

FILED WITH LRC TIME: <u>2:49 pm</u>
JUN 09 2021
Emily B Caudill REGULATIONS COMPILER

STATEMENT OF CONSIDERATION RELATING TO
907 KAR 3:005

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Medicaid Services
Division of Policy and Operations

Not Amended After Comments

I. A public hearing on 907 KAR 3:005 was not requested, and therefore, not held. However, written comments were received during the public comment period.

II. The following individuals submitted comments during the public comment period:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Hal Clark, Vice President of Economics and Policy,	Kentucky Hospital Association
Russ Ranallo, Vice President of Finance, Technical Advisory Committee Chairman	Owensboro Health Hospital TAC
Regina Fragneto, M.D. President	Kentucky Society of Anesthesiologists
Rebecca Randall, Senior Director of Operations	WellCare Health Plans of Kentucky
Randall D. Moore, DNP, MBA, CRNA, Chief Executive Officer	American Association of Nurse Anesthetists
Libby Milligan, Principal	McCarthy Strategic Solutions, LLC Kentucky Association of Nurse Anesthetists
C. Wright Pinson, MD, MBA	Deputy CEO and Chief Health System Officer Vanderbilt University Medical Center
Kristen Safier, Esq., Senior Counsel, Legal Department	Cincinnati Children's Hospital Medical Center
Harini Chenna, MD	
Carey H Costantini, MD	St. Elizabeth Health Care
Dale Santrock, MS, MD	
Sean T. DeGrande, MD, PhD	Seven Hills Anesthesia, NKY Division
Marina Varbanova M.D., Associate Professor, Associate Program Director	University of Louisville, Department of Anesthesiology
Dan Brannon, DO	Seven Hills Anesthesia

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Dan Brannon, DO	Seven Hills Anesthesia

Masroor Alam, MD, Anesthesiologist	Seven Hills Anesthesia
Jiapeng Huang MD, PhD, FASA, FASE, Academic Advisory Dean, Professor & Vice Chairman, Medical Director of Operating Rooms, Professor of Cardiovascular & Thoracic Surgery, Associate Editor, Associate Editor in Chief,	Department of Anesthesiology & Perioperative Medicine, University of Louisville. Journal of Cardiothoracic & Vascular Anesthesia Seminars in Cardiothoracic & Vascular Anesthesia
Joseph K Hassoun, MD	Seven Hills Anesthesia
Mark Grossman, CEO	Seven Hills Anesthesia
R. Andrew Daniel, MD, Chief of Staff	Frankfort Regional Medical Center
Raymond Sullivan, MD	Seven Hills Anesthesia, St. Elizabeth Division President
Damian Dolan, MD	Seven Hills Anesthesia
Ayesa Hilvano, MD	Seven Hills Anesthesia St Elizabeth Healthcare
Dr. Prashant Nayak, MD	Seven Hills Anesthesia
Joshua E. Hansen, MD	

III. The following individuals from the promulgating agency responded to comments received regarding 907 KAR 3:005

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Lisa Lee, Commissioner	Department for Medicaid Services, Commissioner's Office
Veronica Judy-Cecil, Senior Deputy Commissioner	Department for Medicaid Services, Commissioner's Office
Leslie Hoffman, Chief Behavioral Health Officer	Department for Medicaid Services, Commissioner's Office
Lee Guice, Director	Department for Medicaid Services, Division of Policy and Operations
Angela Parker, Director	Department for Medicaid Services, Division of Program Quality and Outcomes

Jonathan Scott, Regulatory and Legislative Advisor	Department for Medicaid Services, Commissioner's Office
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IV. SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Anesthesiologists face challenges in providing anesthesia care to Medicaid recipients.

