

STATEMENT OF CONSIDERATION RELATING TO
907 KAR 3:005

Department for Medicaid Services
Amended After Comments

(1) A public hearing regarding 907 KAR 3:005 was requested and held. The following individuals submitted comments at the hearing:

<u>Name and Title</u>	<u>Organization/Agency/Other Entity</u>
Tricia Shackelford, Attorney	Shackelford Law Office
Dr. Charles Tinsley Stewart	
Dr. Alan Shultz	

(2) The following individuals submitted written comments regarding 907 KAR 3:005:

<u>Name and Title</u>	<u>Organization/Agency/Other Entity</u>
Dr. Wifredo A. Fernandez	
Tricia Shackelford, Attorney	Shackelford Law Office
Kenneth Payne MD FACOG	
David Suetholz, MD	
Molly Rutherford, MD, MPH, President	American Society of Addiction Medicine (ASAM), Kentucky Chapter
Dr. Thomas Nugent	
tenmd2@aol.com	
Timothy Gregg	
Kelly Clark	
Michelle Lofwall	
Mark Jorrisch	
Brad Caldwell, Administrator	Appalachian Recovery Institute
Shannon Simmons, patient	Appalachian Recovery Institute
Jimmy Abne, patient	Appalachian Recovery Institute
Amy Simmons, patient	Appalachian Recovery Institute
Michelle Mullins, patient	Appalachian Recovery Institute
Daniel Jason Trent, patient	Appalachian Recovery Institute
Amy Wagers, patient	Appalachian Recovery Institute
Tonya Gibson, patient	Appalachian Recovery Institute
Steve Jones, patient	Appalachian Recovery Institute
Travis Pennington, patient	Appalachian Recovery Institute
Evelyn Michelle, patient	Appalachian Recovery Institute
Ethel Gray, patient	Appalachian Recovery Institute

Toy E. Coots, patient	Appalachian Recovery Institute
Jessica Bush, patient	Appalachian Recovery Institute
Roger Lee McQueen, patient	Appalachian Recovery Institute
Jonathan McConnell, patient	Appalachian Recovery Institute
Angela Marcum, patient	Appalachian Recovery Institute
Judy McQueen, patient	Appalachian Recovery Institute
Charles Collett, patient	Appalachian Recovery Institute
Tamara Phillips, patient	Appalachian Recovery Institute
Brittany Eversole, patient	Appalachian Recovery Institute
Brandon M. Hacker, patient	Appalachian Recovery Institute
Patrick Owens, patient	Appalachian Recovery Institute
Loretta Lawson, patient	Appalachian Recovery Institute
Nate White, patient	Appalachian Recovery Institute
Sally Smith, patient	Appalachian Recovery Institute
Beva Wagner, patient	Appalachian Recovery Institute
Betty Jo Russel, patient	Appalachian Recovery Institute
Shelia Blackburn, patient	Appalachian Recovery Institute
DeAndrea Bailey, patient	Appalachian Recovery Institute
Brandon Shepherd, patient	Appalachian Recovery Institute
Freda Smith, patient	Appalachian Recovery Institute
Mary Daniel, patient	Appalachian Recovery Institute
Clyde Smith, patient	Appalachian Recovery Institute
Marvin Ray Smith, patient	Appalachian Recovery Institute
Nathan Short, patient	Appalachian Recovery Institute
John Culton, patient	Appalachian Recovery Institute
Roger Blanton, patient	Appalachian Recovery Institute
Brian Sufford, patient	Appalachian Recovery Institute
Crystal Sufford, patient	Appalachian Recovery Institute
April Chandler, patient	Appalachian Recovery Institute
Melissa Murray, patient	Appalachian Recovery Institute
Shayna Frost, patient	Appalachian Recovery Institute
Tonya Farier, patient	Appalachian Recovery Institute
Sarah Padwerski, patient	Appalachian Recovery Institute
Misty Delynn Coffey, patient	Appalachian Recovery Institute
Ricky Mullins, patient	Appalachian Recovery Institute
Ray Collins, patient	Appalachian Recovery Institute
Sabrina Larabee, patient	Appalachian Recovery Institute
Glenn Jackson, patient	Appalachian Recovery Institute
John Stevens, patient	Appalachian Recovery Institute
Elizabeth Murrell, patient	Appalachian Recovery Institute
Aneisa Fox, patient	Appalachian Recovery Institute
Chris R, patient	Appalachian Recovery Institute
Angel Henson, patient	Appalachian Recovery Institute
Krystal Hollon, patient	Appalachian Recovery Institute
Chris France, patient	Appalachian Recovery Institute
Jennifer Pennington, patient	Appalachian Recovery Institute

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Adverse Impact on Patients, Providers, and Community

(a) Comment: Brad Caldwell, Administrator, Appalachian Recovery Institute stated the following:

"I have been involved with addiction treatment for over 10 years and during that time I have seen what substance abuse has done to our communities first hand. I have watched the loss of life and the destruction of families. When Suboxone came in as treatment option for patients, it has given the patient the freedom to be treated in a medical office setting allowing for greater access to treatment and less stigma about having treatment. In addition, Buprenorphine truly is a miracle medication. I have watched over the last 7 years many individual and families that have been treated turn their lives around, getting their families back and holding down a job. Many patients have told me that Buprenorphine treatment has saved their lives.

