Periodic Rules Review and Expiration of Existing Rules
Subchapter 13B – Licensing of Hospitals
Public Comments and Agency Response to Comments

Rule Citation & Title	Date	Commenter	Comment	Agency Response
1) 10A NCAC 13B .1901 – Supplemental Rules	6/01/16	Erin Glendening, DHSR erin.glendening@dhhs.nc.gov	This is a test of the system.	This rule was determined as Necessary Without Substantive Public Interest. This comment has no merit. It is a test of the comment reporting system. We will not change the determination of this rule.
2) 10A NCAC 13B .1905 – Admissions	6/01/16		Rule 13B .1905(e) The verbiage 'domiciliary care' does not agree with the 'adult home long term care' in Rule .1901. This is an antiquated term.	
3) 10A NCAC 13B .1910 – Nursing/Health Care Administration and Supervision	6/8/16	lewis alexander, Mr. lewcabana@hotmail.com	I see that there is no requirements for CNA's to be mentally competent, or rather there is no Mental Medical background check before issuing a certificate by the State, or any requirements for an investigation into each applicants records regarding abuse or familial neglect and jeopardy. Why is the state allowing the hiring facilities to do the background checks, it seems that could be a real set-up for medicaid and medicare fraud, plus what stop gaps measures are in place to prevent outlaw motorcycle gangs from laundering their drug,prostitution, and extortion profits, by buying into heath care, nursing home, or CNA providers, and controlling the prostitution in the nursing homes as well. The CNA's could be their former prostitutes that were never arrested. I know of one CNA that is affiliated with the Hells Angels , and was living with recently arrested Joseph Barry Godwin , an H A member. This CNA has a petition for mental competency recently submitted on her behalf to the Clerk Of Wake County Court, and the clerk did not think that the protection of the disabled and elderly of the nursing home that the CNA was working in , Carillon , was an emergency. The CNA has been diagnosed as Schizophrenic and bipolar manic, takes no medications, has suicide scars on her arms, and no parental rights of her children, and was engaged in prostitution in Riviera Beach Florida while working for Planned parenthood , and getting paid with Federal grant monies canvas for signers for the Affordable Healthcare Act, while on the clock . Her natural mother was also schizophrenic. THE STATE LEGISLATURE NEEDS SOME SERIOUS GUIDANCE Come on , Jeeeeez , wake up y'all,	
4) 10A NCAC 13B .2031 – Additional	6/13/16	4a) Calvin Hung, Carolinas Healthcare System	This rule is not necessary or necessarily beneficial to the patients and/or helpful in the control of healthcare expenses. Many patients cannot tolerate this amount of therapy and, often, the increased therapy time	

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Requirements for Traumatic Brain Injury Patients			can agitate and hinder the patients with brain injury. This requirement is not consistent with the CMS conditions of participation requiring 3 hrs therapy/day. In addition, the additional therapy adds an expense that is not reimbursable and a costly increase to the provision of care without the additional quality benefits	
	6/14/16	4b) Don Huston, Cone Health Rehabilitation Center donald.huston@conehealth.com	Under item (2), I would like to suggest the wording be changed to that of CMS. The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy. 2. The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.	
	7/22/16	4c)	1. Most patients cannot tolerate 4-4.5 hours of therapy, especially upon admission to the service. 2. Providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful. 3. The therapy requirements are not consistent with CMS Conditions of Participation requirements, currently for 3 hours of therapy/day.	
	8/02/16	4d) Mike Vicario, NCHA mvicario@ncha.org	These regulations were developed when TBI and spinal cord injury treatment beds were approved for both hospital and skilled nursing facility locations. NCAC 13B .2031 and .2032 regulate hospital based skilled nursing units and NCAC 13B .5412 and .5413 regulate acute rehabilitation units. There does not appear to be a unit located in either hospital based or a freestanding SNF in NC. Each rule has requirements that are problematic for the following reasons: - most patients cannot tolerate 4 or 4.5 hours of therapy, especially upon admission to the facility. - providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful - the therapy requirements (and perhaps other licensure requirements for the TBI and spinal cord patients) are not consistent with CMS Conditions of Participation requirements for 3 hours of therapy/day. - the CMS Conditions of Participation requirements do not include a specific NHPPD requirement for inpatient rehabilitation. Hospitals are either obliged to ignore the rule and provide therapy that is consistent with patient needs, or provide additional & potentially unnecessary therapy - at their own cost, in order to treat patients with these conditions.	