(a) Comment: Russ Ranallo, Vice President of Finance, Owensboro Health and Technical Advisory Committee Chairman, Kentucky Medicaid Hospital TAC; Regina Fragneto, M.D., President, Kentucky Society of Anesthesiologists; C. Wright Pinson, MD, MBA Deputy CEO and Chief Health System Officer, Vanderbilt University Medical Center; Harini Chenna, MD; Carey H Costantini, MD, St. Elizabeth Health Care; Dale Santrock, MS, MD; Sean T. DeGrande, MD, PhD, Seven Hills Anesthesia, NKY Division; Marina Varbanova M.D., Associate Professor, Associate Program Director, University of Louisville, Department of Anesthesiology; Dan Brannon, DO, Seven Hills Anesthesia; Masroor Alam, MD, Anesthesiologist, Seven Hills Anesthesia; Jiapeng Huang MD, PhD, FASA, FASE, Academic Advisory Dean, Professor & Vice Chairman, Medical Director of Operating Rooms, Professor of Cardiovascular & Thoracic Surgery, Department of Anesthesiology & Perioperative Medicine, University of Louisville, Associate Editor Journal of Cardiothoracic & Vascular Anesthesia, and Associate Editor in Chief, Seminars in Cardiothoracic & Vascular Anesthesia; Joseph K Hassoun, MD, Seven Hills Anesthesia; Mark Grossman, CEO, Seven Hills Anesthesia; R. Andrew Daniel, MD, Chief of Staff, Frankfort Regional Medical Center; Raymond Sullivan, MD, Seven Hills Anesthesia, St. Elizabeth Division President; Damian Dolan, MD, Seven Hills Anesthesia; Ayesa Hilvano, MD, Seven Hills Anesthesia, St Elizabeth Healthcare; Dr. Prashant Nayak, MD Seven Hills Anesthesia, and Joshua E. Hansen, MD, submitted comments pointing out that several payor sources such as Medicare do allow for reimbursement of claims billed as medical anesthesia. Many Kentucky physicians face “significant challenges providing the highest quality of anesthesia care to Kentucky citizens due to the lack of payment for this service for patients with Medicaid insurance”. “As the Medicaid population continues to grow, the situation is becoming unsustainable for some practice groups, particularly those independent practices who see a high volume of Medicaid patients. “

(b) Response: While DMS is primarily making this amendment in order to ensure access to anesthesiology services for Medicaid members and promote appropriate billing, taking steps to allow for broader practice of anesthesia among the Medicaid population is a significant benefit of this amendment. The department will not be amending the regulation in response to the comment.

(2) Subject: Support for allowing anesthesiologists to provide medical direction services within the Kentucky Medicaid program.

(a) Comment: Russ Ranallo, Vice President of Finance, Owensboro Health and Technical Advisory Committee Chairman, Kentucky Medicaid Hospital TAC; Regina Fragneto, M.D., President, Kentucky Society of Anesthesiologists; C. Wright Pinson, MD, MBA Deputy CEO and Chief Health System Officer, Vanderbilt University Medical Center; Harini Chenna, MD; Carey H Costantini, MD, St. Elizabeth Health Care; Dale Santrock, MS, MD; Sean T. DeGrande,

MD, PhD, Seven Hills Anesthesia, NKY Division; Marina Varbanova M.D., Associate Professor, Associate Program Director, University of Louisville, Department of Anesthesiology; Dan Brannon, DO, Seven Hills Anesthesia; Masroor Alam, MD, Anesthesiologist, Seven Hills Anesthesia; Jiapeng Huang MD, PhD, FASA, FASE, Academic Advisory Dean, Professor & Vice Chairman, Medical Director of Operating Rooms, Professor of Cardiovascular & Thoracic Surgery, Department of Anesthesiology & Perioperative Medicine, University of Louisville, Associate Editor Journal of Cardiothoracic & Vascular Anesthesia, and Associate Editor in Chief, Seminars in Cardiothoracic & Vascular Anesthesia; Joseph K Hassoun, MD, Seven Hills Anesthesia; Mark Grossman, CEO, Seven Hills Anesthesia; R. Andrew Daniel, MD, Chief of Staff, Frankfort Regional Medical Center; Raymond Sullivan, MD, Seven Hills Anesthesia, St. Elizabeth Division President; Damian Dolan, MD, Seven Hills Anesthesia; Ayesa Hilvano, MD, Seven Hills Anesthesia, St Elizabeth Healthcare; Dr. Prashant Nayak, MD Seven Hills Anesthesia, and Joshua E. Hansen, MD, submitted comments indicating that meeting the requirements of medical direction will “require an immense amount of time, expertise, and effort by the anesthesiologist”. The comments further point to the multiple steps that are required to be performed by the anesthesiologist in order to receive payment.