As an administrator I am very much aware of the cost. This order appears to be a knee jerk reaction to pharmaceutical and lab testing cost. But the unintended consequences of this order will reduce treatment for those that are most vulnerable and in greatest need. Our organization patient population is 75% Medicaid, 11% Medicare and 14% private insurance. As you are aware our doctors are limited by the DEA to maximum number of patients of 100 with a waiver. The level of Medicaid reimbursement for an office visit is not sufficient to off set the cost of treatment and overhead. It does not take a rocket scientist to see that the limited number of patients allowed to be seen and the low Medicaid reimbursement rate, there is no way to cost effectively treat a patient. For our organization we would be unable to continue to provide substance abuse treatment.

If this emergency order is allowed to stand we will have to close the treatment center which would result in the loss of 7 individuals losing their jobs. The impact on our patients will be even greater as other facilities I have spoken to in the area will have to shut down as well or eliminate seeing Medicaid patients all together. What will happen to these patients and where will they go? Many live here in the community and do not have reliable transportation to be able to go else where for treatment. There are no facilities in the area that can see these patients for the Medicaid reimbursement rate. So, now you place the patient at risk for relapse or purchasing drugs off the street again. Which will only exacerbate the problem of drugs in our community. In addition, we are seeing more and more heroin users coming for help. Which is now one of the biggest problems we're seeing on the street. Heroin related death are on the rise. By limiting and eliminating treatment centers you are creating a greater problem for illegal drug use in our community. Which has a cost of its own in life and financial impact on the community due to crime and violence related to drug use?

This emergency order 907 KAR 3:005E is destructive to the patient and our community. I encourage you to reconsider and allow a waiver for the treatment. Substance abuse treatment is very stressful and difficult. This patient population is high maintenance and risk. Providers that choose to provide this treatment are taking on patients that require a lot of time and care to assure compliance and success. Right now according to the SAMHSA U.S. Department of Health and Human Services there are not enough providers to meet the demand for substance abuse treatment. By implementing this emergency order you will only create and even greater shortage of providers.”

Patients from the Appalachian Recovery Institute listed in subsection (3) expressed much opposition to the policy of not allowing Medicaid providers to bill Medicaid recipients for Medicaid-covered services. Many cited the lack of availability of substance use treatment providers as it is and expressed that this administrative regulation will make it all the more difficult to find treatment as clinics will be forced to shut down or to stop seeing Medicaid recipients. Some indicated that as a result they will likely return to a life of drug addiction, a life of stealing and crime, and possibly end up in prison or dead or suffer other very adverse consequences as a result of the policy.

Individuals who are not Medicaid recipients expressed similar thoughts and indicated that the policy change will have the same impact on their lives as clinics or substance use treatment providers will shut down and they too, even though they are not Medicaid recipients, will be unable to find treatment and suffer very adverse consequences.

Many expressed the extremely positive impact that substance use treatment providers have had on their lives under the prior policy (in which Medicaid providers could bill Medicaid recipients for the services).

Some patients expressed their inability to pay the office visit fee, charge for drug screening, and pay the pharmacy to fill their suboxone prescription without the help of Medicaid as they receive suboxone under the Medicaid program while paying clinics for the other services on a cash-on-the-side basis.

Patients of the Appalachian Recovery Institute (ARI) indicated that doctor(s) cannot afford to provide substance abuse treatment at the Medicaid reimbursement rate and; thus, will be forced to close the clinic if doctors can no longer charge Medicaid patients on a cash-on-the-side basis.

David Suetholz, MD stated:

“I was informed today by Kentucky ASAM that if you provide services to an individual who takes Suboxone and they are enrolled in a Medicaid plan you cannot charge them cash. If this is so then you are going to have a lot of drug addicts go back to the street. My office is cash only, but I am able to preauthorize meds for Medicaid patients. If I opt out of Medicaid all together then the patients WILL NOT have anyone in this community

to provide them a service. There are limited physicians in Northern Kentucky who provide Suboxone treatment.

My gut feeling is that the Medicaid providers who are taking a hit on the medication are promoting this. If physicians drop out then this is a windfall for them because the patients will have no physician and no money to purchase the medication.

In real numbers a heroin addict will spend an average of 1,200 to 1,800 dollars per month. If he or she has Medicaid they will steal or prostitute for the money. If I charge them 230 dollars per month and do their drug screen and give them counseling as well as sending them to KYBVR and AA, plus pre auth their meds from Medicaid then they are several hundred dollars ahead and not chasing their tails every day.

This is a totally different game and providers like myself work hard at caring for these individuals but we do have to make a living. My Medicaid patients do not care about the charge in fact one said, "no pain, no gain", in fact it is true. The cost is an incentive to improve and reduce their dose over time. If this ruling stands then your number of overdose deaths is going to spike, guaranteed."