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	8/08/16	4e) Suzanne Kauserud, Carolinas Rehabilitation Suzanne.Kauserud@carolinashealthcare.org	At Carolinas HealthCare System (including Levine Children's Hospital Rehabilitation Unit, Carolinas Rehabilitation and Pineville Inpatient Rehabilitation) we believe that Ideally the prescription of therapy hours per day would be a decision the treatment team led by the physiatrist would make. This decision would be based on the needs and medical status of the patient, not prescribed in statutory ruling. In an ideal future state of healthcare reform, inpatient rehabilitation facilities would be incentivized to provide the right amount of therapy to make the greatest gains in the shortest period of time based on individual patient needs. Understanding we are not in that ideal healthcare environment currently and that North Carolina's regulations for therapy intensity are an anomaly in the inpatient rehabilitation industry we suggest the following changes to the regulations to further align with the national therapy delivery trends while maintaining this recognition of the unique needs of the SCI and BI populations. We propose for a clarification on the term 'combined rehabilitation therapy services' to state: Combined rehabilitation therapy services should consist of a combination of skilled therapy services recognized by the Medicare program (a minimum of 3 hours of therapy/5 days per week of a combination of skilled physical, occupational or speech therapy services) and additional therapist directed activities that support the patient's individual plan of care. Examples of these therapist directed services could include but are not limited to: therapeutic recreation, psychology services (one on one or group), cognitive support groups, social activities, community reentry, art therapy, educational activities, music therapy, or rehabilitation tech led activities (under the direction of a PT/OT/SLP/RT/Psychologist). Additional therapist directed activities for the SCI population would be 1 hour per day/5 days per week and in the TBI population would be 1.5 hours of therapy per day/5 days per week. The regulations would also need to be clarified to indicate therapy delivery is a minimum of 5 days per week. TBI Therapy regulations ADULTS: Patients would receive 4.5 hours per day/5 days per week of combined rehabilitation therapy services consisting of a combination of skilled therapy services recognized by the Medicare program (a minimum of 3 hours of therapy/5 days per week of a combination of skilled physical, occupational or speech therapy services) and additional therapist directed activities that support the patient's individual plan of care. Examples of these therapist directed services could include but are not limited to: therapeutic recreation, psychology services (one on one or group), cognitive support groups, social activities, community reentry, art therapy, educational activities, music therapy, or rehabilitation tech led activities (under the direction	

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			of a PT/OT/SLP/RT/Psychologist). Specific concerns relative to the PEDIATRIC population: In addition, regarding the unique population of pediatrics we very often find that the regulations for therapy intensity for TBI and SCI are not developmentally appropriate and can be challenging for them to tolerate. We would propose that for all patients under the age of 18 the prescription of therapy hours per day would be a decision the treatment team led by the physiatrist would make with the minimum hours aligning with Medicare's 3 hours of therapy/5 days per week (PT/OT/SLP). Additional therapies, therapeutic recreation, psychology services (one on one or group), cognitive support groups, social activities, community reentry, art therapy, educational activities, music therapy, or rehabilitation tech led activities (under the direction of a PT/OT/SLP/RT/Psychologist), would be above and beyond the PT/OT/SLP intensity prescribed by the treatment team. For the pediatric population between the ages of 18 – 21 we would propose aligning with the recommendations above pertaining to the adult population.	
5) 10A NCAC 13B .2032 – Additional Requirements for Spinal Cord Injury Patients	6/13/16	5a) Calvin Hung, Carolinas Healthcare System	This rule is not necessary or necessarily beneficial to the patients and/or helpful in the control of healthcare expenses. Many patients cannot tolerate this amount of therapy and the requirement is not based on the patients' need. This requirement is not consistent with the CMS conditions of participation requiring 3 hrs therapy/day. In addition, the additional therapy adds an expense that is not reimbursable and a costly increase to the provision of care without the additional quality benefits.	
	6/14/16	5b) Don Huston, Cone Health Rehabilitation Center donald.huston@conehealth.com	Under item (2), I would like to suggest wording to be changed to CMS wording: The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy. 2. The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.	