(b) Response: The department agrees that anesthesiologists will need to comply with multiple steps in order to receive reimbursement for medical direction services. The department will not be amending the administrative regulation in response to the comment.

(3) Subject: Medical direction has contributed significantly to a current very low level of perioperative morbidity and mortality in Northern Kentucky.

(a) Comment: Sean T. DeGrande, MD, PhD, Seven Hills Anesthesia, NKY Division, submitted comments pointing out that utilizing medical direction when possible has contributed significantly to a current very low level of perioperative morbidity and mortality in Northern Kentucky.

(b) Response: While DMS is primarily making this amendment in order to ensure access to anesthesiology services for Medicaid members and to ensure appropriate billing, the department will track how and if the introduction of this service improves outcomes for Medicaid members. Ongoing improved outcomes would be significant in the continued use of this service. The department will not be amending the administrative regulation in response to the comment.

(4) Subject: Reimbursement for personally performed services.

(a) Comment: Russ Ranallo, Vice President of Finance, Owensboro Health, submitted comments arguing that while the total number of medical direction services performed is likely to be small, it is still important to provide reimbursement for all medically necessary services that are performed in person.

(b) Response: The department agrees with the need to provide reimbursement for medical direction in this circumstance, and agrees that the total number of medical direction services performed will likely be small. The department anticipates that the vast majority of nurse anesthetist services will continue to be performed independently. The department will not be amending the regulation in response to the comment.

(5) Subject: Request to allow out-of-state providers to perform anesthesia services.

(a) Comment: C. Wright Pinson, MD, MBA, Vanderbilt University Medical Center; and Kristen Safier, Esq., Senior Counsel, Legal Department, Cincinnati Children's Hospital Medical Center, submitted comments requesting that the regulation be clarified to allow out-of-state providers to

perform services.

(b) Response: The regulation allows for facilities to enroll in Kentucky Medicaid and utilize qualified providers. This is the most common scenario for out-of-state providers when anesthesia services are provided. The department will not be amending the regulation in response to the comments.

(6) Subject: Withdraw anesthesia under medical direction changes to 907 KAR 3:005 and 3:010.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists; and Randall D. Moore, DNP, MBA, CRNA, Chief Executive Officer, American Association of Nurse Anesthetists submitted comments requesting that the administrative regulation be withdrawn. The commenters pointed to a few studies arguing that CRNA anesthesia is the lowest cost option and that a reduction in quality of care is difficult to demonstrate.

(b) Response: The impetus for these changes – in addition to strong stakeholder support from state university teaching hospitals and the state anesthesiologist associations – involves improving access to anesthesiology services and promoting correct billing practices when services are provided under medical direction. In order for Kentucky Medicaid recipients to continue to have access to certain out-of-state facilities, the department is electing to more clearly and adequately reimburse for medical direction services. The department will not be amending the administrative regulation in response to the comment.

(7) Subject: Request for additional information regarding out-of-state anesthesia under medical direction requirements.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists submitted comments relating the association's understanding that Vanderbilt University Medical Center was "one of the stakeholders strongly leading this initiative" and that an out-of-state facility should simply not bill or track medical direction services in response to Kentucky's regulatory prohibition on anesthesia under medical direction.