Molly Rutherford, MD, MPH, President, Kentucky Chapter of the American Society of Addiction Medicine (ASAM), Dr. Thomas Nugent, Timothy Gregg, Kelly Clark, Michelle Lofwall, and Mark Jorrisch stated the following:

"While the regulation might intend to increase access to life saving buprenorphine treatment, it will have the opposite effect, at least in the short term. Patients' lives will be endangered as a result. If the state would like to encourage physicians to contract with Medicaid payers, they should also work with physicians and payers to negotiate an appropriate reimbursement for these services, which will save the state thousands of dollars. Also, Kentucky should support ongoing National efforts to increase the patient limit (currently 30/100) for physicians practicing OBOT.

<http://www.asam.org/advocacy/aaam/media-toolkit>

This link from ASAM provides evidence supporting expanded access to MAT. I encourage everyone involved in regulating this treatment to read these documents.

Medication assisted treatment for opioid dependence saves lives and money. "\$1 in treatment saves \$7 in societal costs."

(b) Response: The Department for Medicaid Services (DMS) fully appreciates the value of substance use treatment services and added these services to its array of covered services on January 1, 2014. Previously DMS covered these services for pregnant women and some children but not for the entire Medicaid population.

The amended administrative regulation does not preclude Medicaid providers from providing substance use treatment services to Medicaid recipients.

The provision in the administrative regulation establishing that a Medicaid recipient shall not be billed for a Medicaid-covered service rendered to the recipient by a Medicaid provider applies to all Medicaid covered services. The reason for the policy is to not allow Medicaid providers to determine which services they will provide to Medicaid services via the Medicaid program and which ones for which to bill Medicaid recipients. Without this protection, any Medicaid provider that was dissatisfied with Medicaid reimbursement [whether from the Department for Medicaid Services or from a managed care organization (MCO) as approximately ninety (90) percent of Medicaid recipients are now enrolled with a managed care organization] for a given service or services could leverage their status as a provider to the recipient to coerce the recipient into paying for the given service. Enabling Medicaid providers to select which services for which to bill DMS (or an MCO) and for which to bill Medicaid recipients then the Medicaid Program would be failing one of its primary missions - to cover health insurance expenses of lesser-income individuals.

DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(2) Subject: Postpone Regulation

(a) Comment: Molly Rutherford, MD, MPH, President, Kentucky Chapter of the American Society of Addiction Medicine (ASAM), Dr. Thomas Nugent, Timothy Gregg, Kelly Clark, Michelle Lofwall, and Mark Jorrisch stated the following:

"I suggest an amendment to 907 KAR 3-005E that postpones enforcement of this regulation in order to allow physicians time to make arrangements for patients to get care elsewhere and/or comply with the new regs. The state should provide assistance with this process."

Kenneth J. Payne MD FACOG stated the following:

"I support Dr. Rutherford comments on postponing implementation of the 907 KAR 3-005E. I think it creates immediate access to care issues. In my role as the Kentucky Section Chair for the American College of Obstetrics and Gynecology, I have had several physicians throughout our Commonwealth call me to express concerns. Many of the buprenorphine licensed physicians in the state perform medical assisted treatment services (OBOT) on a part-time basis in cash only clinics (non-Medicaid basis) while they have a separate full time practice that accepts Medicaid payments for other services. These physicians do not want to jeopardize their full time practices and based on my conversations with physicians around the state, will most likely stop offering OBOT services to Medicaid patients. Currently, there are not enough physician practices accepting Medicaid reimbursement to handle the patients who will be displaced by enacting 907 KAR 3-005E.

This action also puts physicians and their patients in quite a quandry. According to the policy promulgated as 907 KAR 3-005E physicians should no longer treat Medicaid patients on a non-Medicaid basis. If patients and physicians already have an established therapeutic relationship, it becomes difficult to abruptly end. Physicians have a duty to continue providing care for established patients until appropriate transfer to another physician can be arranged. However, there's realistically nowhere to refer/tranfer these patients for ongoing care. From a sheer numerical perspective, if there are 300+ physicians in Kentucky with buprenorphine prescribing capabilities who each currently see 20 Medicaid patients and if physicians cannot continue to see those patients, then 6000 Kentuckians could be left without access to treatment. Obviously, this is an assumption but nonetheless staggering. If Kentucky plans to address the addiction epidemic, these issues will need to be addressed prior to limiting access to care.

Furthermore, as a practicing obstetrician, I am very concerned about the possible cessation of treatment for pregnant women currently on outpatient maintenance therapy. During pregnancy, it is imperative to attempt to maintain a stable intrauterine environment for the developing fetus. Buprenorphine and methodone are the only two currently approved medications for use in the pregnant population. Many pregnant patients being maintained on buprenorphine products are receiving treatment from practices on a non-Medicaid basis. If those services were to abruptly halt, I fear for the outcomes on those mothers and their unborn children.

While I support the overall mission of the legislation to prevent exploitation of a vulnerable population, I think more due diligence is in order. A few quick thoughts to consider. Initially, to prevent patient displacement and to limit physician jeopardy, maybe consider a moratorium on current providers accepting new Medicaid patients (say effective 12/31/2014) on a non-Medicaid basis while the behavioral health organizational framework is established and functional. This would allow current patients to continue on a non-Medicaid basis model to treatment completion. I have a couple of other ideas that may serve to mitigate the possible unintended consequences of 907 KAR 3-005E. My number is listed at the bottom of this email if you'd like to discuss."