	7/22/16	5c)	1. Most patients cannot tolerate 4-4.5 hours of therapy, especially upon admission to the service. 2. Providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful. 3. The	

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			therapy requirements are not consistent with CMS Conditions of Participation, currently for 3 hours of therapy/day.	
	8/02/16	5d) Mike Vicario, NCHA mvicario@ncha.org	These regulations were developed when TBI and spinal cord injury treatment beds were approved for both hospital and skilled nursing facility locations. NCAC 13B .2031 and .2032 regulate hospital based skilled nursing units and NCAC 13B .5412 and .5413 regulate acute rehabilitation units. There does not appear to be a unit located in either hospital based or a freestanding SNF in NC. Each rule has requirements that are problematic for the following reasons: - most patients cannot tolerate 4 or 4.5 hours of therapy, especially upon admission to the facility. - providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful - the therapy requirements (and perhaps other licensure requirements for the TBI and spinal cord patients) are not consistent with CMS Conditions of Participation requirements for 3 hours of therapy/day. - the CMS Conditions of Participation requirements do not include a specific NHPPD requirement for inpatient rehabilitation. Hospitals are either obliged to ignore the rule and provide therapy that is consistent with patient needs, or provide additional & potentially unnecessary therapy - at their own cost, in order to treat patients with these conditions.	
	8/08/16	5e) Suzanne Kauserud, Carolinas Rehabilitation Suzanne.Kauserud@carolinashealthcare.org	At Carolinas HealthCare System (including Levine Children's Hospital Rehabilitation Unit, Carolinas Rehabilitation and Pineville Inpatient Rehabilitation) we believe that Ideally the prescription of therapy hours per day would be a decision the treatment team led by the physiatrist would make. This decision would be based on the needs and medical status of the patient, not prescribed in statutory ruling. In an ideal future state of healthcare reform, inpatient rehabilitation facilities would be incentivized to provide the right amount of therapy to make the greatest gains in the shortest period of time based on individual patient needs. Understanding we are not in that ideal healthcare environment currently and that North Carolina's regulations for therapy intensity are an anomaly in the inpatient rehabilitation industry we suggest the following changes to the regulations to further align with the national therapy delivery trends while maintaining this recognition of the unique needs of the SCI and BI populations. We propose for a clarification on the term 'combined rehabilitation therapy services' to state: Combined rehabilitation therapy services should consist of a combination of skilled therapy services recognized by the Medicare program (a minimum of 3 hours of therapy/5 days per week of a combination of skilled physical, occupational or speech therapy services) and additional therapist directed activities that support the patient's individual plan of care. Examples of these therapist directed services	

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6) 10A NCAC 13B .3001 – Definitions	6/17/16	W. Stan Taylor, WakeMed staylor@wakemed.org	Under 10A NCAC 13B .3001 (32), the definition of 'Observation' is not consistent with Federal interpretation. Observation can be for 48 or 72 hours in many circumstances. As such any reference to 'Observation' should remove the '24 hours' language. In this instance the language should be changed to: 'Observation bed' means a bed used to evaluate	

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			and determine the condition and disposition of a patient and is not considered part of the hospital's licensed bed capacity.	
7) 10A NCAC 13B .3101 – General Requirements	6/17/16	7a) W. Stan Taylor, WakeMed staylor@wakemed.org	In practice, I'm fairly sure that 10A NCAC 13B 3101 (d) (1)-(3) are not followed in practice. Such changes are typically noted when the License is renewed each year. In fact, in some circumstances I'm pretty sure that item (5) is only reported at the time of license renewal. As for item (6), the same applies. I also tend to believe that 'prior to' is not a viable option in some circumstances. I'd strike all but item (4) or strike the 'prior to the occurrence' language. For item (f), there are precedents where licensure of facilities outside of the 'single county' have been allowed. Given the mergers & consolidations over the past decade, most counties now have ownership by a system that resides outside of the home county. I would change this to the Federal definition - within 30 miles of the primary site.	
	8/08/16	7b)	Can notice be modified to prior to or within 10 days following? (d)(2) Please clarify notification requirements increase or decrease in bed capacity. (Recommend this be added closer to 3101 d2; TEMPORARY CHANGE IN BED CAPACITY) (e)(7-8) remove 'data' (f) 'A license shall include only facilities or premises within a single county.'	
