Ambulatory Surgical Center Requirements & Miscellany Proposed Regulations

Public Comments Received 12/03/2020 – 01/15/2021

DATE	NAME/AFFILIATION	COMMENTS	HCS RESPONSE
12/14/2020	Henry Krull, MD, Surgery Center of Kenai	As a surgeon and part-owner of an ambulatory surgery center (Surgery Center of Kenai), I strongly support deleting the ASC transfer agreement requirement from current regulations. This requirement has restricted our ability to care for patients at our center, due to our only, monopolistic hospital that for the last 5 years has refused to sign.	Thank you for your comments and support
01/05/2021	Harold Gear, Alaska Surgery Center Management LLC	I am writing <u>in support of</u> this long overdue change in the 7 AAC 12. regulations pertaining to TRANSFER AGREEMENTS.	Thank you for your comments and support
		Firstly, the requirement is moot as all Alaska hospitals accept Federal money and as such they must accept emergent patients per EMTALA.	
		Secondly, the regulations require that ASCs attain a transfer agreement in order to receive a state license, however, the regulations do not require acute care hospitals to issue them. This inequity has resulted in situations, such as, Surgery Center of Kenai requesting a transfer agreement from Central Peninsula Hospital and being rejected because 'they (CPH) refuse to assist a competitor'. This being a direct quote from CPH's CEO Rick Davis.	
		I would add that this requirement for having a transfer agreement will still be hanging over the licenses of many other AK service providers, such as; ALFs, SNFs and birthing centers, and as such DHSS should remove the requirement here also.	
		I have in-depth experience in being extorted by acute care hospitals over the years as a former ASC developer in Alaska begging for transfer agreements and I would be very happy to discuss in more detail if you are interested.	
01/05/2021	Juan Uson	I am hoping that my opinion counts. I am supportive of DHSS deleting the regulation of ASC are required to have executed a transfer agreement with the nearby hospital. Oftentimes the regulation of must have a hospital transfer agreement is use as an ammunition for that hospital to prevent the development of a more efficient, safe and a better option economically for patients and payers.	Thank you for your comments and support
01/09/2021	Edwin D. Vyhmeister MD	I support this Ambulatory Surgery Centers Regulatory requirements Change.	Thank you for your comments and support

01/13/20	Jared Kosin, Alaska State Hospital & Nursing Home Association	On behalf of Alaska's hospitals, the Alaska State Hospital and Nursing Home Association ("ASHNHA") urges the State of Alaska to not adopt its proposed changes to regulations as they pertain to 7 AAC 12.910. The proposed changes to 7 AAC 12.910 are not necessary to "comply with federal regulations" and they erode a key tool for health, safety, and quality standards—i.e. transfer agreements—that ensure there is a coordinated plan in place between hospitals and ambulatory surgical centers ("ASCs") for emergencies that arise during surgery. This is bad public policy for Alaskans.	Thank you for your comments
		Proposed Changes to State Regulations	
		The Department of Health & Social Services proposes to change regulations for Ambulatory Surgical Center Requirements and Miscellany to "comply with federal regulations." While several changes are proposed, ASHNHA wishes to direct its comments to the revisions in 7 AAC 12.910.	
		The proposed changes to 7 AAC 12.910 eliminate a longstanding requirement that ambulatory surgical centers ("ASCs") have a "signed agreement with a general acute care hospital for transfer of patients who require medical or emergency care beyond the scope of the ability or license of the facility." 7 AAC 12.910(d). The proposed changes then replace the transfer agreement requirement with general notice about the ASC's operations and patient population served.	
		The rationale for this change is to "comply with federal regulations." In 2019, the Centers for Medicare and Medicaid Services ("CMS") adopted its final rule concerning requirements for ASCs. Despite certain public objections, CMS removed a federal requirement in 42 CFR 416.41(b) that ASCs must:	
		 (i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or 	
		(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.	
		ASHNHA appreciates the State's intent of following the federal government's lead, but this is a matter of public policy where it makes sense to keep more stringent health, safety, and quality standards in place at the state level.	
		Maintaining Transfer Agreements Promotes Safety and Coordination During Emergencies	
		As we have all learned from the COVID-19 pandemic, proactive emergency planning and coordination are critical when crisis hits. Although rare, complications do occur during ambulatory surgical procedures, and when this happens, the patient's life can depend on a coordinated transfer to a hospital for appropriate treatment. The transfer agreement is the emergency planning / coordination document for this situation, and the current regulatory framework in place with 7 AAC 12.910 ensures that plan is always in place, ready for crisis.	
		Some suggest that requirements from the Emergency Medical Treatment and Labor Act ("EMTALA") render transfer agreements between hospitals and ASCs as unnecessary. This is not so. The requirement under EMTALA that hospitals receive, stabilize, and treat individuals in need of immediate emergency	

		 medical treatment is not a replacement for, or duplicative of, a transfer agreement that specifies protocols and coordination for how care teams from the hospital and ASC will work together during a surgical emergency. Conclusion On behalf of Alaska's hospitals, ASHNHA urges the State of Alaska to not adopt its proposed changes to regulations as they pertain to 7 AAC 12.910. The proposed changes to 7 AAC 12.910 are not necessary to "comply with federal regulations" and they erode a key tool for health, safety, and quality standards— i.e. transfer agreements—that ensure there is a coordinated plan in place between hospitals and ASCs for emergencies that arise during surgery. This is bad public policy for Alaskans. ASHNHA appreciates the State's intent of following the federal government's lead, but this is a matter of public policy where it makes sense to keep more stringent health, safety, and quality standards in place at the state level. 	
01/15/2021	James V. Zirul, D.O.	This e mail is a comment in agreement of removing the Transfer Agreement and replacing the 30-day history and physical requirement defers to the operating physician's clinical judgment in Title 7 of the Alaska Administrative Code. I am an Otolaryngologist (ENT) surgeon who performs surgery at the Surgery Center of Kenai and at Central Peninsula Hospital. Both institutions service the central Kenai Peninsula. At the inception of the Surgery Center of Kenai – a surgery center certified by the State of Alaska – the local hospital refused to grant a transfer agreement as a mechanism to remove competition even though the surgeons performing major surgical procedures had privileges at the hospital. To maintain our certification, a transfer agreement was signed with an Anchorage hospital so we could offer a choice for cost effective care and continue to service the local community. This behavior is not uncommon with other surgery centers in the United States and is one of the reasons why CMS dropped the transfer agreement this past year as they recognized that outpatient surgery centers can significantly decrease the cost of care for outpatient surgery. They recognized that use of a transfer agreement to remove competition was denying access for cost effective care and choice for patients of where they want their care. I also agree with revising the 30-day requirement for history and physicals as healthy patients with limited co morbidities can be efficiently evaluated, as required by CMS and other certifying agencies, with a pre-operative evaluation of the patient before the patient goes back to the operating agencies, with a pre-operative evaluation of the patient before the patient goes back to the operating room.	Thank you for your comments and support