(b) Response: DMS has yet to enforce the provision (prohibiting Medicaid providers from billing Medicaid recipients for Medicaid-covered services) despite enacting it in August 2014.

(3) Subject: Medicaid Reimbursement Versus Operational Costs of Treatment Centers

(a) Comment: An individual with the email address of tenmd2@aol.com stated the following:

“Just the numbers:

Approximate Medicaid reimbursement for addiction treatment allows two monthly visits (while federal law requires weekly visits for at least the first month) and each visit yields the physician approximately \$30.

\$60 a month for 100 patients (maximum allowed by federal law) is \$6000 per month.

My office rent and utilities are \$1300-\$1400 per month. Nurse \$500 per week is \$2000 per month. Office manager \$500 per week is \$2000 per month. Office tech is \$150 per week or \$600 per month. Malpractice is \$1000 per month. Other expenses at least \$500. per month.

That totals \$7400 per month to keep the clinic open while only allowing \$6000 per month in gross revenue. For a net loss of \$1400 per month.

At a time when most authorities are calling for an expansion of the availability of Medication Assisted Therapy (MAT) for opiate addiction this statute is forcing the closure of treatment clinics and the return of patients to illegal activities. This places patients at extreme risk of relapse and overdose death.

I think that any patients discharged from treatment because of this statute should be told to go to their county health department for guidance as this is a Kentucky State statute and the State of Kentucky should now assume care for these patients as we physicians cannot accept the financial burden nor philosophical responsibility for something the state has done.”

Tricia A. Shackelford, Shackelford Law Office, PLLC stated the following:

“On August 20, 2014, the Cabinet for Health and Family Services, Department for Medicaid Services, Division of Policy and Operations (“**Medicaid**”) issued 907 KAR 3:005E (the “**E-Reg**”). In relevant part, the E-Reg provides that:

“(b) A provider may provide a service to a recipient on a non-Medicaid basis¹:

1. If the recipient agrees to receive the service on a non-Medicaid basis before the service begins; and
2. ~~[Whether or not] The [:~~
 - a. ~~Provider is a Medicaid participating provider; or~~
 - b.] service is not a Medicaid covered service.²

In other words, the only way that a Medicaid Provider can provide a Medicaid covered service to a Medicaid beneficiary is by billing Medicaid and accepting the Medicaid reimbursement rate. This includes behavioral health services and suboxone treatment because Medicaid covers such services.

These changes to 907 KAR 3:005 effectively force Medicaid providers to accept the Medicaid reimbursement rate for behavioral health services and suboxone treatment. At the Medicaid rate of reimbursement, addiction treatment providers simply cannot meet the standard of care recommended by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (“**CSAT**”) or to operate at all and, therefore, will be left with three options (i) opt out of Medicaid participation, (ii) refuse to treat Medicaid beneficiaries, or (iii) cease operation. Under any of these three options, Medicaid patients will be denied access to the treatment they need to return to meaningful lives; they will continue their addictive lifestyles, which will result in an additional strain to the economic resources of the Commonwealth and increases in substance abuse related crime, joblessness, and healthcare costs. Therefore, my patients strongly urge Medicaid to repeal this E-Reg and restore 907 KAR 3:005 to the following wording

- (b) A provider may provide a service to a recipient on a non-Medicaid basis:
1. If the recipient agrees to receive the service on a non-Medicaid basis before the service begins; and
 2. Whether or not the:
 - a. Provider is a Medicaid participating provider; or
 - b. Service is a Medicaid covered service.

This proposal is inherently reasonable and results in heightened recovery rates for Medicaid beneficiaries suffering from opioid addictions, which in turn, works to preserve the Commonwealth’s limited resources.

Operating an IOT facility is an expensive undertaking. These are some of the costs of operation:

- malpractice coverage for the facility and the individual providers (malpractice coverage for a psychiatrist in an IOT setting is approximately \$7,700);
- rent/mortgage (average of \$14,000 per year);
- salaries –
 - psychiatrist/physician - \$165,000 per year
 - registered nurse - \$65,000 per year

- physician assistant - \$54,000 per year
- office manager - \$60,000 per year
- billing specialist - \$40,000 per year
- secretary - \$23,000 per year;
- continuing education costs; and
- costs of utilities, medical equipment, security cameras, and medication vaults.

Under federal law, providers who wish to dispense suboxone must obtain a separate registration for such treatment.³ In the first year, after obtaining authorization to provide suboxone treatment, providers are authorized to treat no more than thirty (30) patients.⁴ After the first year, a provider can increase the number of patients they are treating to 100.⁵ Therefore, behavioral health providers are limited in the revenues they can generate because the federal government caps the number of patients that a provider can treat with suboxone therapy.