8) 10A NCAC 13B .3110 – Itemized Charges	6/17/16	W. Stan Taylor, WakeMed staylor@wakemed.org	Is the itemized charges language a Federal requirement? Does this duplicate Federal rules & standards? If it is a Federal Requirement then I'm not sure its necessary in the State's rules. In any case, item (c)(12) doesn't seem to apply.	
9) 10A NCAC 13B .3201 Hospital Requirements	8/08/16		(9)(f) medical records services --consider updating to Health Information Management services	
10) 10A NCAC 13B .3204 – Transfer Agreement	6/17/16	W. Stan Taylor, WakeMed staylor@wakemed.org	(b) is really covered by Federal laws. It seems unnecessary here.	
11) 10A NCAC 13B. 3205 – Discharge of Minor or Incompetent	8/08/16		Having the parent or guardian direct the discharge be made otherwise 'in writing' is not always practical. Please add that verbal consent or two witnesses on phone consent is acceptable.	
12) 10A NCAC 13B .3302 – Minimum Provisions of	8/08/16		The physician does not be the one to inform the patient their right to refuse – not a physician specific duty. Please change to health care professional.	

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Patient's Bill of Rights				
13) 10A NCAC 13B .3303 – Procedure	8/08/16		B) clarify wording. For the address/phone number.	
14) 10A NCAC 13B .3502 – Required Policies, Rules and Regulations	8/08/16		- 3 years seems reasonable. Would it be possible to match ASC's up to this requirement so they are the same with consistency across NC rules for all health care facilities?	
15) 10A NCAC 13B .3503 – Functions	8/08/16	15a) Conor Brockett, North Carolina Medical Society cbrockett@ncmedsoc.org	The Medical Care Commission ('Commission') originally classified Rule .3503 as 'necessary without substantive public interest.' The North Carolina Medical Society ('NCMS') objects to the rule as unclear and ambiguous, and requests the Commission reclassify it as 'necessary with substantive public interest.' Specifically, NCMS finds paragraph (9) problematic. That provision specifies that the governing body shall 'review and approve the medical staff bylaws, rules, and regulations body.' Aside from the confusing wording of this provision, the rule is also unclear on the question of waiver. Recently, NCMS has learned of facilities that have adopted mechanisms allowing the facility to waive or unilaterally amend provisions in the medical staff bylaws at any time. Because Rule .3503 does not speak to this scenario, and is therefore unclear, the NCMS requests that the Commission change the classification to 'necessary with substantive public interest,' and pursue changes that will resolve the ambiguity.	
	8/08/16	15b)	# 18 needs clarification as the board should assure arrangements are made but the Board is not actually going to make the arrangements.	
16) 10A NCAC 13B .3601 – Chief Executive Officer	8/08/16		Some systems may use a different title than CEO. Please clarify that CEO is the responsible executive no matter what the title.	
17) 10A NCAC 13B .3701 – General Provisions	8/08/16	Conor Brockett, North Carolina Medical Society cbrockett@ncmedsoc.org	The Medical Care Commission ('Commission') originally classified Rule .3701 as 'necessary without substantive public interest.' The North Carolina Medical Society ('NCMS') objects to the rule as unclear and ambiguous, and therefore requests the classification be changed to 'necessary with substantive public interest.' Rule .3701 states that 'the facility shall have a medical staff ORGANIZED in accordance with the FACILITY'S by-laws, which shall be accountable to the governing body...[.]' (Emphasis added.) Put simply, a medical staff must be actually organized as set forth in its own bylaws, not the facility's. All aspects of the medical staff bylaws, including the organizational	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			structure, are later subject to approval by the hospital's governing body. The governing body's review of the medical staff's bylaws may or may not involve the facility's own bylaws, so we find it unusual and confusing that Rule .3701 creates a direct requirement that medical staff organizational structures always be scrutinized for compliance against the facility's bylaws. Our positions that (1) medical staff bylaws are the primary source for the staff's organizational structure, and that (2) the responsibility to maintain that structure resides with the medical staff, find support in other Commission rules and federal regulation. For example, 10A N.C.A.C. .3705 correctly identifies the medical staff as responsible for adopting the organizational structure in its own bylaws that are 'subject to the approval of the governing body.' See also 10A N.C.A.C. .3701. Federal conditions of participation require each hospital to have a medical staff that 'must adopt and enforce bylaws to carry out its responsibilities,' and that '[d]escribe the organization of the medical staff.' 42 C.F.R. § 482.22(c). These other provisions and common industry practice leave us guessing as to the meaning, practicality, and appropriateness of Rule .3701. Accordingly, NCMS respectfully requests that the Commission change the designation of Rule .3701 to 'necessary with substantive public interest' and use this opportunity to update and clarify its provisions.	
