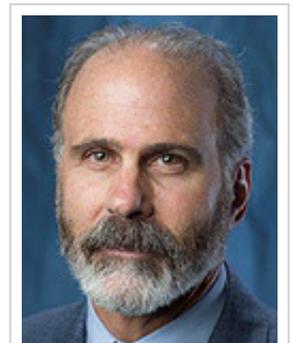
### **Con: Agreements "Neither Necessary nor Sufficient"**

Gary M. Reisfield, MD, director of the Division of Addiction Psychiatry in the Departments of Psychiatry and Anesthesiology at the University of Florida College of Medicine in Gainesville, said his center uses controlled substance agreements under state mandate in Florida — but he has a less favorable view of them.

"The risks of opioid therapy are of sufficient frequency and magnitude that we must have discussions with our patients about these risks as well as realistic expectations regarding benefits and mutual expectations regarding the provision of this therapy," he told *Medscape Medical News*.

"In this regard, written treatment agreements are neither necessary nor sufficient."

Discussion, in the form of ongoing dialogue, regarding the dynamic risk-



benefit ratio needs to happen, he said. "A sheet of paper is neither necessary nor sufficient for effecting these discussions."

**Dr Gary M.  
Reisfield**

"A well-written, patient-centered document may serve as a useful reference for our patients, but I do not believe that a signature is necessarily helpful to the therapeutic relationship."

Regarding dismissal of noncompliant patients, Dr Reisfield said the option is rarely even a reasonable measure.

Managing long-term opioid therapy is like flying a plane — if you can't land the plane, you shouldn't be flying it. Dr Gary M. Reisfield

"Dismissing patients from practices is almost never ethically justifiable," he asserted.

"Part of managing long-term opioid therapy is constructively dealing with aberrant behaviors — whether by counseling, tightening treatment boundaries, tapering and discontinuing opioid therapy, consultation with an addiction specialist, or referral to treatment," he said.

"Managing long-term opioid therapy is like flying a plane – if you can't land the plane, you shouldn't be flying it," he added.

"Absent compelling evidence of diversion or persistent disruptive behavior, with or without a written treatment agreement, patients should not be dismissed from practices."

### **Agreements Likely Here to Stay**

Whether favored or not, the requirement of opioid agreements is something clinicians are likely not going to have much of a choice about in coming years, Dr Katzman said.

"There are more and more states including mandates for these agreements in legislation, rules and regulations, and guidelines," she said.

"I don't expect that trend to stop, even though there is no consistent evidence that they accomplish their purpose."

*Dr Payne, Dr Katzman, and Dr Reisfield have disclosed no relevant financial relationships.*

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