The operating costs, without facility insurance or a physician assistant salary, would be \$31,225 per month. It is IMPOSSIBLE to provide even the sixteen core services at the Medicaid reimbursement rate unless the facility operates as a “mill” churning patients through as opposed to providing personalized service tailored to each individual patient. Through the implementation of the E-Reg, Medicaid is creating two standards of care for addicts seeking treatment within the Commonwealth: individuals who have the means to pay for treatment at facilities that can charge to operate and provide the CSAT recommended standard of care and Medicaid beneficiaries who have no other choice but to accept care at facilities that can or choose to operate at the Medicaid reimbursement rates. Moreover, the E-Reg places the burden on the taxpayer to fund the cost of recovery. Once in treatment and stable, opioid dependents can normally become productive members of society who are able to pay for his or her own treatment and who can successfully have meaningful family lives.

It is also important to note that the Commonwealth can protect exploitation of Medicaid beneficiaries by requiring regular KASPER monitoring of both the providers who prescribe suboxone and Medicaid beneficiaries receiving suboxone treatment. This would ensure that suboxone is not be diverted for addictive purposes.

¹ See 21 U.S.C. 823(g)(1) (2008).

¹ See 21 U.S.C. 823(g)(2)(B)(iii).

¹ See *id.*”

(b) Response: The provision in the administrative regulation establishing that a Medicaid recipient shall not be billed for a Medicaid-covered service rendered to the recipient by a Medicaid provider applies to all Medicaid covered services. The reason for the policy is to not allow Medicaid providers to determine which services they will

provide to Medicaid services via the Medicaid program and which ones for which to bill Medicaid recipients. Without this protection any Medicaid provider that was dissatisfied with Medicaid reimbursement [whether from the Department for Medicaid Services or from a managed care organization (MCO) as approximately ninety (90) percent of Medicaid recipients are now enrolled with a managed care organization] for a given service or services could leverage their status as a provider to the recipient to coerce the recipient into paying for the given service. Enabling Medicaid providers to select which services for which to bill DMS (or an MCO) and for which to bill Medicaid recipients then the Medicaid Program would be failing one (1) of its primary missions - to cover the health care expenses of lesser-income individuals.

DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(4) Subject: Pain Medication Exploitation

(a) Comment: Dr Wilfredo A. Fernandez made the following comments:

"Kentucky is one of the leading states in prescription pain medications sold. How does 907 KAR 3:005E address patients that are vulnerable to exploitation via opioid prescription practices that begin the pathway to addiction?"

(b) Response: The administrative regulation prohibits Medicaid recipients from being billed for Medicaid covered services rendered by Medicaid-enrolled providers. DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(6) Subject: Kentucky's Overdose Rate

(a) Comment: Dr Wilfredo A. Fernandez made the following comments:

"Kentucky is one of the leading states in overdose rates. How does 907 KAR 3:005E address the disruption in continuity of care that leads to overdoses and increased death rates?"

(b) Response: The administrative regulation prohibits Medicaid recipients from being billed for Medicaid covered services rendered by Medicaid-enrolled providers. DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(7) Subject: Substance Use Epidemic Among Whites

(a) Comment: Dr Wilfredo A. Fernandez made the following comments:

"How does 907 KAR 3:005E address the disproportionate epidemic of substance abuse that affects whites in Kentucky?"

(b) Response: The administrative regulation is not race-oriented. DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use

treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(8) Subject: Sustaining Treatment Gains/Preventing Relapse/Limiting Access

(a) Comment: Dr Wilfredo A. Fernandez made the following comments:

“907 KAR 3:005E limits access and choice. How does 907 KAR 3:005E sustain treatment gains already attained in an effort to prevent relapse?”

907 KAR 3:005E causes environmental effects on patients with underlying wide-range issues and psychological conditions that can lead to relapse. Are patients under 907 KAR 3:005E adversely affected?

907 KAR 3:005E does not make treatment readily available. 907 KAR 3:005E does not make ease of entry.

907 KAR 3:005E demotivates patients and providers.

Under 907 KAR 3:005E Therapeutic Alliances are terminated. Under 907 KAR 3:005E no value is placed on retention.

907 KAR 3:005E creates discontinuity of care where abstinence cannot be monitored. Patient can relapse, overdose or remain under treated for years(i.e. continue to live in addiction).”

(b) Response: The administrative regulation prohibits Medicaid recipients from being billed for Medicaid covered services rendered by Medicaid-enrolled providers. DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider

networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(9) Subject: Incorporating the Science of Addiction

(a) Comment: Dr Wilfredo A. Fernandez stated:

“Does 907 KAR 3:005E incorporate the complex biochemical and neurophysiological science of addiction for successful treatment outcomes?”

(b) Response: 907 KAR 3:005 establishes the Medicaid Program coverage provisions for physician's services. Included in the scope of these services are substance use treatment services provided in a physician's setting. The administrative regulation does not prohibit providers from incorporating the science of addiction into their treatment regimens.

(10) Subject: 907 KAR 3:005 Ignores Individualized Treatment Needs

(a) Comment: Dr Wilfredo A. Fernandez stated:

“907 KAR 3:005E uses a blunt regulation that limits individual treatment needs. Treatment assessments to address individual needs or treatment goals are ignored.”

(b) Response: DMS disagrees that the administrative regulation ignores assessments to address individual needs. Included in the scope of substance use treatment services in the physicians services' program are screenings, assessments, laboratory (urine drug screenings), customized service planning, evaluation and management office visits, and more.