18) 10A NCAC 13B .3702 – Establishment	8/08/16	Conor Brockett, North Carolina Medical Society cbrockett@ncmedsoc.org	The Medical Care Commission ('Commission') originally classified Rule .3702 as 'necessary without substantive public interest.' The North Carolina Medical Society ('NCMS') objects to the rule as unclear and ambiguous, and requests the Commission reclassify it as 'necessary with substantive public interest.' The first sentence of Rule .3702 states that, 'The medical staff shall be ESTABLISHED in accordance with the by-laws, rules or regulations of the medical staff and with the written policies, rules, or regulations of the facility.' (Emphasis added.) This concept or requirement seems to again address the structure of the medical staff and its relationship to the facility governing body, just as Rule .3701 does. As discussed previously, NCMS believes Rule .3701 is unclear in its brief discussion of how a medical staff should be organized. Because the concepts of 'organization' and 'establishment' are difficult to tease apart in this context, and because Rule .3701 references facility by-laws while Rule .3702 only references facility 'policies, rules, or regulations,' NCMS believes the interplay between these two rules results in ambiguity and confusion, and therefore necessitates that both be amended. It is also vague how a medical staff and governing body should satisfy the mandate of Rule .3702's first sentence. Is this the applicable standard of review when the medical staff proposes new or amended bylaws for governing body approval? Is	

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			this requirement only in force when a medical staff is first brought into existence, as the term 'shall be established' suggests? Is this a continuing obligation whenever a facility adds or removes a particular service line, or adjusts facility policy? NCMS's perspective on the second sentence of Rule .3702 relates as much to pertinence and context as it does to meaning and clarity. This provision discusses the governing body's consideration of medical staff recommendations in whether to grant clinical privileges to qualified practitioners. The title of Rule .3702 and its first sentence focus on the establishment and structure of the medical staff as an entity, so the secondary focus on one of many medical staff responsibilities seems misplaced and should be also revisited. For all of these reasons, the Commission should reconsider its original determination and classify Rule .3702 as necessary with substantive public interest. Closer consideration by the Commission and by interested stakeholders could bring some welcome clarity.	
19) 10A NCAC 13B .3704 – Status	8/08/16		- Definition of 'active medical staff'?	
20) 10A NCAC 13B .3705 – Medical Staff Bylaws, Rules or Regulations	7/11/16	20a)	To whom it may concern Re: Medical Staff Bylaws, Rules or Regulations, I have several grave concerns regarding proposals for medical staff bylaws at the hospitals in our state. This is an area that most physicians are not interested in nor do not have the time to work through and discuss this properly. But they certainly should be carefully constructed. My first concern is that the chairs of the department and section are being nominated by people outside the department and not by their peers. A department / section's peers are most suited to select their chairman and are aware of many section wide or personal issues that may not be apparent to others, and could also lead to consequential conflicts of interest to select a person not qualified or who may be easier to manipulate/ pass things through. My second concern revolves around the area of exclusive contracts. Many new bylaws are allowing administrations the ability to close any sub specialty they wish and prohibit community or non-hospital employed physicians from utilizing the hospital for their expertise. Sometimes, even physicians who already have privileges can be closed out from the hospital they work out of. These hospitals are also the hospitals that argue against Certificate Of Need changes which would allow physicians to build facilities to practice in at a likely lower cost to the public with better efficiency. These same hospitals are also the ones who ask for tax exempt bonds from the commission to often expand services. As you know, hospitals must demonstrate a community	

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			benefit to qualify for those bonds, and excluding competent physicians is not necessarily a community benefit. My third concern is that credentialing is now being done at a centralized location off hospital campus in many instances - which results in the local hospital staff credentialing committees to be relegated to rubber stamping only and not using their local knowledge and expertise to best help build the medical staff appropriately. My fourth concern is that in many of these new bylaws, the Boards of Trustees are being given the authority to unilaterally 'waive' any bylaws for any reason they wish. The Joint Commission currently to my knowledge does not allow unilateral change of bylaws except for a change in law or federal regulations Waiving and amending bylaws is much of the same language. My last concern is that credentialing and restricting hospital privileges is now being given to those other than peers. Peers are no longer evaluating MD performance and credentialing, and this is being given to people of any level in the health care system that may or may not have direct knowledge of what is required to be a physician staff member. Credentialing and hospital privelages should always involve medical doctors and those of their peers at every step of the credentialing process. Thank you for your time and I hope that these concerns will be addressed by the Commission.	