(b) Response: While Vanderbilt University Medical Center has commented on this administrative regulation, DMS disagrees that this facility is "strongly leading this initiative". Vanderbilt University Medical Center's comments and interest were relayed to DMS after initial drafting of the amendments to this regulation were complete.

The impetus for these changes – in addition to strong stakeholder support from state university teaching hospitals and the state anesthesiologist associations – involves improving access to anesthesiology services and promoting correct billing practices when services are provided under medical direction. In order for Kentucky Medicaid recipients to continue to have access to certain out-of-state facilities, the department is electing to more clearly and adequately reimburse for medical direction services.

Clarifying this issue, about 1 to 1.1 million people under the age of 18 live in Kentucky. More than 700,000 of those children are covered by Kentucky Medicaid or the Kentucky Children's Health Insurance Program (KCHIP). Pursuing a course of action that continues to prohibit reimbursement for medical direction provided by out-of-state facilities would threaten access for Kentucky Medicaid recipients. Kentucky Medicaid is unwilling to risk loss of access to some of the region's best children's hospitals for more than two-thirds of Kentucky's children.

In addition, many vulnerable Kentucky adults depend on Medicaid having access to these

hospitals. Refusing to amend medical direction billing practices would similarly threaten hospital and surgical access for too many recipients, especially those living in counties that border other states.

(8) Subject: Steady decline in billing for medical direction services.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists submitted comments highlighting Medicare claims data and arguing that this billing model has been in “a steady decline since 2010”.

(b) Response: The department acknowledges that this does not appear to involve a substantial percentage of anesthesia claims. However, the expanded authority to bill for medical direction is needed within some practice settings. Furthermore, a recent audit conducted by the department indicated that medical direction services were occurring within Kentucky Medicaid and being billed separately by anesthesia providers. Because this service appears to have been prevalent in Kentucky Medicaid even without the availability of modifiers or regulatory approval, it is possible that these services are being otherwise billed within the Medicare program. The Department believes the change is necessary to ensure appropriate billing for medically directed anesthesiology services.

The department will not be amending this administrative regulation in response to the comment.

(9) Subject: Discussion of 2014 version of 907 KAR 3:005.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists submitted comments requesting clarification of information contained in a 2014 version of a Statement of Consideration of that administrative regulation that indicated that medical direction of anesthesia services had not been covered previously and arguing that this was due to fiscal reasons. The comments further ask for clarification about what has changed.

(b) Response: The 2014 Statement of Consideration was prepared by and for a completely different staff that was working to implement a fundamentally different Medicaid program and Medicaid population. Furthermore, the department’s research indicates that Kentucky Medicaid has not reimbursed for medical direction care for many years, this was not a decision made initially in 2014. In the ensuing seven years, additional research and analysis has been conducted, particularly in relation to how some services similar to medical direction were already occurring within the Medicaid program. Highlighting this, a recent audit conducted by the department indicated that medical direction services were occurring within Kentucky Medicaid and being billed separately by anesthesia providers. Because this service appears to have been prevalent in Kentucky Medicaid even without the availability of modifiers or regulatory approval, it is possible that these services are being otherwise billed within the Medicare program. The department will not be amending the administrative regulation in response to the comment.

(10) Subject: Medical direction and fraudulent billing.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists submitted comments stating that “It is published in the literature, and documented publicly that Medical Direction is the most fraudulently billed anesthesia model (intentionally or unintentionally). VUMC, along with many others, have faced legal questioning and financial hardships related to medical direction billing. It should be known

that anesthesia billing is frequently on the Federal Office of Inspector General (OIG) Work Plan for auditing and effects providers, anesthesia groups, and facilities alike. *KyANA would appreciate clarification on the additional steps that Kentucky Medicaid will take to ensure compliance and prevent fraudulent billing.*”

(b) Response: The department would like to emphasize that fraudulent billing is a serious concern and a possibility with any type of Medicaid covered healthcare service. The department is operationalized to investigate fraudulent billing and charged with the ultimate responsibility to ensure that all services are billed appropriately. From the department’s perspective, fraudulent billing can happen for any service.