(11) Subject: 907 KAR 3:005 Doesn't Employ a Chronic Care Model/Doesn't Foster Mutual Help/Disorganized Care

(a) Comment: Dr Wilfredo A. Fernandez stated the following:

“907 KAR 3:005E does not employ a chronic care model that adjusts to patient needs. 907 KAR 3:005E does not foster a Mutual-help program. 907 KAR 3:005E allows

patients to be vulnerable to disorganized care and underutilization of medication. 907 KAR 3:005E does not education patients, families or providers. A multi-discipline approach is made illegal.”

(b) Response: DMS disagrees with these assessments. During the course of this year, DMS has expanded its behavioral health services to include substance use treatment services and has expanded the types of behavioral health practitioners authorized to enroll as independent practitioners to include licensed psychologists, licensed professional clinical counselors, licensed clinical social workers, licensed psychological practitioners, licensed marriage and family therapists, licensed behavior analysts, and licensed professional art therapists. DMS has authorized the following associate level behavioral health practitioners to work for the aforementioned independently-enrolled practitioners: certified alcohol and drug counselors, certified social workers, licensed professional counselor associates, licensed psychological associates, marriage and family therapy associates, licensed assistant behavior analysts, and licensed professional art therapist associates. Additionally, DMS has created new behavioral health provider types including behavioral health service organizations, multi-specialty groups, and residential crisis stabilization units.

DMS has also expanded the scope of community mental health centers to include substance use treatment services (beyond pregnant women and children to which DMS historically DMS limited such coverage.)

By authorizing more and more types of providers and practitioners to provide behavioral health services (including substance use treatment services) DMS is striving to enhance Medicaid recipient access to such care and promoting the coordination of physical health services with behavioral health services.

(12) Subject: 907 KAR 3:005 Eliminates Choice

(a) Comment: Dr Wilfredo A. Fernandez stated the following:

“907 KAR 3:005E eliminates patient, family, or employer choices.”

(b) Response: In that the administrative regulation prohibits Medicaid providers from billing Medicaid recipients for Medicaid-covered services the administrative regulation restricts choice; however, providers who wish bill Medicaid recipients for Medicaid-covered services have the choice of disenrolling from the Medicaid Program in order to continue operating in the fashion in which they’ve been operating.

Regarding choice, DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO's provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

DMS strongly encourages substance use treatment providers to choose to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(13) Subject: 907 KAR 3:005 Favors Untested Treatment Methods

(a) Comment: Dr Wilfredo A. Fernandez stated the following:

"907 KAR 3:005E favors untested treatment methods. Is 907 KAR 3:005E forcing patients into trial research programs without their consent?"

(b) Response: The administrative regulation neither promotes untested treatment methods nor forces patients into trial research programs.

(14) Subject: 907 KAR 3:005 Employs a One Size Fits All Model

(a) Comment: Dr Wilfredo A. Fernandez stated the following:

"907 KAR 3:005E does not incorporate improved management strategies. A one size fits all is the employed."

(b) Response: The administrative regulation does not address management strategies. DMS disagrees that a one (1) size fits all model is employed. Included in the scope of substance use treatment services in the physicians services' program are screenings, assessments, laboratory (urine drug screenings), customized service planning, evaluation and management office visits, and more.

(15) Subject: Impact of House Bill 1

(a) Comment: Tricia A. Shackelford, Shackelford Law Office, PLLC stated the following:

Discussion

The Commonwealth of Kentucky is one of the states that leads the nation in the prescription of painkillers⁶ and has one of the highest rates of death for drug overdose

⁶ See Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (2010).

deaths⁷. The Kentucky Legislature passed House Bill 1 in a special session in April 2012.⁸ While this law has been successful in addressing problems related to the abuse of pain medication within the Commonwealth, an unintended consequence of House Bill 1 has been a surge in heroin use and deaths. The excessive usage of heroin in Lexington came after the passage of House Bill 1.⁹ In March 2013, the Kentucky Injury Prevention and Research Center at the University of Kentucky of Public Health released a report that showed a decrease in prescription pill overdoses and emergency room visits but a huge increase in heroin overdoses from 2011 to 2012.¹⁰ Heroin contributed to 129 deaths in Kentucky in 2012 – at 207% increase from 42 heroin-related deaths in 2011¹¹ - and heroin overdose related emergency department visits increased 197% from 266 visits in 2011 to 789 visits in 2012¹². In the past week, 10 suspected heroin overdose patients presented at emergency departments in Northern Kentucky, resulting in 2 deaths.¹³ Clearly, heroin use is a major public health problem within the Commonwealth.

Medicaid justifies the promulgation of the E-Reg by citing the potential for exploitation of opioid addicted Medicaid beneficiaries. This is, however, faulty logic. The cost of suboxone treatment can be in the range of \$300 per month. Many heroin addicts have a \$150 per day habit.¹⁴ A \$150 per day habit easily translates to a monthly financial outlay of upwards of \$4,500 per month. Heroin addicts traditionally lose time at work due to their addiction and quickly may become unemployable. Without a source of income, there is an increased likelihood that the addict will resort to criminal activity to obtain their drugs. The rise in heroin use is also destroying countless families across the Commonwealth. Families touched by addiction often become involved with the Kentucky Cabinet for Health and Family Services, Department for Child Based Services (the “**Cabinet**”) because of problems with dependency, neglect, and abuse, which also stresses the resources of the Cabinet and the Commonwealth. Addiction also impacts the health of the addict, which increases medical costs to the addict. This results in

⁷ See U.S. Centers for Disease Control, National Vital Statistics System (2008).