	7/14/16	20b) Robert McBride, OrthoCarolina robert.mcbride@orthocarolina	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating my ability to practice. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. These and many other recent changes are very detrimental to the public good and I would please ask for your help. Thank you, Dr. Robert McBride (President and Chairman of the Board of OrthoCarolina and a member of the State Health Coordinating Council)	
	7/15/16	20c) THOMAS FEHRING, ORTHOCAROLINA HIP & KNEE CENTER THOMAS.FEHRING@ORTHOCAROLINA.COM	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating	

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	7/15/16	20d) David Janeway, OrthoCarolina david.janeway@orthocarolina.com	I have been in product practice in Winston-Salem for 26 years. My practice continues to provide care continues to pay property taxes and continues to pay sales tax on items purchased to run our office. I am opposed to the recent changes in hospital bylaws which have been implemented at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating my ability to practice. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. These and many other recent changes are very detrimental to the public good and I would please ask for your help.	
	7/15/16	20e) Brad Winter, OrthoCarolina brad.winter@orthocarolina.com	I am opposed to the changes made to the Medical Staff Bylaws by Novant Health which could place significant harm to the ability of the residents of the Winston Salem area to obtain medical care. The recent bylaws changes give Novant Health the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (orthopedics, general surgery, cardiology, etc.) eliminating my ability to practice. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. This places the community at significant risk for loss of access to needed patient care. It also places my ability to practice orthopedic surgery at risk. Please review these changes to the Medical Staff bylaws at Novant Health.	
	7/15/16	20f) Mark Suprock, OrthoCarolina mark.suprock@orthocarolina.com	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any	

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	7/15/16	20g) William Craig, OrthoCarolina william.craig@orthocarolina.com	I am opposed to the recent bylaw changes at Novant Health Forsyth Medical Center. As a private practice physician practicing at Forsyth Medical Center I believe these changes are not in the best interest of the medical staff or community. One change would allow for the hospital to close any service line (gen surgery, ortho, urology) thus limiting the physicians who could practice at the facility. Another change would allow for a physicians privileges to be eliminated without a peer physician being involved. These changes could force physicians to have to leave the community without reason or true peer review. Thank you for considering these issues. William Craig MD OrthoCarolina Winston	
	7/15/16	20h) Teresa Biggerstaff, tbigger@me.com	I am opposed to the recent changes in hospital bylaws which have been implemented at Novant hospitals. These changes put the practice of medicine (in my case Oral and Maxillofacial Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, oral surgery, cardiology, etc.) eliminating my ability to practice in the area. This ability creates nearly a monopoly situation for the hospital--they can essentially employ all of the physicians that work in their hospital and shut all others out--eliminating all competition for their own physicians that they employ. This is harmful to the public, as all monopolies are. I ask that you please review this and protect the independently practicing physicians (those that are not owned by a hospital system) from unfair practices. Thank you. Teresa Biggerstaff DDS, MD Advanced Oral and Facial Surgery of the Triad	
	7/15/16	20i)	I oppose recent bylaw changes at Forsyth Medical Center in Winston Salem. The new bylaws allow hospital administrators to arbitrarily control service lines and specialty practices. This limits the ability of individual physicians to practice medicine and limits patient access.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
	7/16/16	20j) Daniel Biggerstaff, OrthoCarolina scott.biggerstaff@orthocarolina.com	I am opposed to the recent changes in the bylaws at Novant Forsyth Medical center in Winston-Salem. The changes that were made put the ability of independent physicians at risk and in my situation the ability to practice Orthopaedic surgery. I am most concerned about the following. 1- The ability for the Novant Forsyth Medical center to create exclusive contracts with certain service lines and prohibit others (i.e. Orthopaedics, cardiology, pulmonary, etc) from practicing at the community hospital. In a state that has CON laws, that would force me and my partners to leave a community that our practice has served for over 30 years. 2- I am also concerned about the ability for the administration to eliminate a physician's privileges without a peer physician on the staff being involved. 3- It is also disturbing that the department/section chairs are no longer elected by the members of the repsective section but are being nominated by people outside of the department/section. This allows the administration to choose who they want instead of physician members of the section choosing who they want to represent them. 4- Finally, the board of trustees has given themselves the ability to waive bylaws for any reason. These are a few of the examples of the bylaws changes that will put the ability of independent physicians to practice in jeopardy and would be detrimental to the public good. I ask for your help. Thank you! Scott Biggerstaff, MD OrthoCarolina	