The department utilizes multiple partners, including Medicaid MCOs, to ensure that services are billed appropriately. Any entity that chooses to bill for anesthesia under medical direction should provide services appropriately and ensure appropriate documentation.

Finally, the department would encourage any provider or association that has evidence of fraudulent billing to submit that information to the department, or any of the other civil and criminal entities that would assist the department in investigating such evidence. The department will not be amending the administrative regulation in response to the comment.

(11) Subject: Cost to department to implement medical direction.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists submitted comments requesting additional information about how adding a new service would have no cost to Kentucky Medicaid.

(b) Response: The department often adds cost neutral services to the Medicaid program. As the source of health coverage for more than one-third of Kentuckians, the department regularly implements new services and eliminates or constrains existing services. Because the population of Medicaid recipients is so large, utilizing new services can create scenarios where cost efficiencies are realized. Reasons for cost efficiencies can include shifting costs from more expensive services to less expensive services, or to intensify the number of providers available for a specific service and to encourage better outcomes.

More significantly, a recent audit indicates that multiple providers have already been utilizing medical direction and submitting separate claims. As such, by more clearly establishing claim editing within DMS and MCO systems, the department may not see any additional costs. As a result, the department cannot reliably assess a cost increase or decrease for the adding of medical direction services. The department will not be amending the regulation in response to the comment.

(12) Subject: Medical supervision of anesthesia and Anesthesia under Medical Supervision.

(a) Comment: C. Wright Pinson, MD, MBA, Vanderbilt University Medical Center, submitted comments requesting that medical supervision become a covered service within Kentucky Medicaid.

(a) Comment: Rebecca Randall, Sr. Director, Operations, Wellcare Health Plans of Kentucky submitted comments acknowledging that medical supervision of anesthesia is not addressed in either administrative regulation (907 KAR 3:005 and 907 KAR 3:010) and inquiring as to whether these services are covered.

(b) Response: The department is not covering medical supervision of anesthesia or anesthesia under medical supervision at this time. The administrative regulation will not be amended in response to the comment.

(13) Subject: Request to collaborate with Kentucky Association of Nurse Anesthetists prior to changing anesthesia policy.

(a) Comment: Libby Milligan, Principal, McCarthy Strategic Solutions, LLC, on behalf of the Kentucky Association of Nurse Anesthetists stated that “we were not privy to beginning discussions of these regulations, we welcome the opportunity to be a part of the solution.”

(b) Response: The impetus for these changes – in addition to strong stakeholder support from state university teaching hospitals and the state anesthesiologist associations – involves improving access to anesthesiology services and promoting correct billing practices when services are provided under medical direction. In order for Kentucky Medicaid recipients to continue to have access to anesthesiology services and to ensure appropriate billing by all facilities, including out-of-state facilities, the department is electing to more clearly and adequately reimburse for medical direction services.

Furthermore, the department does not customarily engage in broad pre-filing access to Medicaid administrative regulations for the provider community. Due to recent statutory changes, the comment period associated with the filing of administrative regulations has more than doubled. Requesting that all stakeholders monitor and participate in the administrative regulation promulgation process established in KRS Chapter 13A is not a method of excluding any provider groups or other stakeholders. Instead, the department is attempting to utilize scarce resources as effectively as possible in order to make needed policy changes. The department has fully considered all comments made by all stakeholders through this Statement of Consideration process. In addition, multiple teleconferences have been held with the Kentucky Association of Nurse Anesthetists in discussing and explaining the need for these changes. The department will not be amending the administrative regulation in response to the comments.

V. 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. This administrative regulation is not being amended after comments.