⁸ KRS 218A.175, which regulates pain management practices, is the codification of House Bill 1, and became effective on March 4, 2013.

⁹ See Lexington, Officials Continue Seeing Disturbing Trends with Heroin Use, Overdoses, http://www.kentucky.com/2014/03/02/3117995_lexington-officials-continue-seeing.html (March 2, 2014); see also

¹⁰ *Id.*

¹¹ Kentucky Injury Prevention and Research Center, University of Kentucky of Public Health, *Drug Overdose Deaths, Hospitalizations, and Emergency Department Visits in Kentucky, 2000-2012 at 2*, January 14, 2014.

¹² See *id.* at 3.

¹³ See <http://www.cincinnati.com/story/news/2014/10/12/methadone-heroin-epidemic-medicine-assisted-treatment-northern-kentucky/17153291?from=global&session=&autologin=>.

¹⁴ See Best Intentions: Prescription Drug Crackdown Leads to Massive Rise in Heroin Abuse, Spike in Crime (February 11, 2013).

increased costs to Medicaid because these addicts do not have other means to pay for the medical services they require to treat the effects of drug use on their overall health.

CSAT has recommended Core and Enhanced Services for IOT programs. CSAT recommends that IOTs provide sixteen Core Services:

- Group counseling and therapy;
- Individual counseling;
- Psychoeducational programming;
- Pharmacotherapy and medication management;
- Monitoring alcohol and drug use;
- Case management;
- 24-hour crisis coverage;
- Community-based support groups;
- Medical treatment;
- Psychiatric examinations and psychotherapy;
- Vocational training and employment services;
- Family involvement and counseling;

Comprehensive biopsychosocial screening and assessment;

- Program orientation and intake/admission;
- Individual treatment planning and review; and
- Transitioning management and discharge planning.¹⁵

In addition, CSAT lists eight enhanced services that IOTs should consider providing:

- Adult education;
- Transportation services;
- Housing and food;
- Recreational activities;
- Adjunctive therapies;
- Nicotine cessation treatment;
- Licensed child care; and

¹⁵ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, *Substance Abuse: Clinical Issues in Intensive Outpatient Treatment* at 27.

- Parenting skills.¹⁶

The Solution

Simply put, the Commonwealth is in dire need of behavioral health and behavioral health providers and IOT facilities to combat the growing heroin addiction epidemic. The E-Reg will cause a large number of IOT facilities to close their doors and those that do remain open will stop treating Medicaid beneficiaries, who represent a large number of the opioid addicted population in the Commonwealth. Ideally, the solution is for Medicaid to repeal the E-Reg and restore the status quo by reinstating the language of 907 KAR 3:005 prior to August 20, 2014. Alternatively, the effective date of the E-Reg should be deferred for a period of no less than six months to allow providers within the Commonwealth who will be affected by these reimbursement changes to restructure their practice and transition patients in the event that such providers elect to no longer treat Medicaid patients.

Thank you for your attention to these vitally important issues. I am happy to meet with you to further discuss these comments.”

Dr. Charles Tinsley Stewart stated the following:

“Due to House Bill 1, people turned to heroin, and addicts showed up at his practice which he had not seen before. Statistics show that it gets worse each year. Dr. Stewart is hearing rumors that IOP provider’s, like himself will have to shut down to the change in regulation, which will add to the burden of heroin abuse. Dr. Stewart wanted to point out that his practice charges the bare minimum to get by.”

(b) Response: DMS agrees that heroin overdose deaths have been increasing but they have been increasing in many states, not just in Kentucky (the state to which HB 1 applies.)

DMS notes that the overwhelming majority of Medicaid recipients needing or seeking substance use treatment services are enrolled with a managed care organization (MCO.) MCO reimbursement to providers is negotiated between each individual provider and the respective MCO. Prospective providers participate in MCO provider networks via contractual agreements negotiated between the two (2) parties. These agreements are not reached unilaterally.

MCOs are required to meet standards for recipient access (provider network adequacy standards.) DMS continually monitors each MCO’s provider network adequacy. The fact that MCOs must meet adequacy standards (including for substance use treatment services) is a bargaining point for Medicaid providers/prospective Medicaid providers including substance use treatment providers.

¹⁶ *Id.*

DMS strongly encourages substance use treatment providers to do as all Medicaid providers do and negotiate with MCOs (including reimbursement terms and conditions) and join MCO provider networks and help facilitate Medicaid recipient access to care.

(16) Subject: Behavioral Health Service Organization Implementation

(a) Comment: Dr. Alan Shultz stated the following:

“Suboxone clinics, working with the behavioral health service organization. Everything from our perspective is going to be fine. It’s not a matter of reimbursement or anything like that. My question is when do we go through – when do we start this statute going because – and we can do it in a staggered fashion. We – not us alone, but the entire group of doctors, we’re talking about right off the bat 1,000 patients and it’s going to be hard to get them into a treatment program, really hard.

Dr. Schultz questioned further about the timeline for implementation and asked when it will start.

(b) Response: Though this administrative regulation (907 KAR 3:005E) was enacted as an emergency administrative regulation on August 20, 2014, DMS has not yet enforced the non-Medicaid basis provision.

Regarding behavioral health service organizations, DMS has promulgated two (2) emergency administrative regulations which establish the provisions for behavioral health service organizations – 907 KAR 15:020E and 907 KAR 15:025E. DMS also is currently promulgating two (2) companion ordinary administrative regulations with the emergencies. The emergency administrative regulations became effective on July 22, 2014; thus, any entity that obtains a BHSO license from the Office of Inspector General and enrolls with the Medicaid Program can provide BHSO services as soon as completing those steps and in their own timeframe.

(17) Subject: Clarification Regarding Non-Medicaid Basis

(a) Comment and Response: The Department for Medicaid Services (DMS) is amending the administrative regulation to clarify that if a Medicaid provider renders a Medicaid-covered service to a Medicaid recipient that no one shall bill the recipient for the service.

(18) Subject: Clarification Behavioral Health Practitioners

(a) Comment and Response: DMS is amending the administrative regulation to elaborate on the behavioral health practitioners who can work in a physician’s practice/provider group.

SUMMARY OF STATEMENT OF CONSIDERATION
AND
ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The Department for Medicaid Services (DMS) has considered the comments received regarding 907 KAR 3:005 and is amending the administrative regulation as follows:

Page 2
Section 1(2)(g)
Line 5

After “assistant”, insert the following:
working under the supervision of a physician

Page 2
Section 1(3)
Line 8

Before “administers”, insert the following:
or advanced practice registered nurse

Page 6
Section 1(31)
Line 23

After “(31)”, insert the following:
“Provider group” means a group of at least:
(a) Two (2) individually licensed physicians who:
1. Are enrolled with the Medicaid Program individually and as a group; and
2. Share the same Medicaid provider number; or
(b) At least one (1) APRN and at least one (1) physician who:
1. Are enrolled with the Medicaid Program individually and as a group; and
2. Share the same Medicaid provider number.
(32)

Page 7
Section 1(32), (33), (34), (35), (36), and (37)
Lines 10, 11, 15, 16, 17, and 22

Renumber these six (6) subsections by inserting “(33)”, “(34)”, “(35)”, “(36)”, “(37)”, and “(38)”, respectively, and by deleting “(32)”, “(33)”, “(34)”, “(35)”, “(36)”, and “(37)”, respectively.

Page 8
Section 2(1)(b)
Line 12

After “service.”, insert a return and the following:
(c)1. If a provider renders a Medicaid-covered service to a recipient, regardless of if the service is billed through the provider’s Medicaid provider number or any

other entity including a non-Medicaid provider, the recipient shall not be billed for the service.

2. The department shall terminate from Medicaid Program participation a provider who participates in an arrangement where an entity bills a recipient for a Medicaid-covered service rendered by the provider.

Page 12
Section 4(4)
Line 2

After “(4)”, insert the following:

An injectable drug listed on the Physician Injectable Drug List that is administered by a physician, APRN, or provider group shall be covered

Page 17
Section 7(2)
Line 13

After “and a physician”, insert the following:

or an APRN and a physician

Page 18
Section 8(2)
Line 2

After “(2)”, insert the following:

A provider group that is the billing provider;
(3)

After “a”, insert a colon, a return, and “(a)”.

Page 18
Section 8(2) and (3)
Lines 2 and 3

After “; or”, insert a return and the following:

(b) Provider group that is the billing provider;
(4) A physician assistant who works for a:
(a) Physician who is the billing provider; or
(b) Provider group that is the billing provider;
(5) A licensed professional clinical counselor who works for a:
(a) Physician who is the billing provider; or
(b) Provider group that is the billing provider;
(6) A licensed clinical social worker who works for a:
(a) Physician who is the billing provider; or
(b) Provider group that is the billing provider;
(7) A licensed marriage and family therapist who works for a:
(a) Physician who is the billing provider; or
(b) Provider group that is the billing provider;
(8) A licensed professional art therapist who works for a:

- (a) Physician who is the billing provider; or
- (b) Provider group that is the billing provider; or
- (9) A licensed behavior analyst who works for a:
- (a) Physician who is the billing provider; or
- (b) Provider group that is the billing provider;
- (10)

Delete "(3)".

Page 18

Section 8(3)

Line 3

After "for a", insert a colon, a return, and "(a)".

Line 4

After "provider", insert the following:

: or

(b) Provider group that is the billing provider

Page 19

Section 14

Line 22

After "907 KAR 17:010.", insert a return and the following:

Section 15. Incorporation by Reference. (1) The "Physician Injectable Drug List", February 21, 2014, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at:

(a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Monday through Friday, 8:00 a.m. to 4:30 p.m.; or

(b) Online at the department's Web site at <http://www.chfs.ky.gov/dms/incorporated.htm>.