	7/17/16	20k) Alden Milam, OrthoCarolina milam_alden@yahoo.com	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating my ability to practice. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. These and many other recent changes are very detrimental to the public good and I would please ask for your help. Thank you, Dr. R Alden Milam IV MD (Vice-President of OrthoCarolina)	
	7/17/16	20l) Leo Spectror, OrthoCarolina Leo.Spector@orthocarolina.com	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Spine Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			my ability as an independent orthopedic spine surgeon to practice. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. These and many other recent changes are very detrimental to the public good potentially limiting access to providers and I would please ask for your help. Respectfully, Leo Spector MD	
	7/17/16	20m) Robert Morgan, OrthoCarolina robert.morgan@orthocarolina.com	As a practicing orthopaedic surgeon in North Carolina, I am against recent changes to the hospital bylaws at Norvant-Forsyth. These changes not only could jeopordize my ability to practice medicine but also could be detrimental to publix access to healthcare. Allowing the hospital administration to eliminate physician priveleges without a peer physician on staff being involved and allow them to close any 'service line' could make me unable to practice medicine in my hometown. I ask you to strongly consider how these hosptial bylaw changes could affect healthcare in our communites. Thank you for your time and assistance. -Robert Morgan, MD OrthoCarolina	
	7/18/16	20n) John Ternes, OrthoCarolina John.Ternes@orthocarolina.com	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Independent, non hospital owned, orthopedic groups have consistently shown the ability to provide lower cost care than hospitals. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating my ability to practice. If a hospital has the ability to cherry pick which service lines they provide, they will naturally exclude those service lines that provide care for the expensive indigent patients. Orthopedics, General Surgery, INternal Medicine,and OB/GYN should be considered core service lines of all community hospitals. This, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. These and many other recent changes are very detrimental to the public good and I would please ask for your help. Thank you, Dr. John P. Ternes	
	7/18/16	20o) William Griffin, Orthocarolina william.griffin@orthocarolina.com	I am very concerned about the proposed bylaws changes from Novant. They effectively allow the hospital administration to exclude individual physicians or entire groups of physicians from practicing at their hospitals for no cause, and with no peer review or appeal process. This could lead to an individual physician who has been practicing in good standing for years to suddenly have no facility available for his patients. Physicians would have to close their practice and leave the	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			area. This concept is incompatible with good patient care and is particularly onerous in a state with strict CON laws. Their are no health care related advantages to these proposed bylaws. This is purely a restraint of trade type of maneuver to limit available competition in the market. I am hopeful that the committee will help reverse these proposed changes. By doing so, you will improve patient access to less expensive health care. Thank you for your attention to this matter. Bill Griffin MD	
	7/18/16	20p) OrthoCarolina,	These recent changes in bylaws will affect my ability and many of my colleagues to practice medicine. This is in the harm of public good.	
	7/19/16	20q) Bryan Jennings, Jennings Orthopedic Associates, PA	The large hospital corporation (Novant Health), where I practice as an independent physician, has recently undergone revision of its by-laws to make them more unified across their hospital system. I was involved in the review and revision process as a member of the medical staff and medical staff leadership. The new by-laws were passed at 7 of 8 institutions. I only work at 2 of their institutions and Medical Park Hospital is the only entity in the corporation that did not pass the revised by-laws. I did not support them at either institution. Overall, I do not have a problem with 'the process' and understand the corporations point of view for wanting unified bylaws. However, after reviewing the finalized written documents I have significant concerns about a few of the revised corporate by-laws. 1) The first concern I have allows Novant to establish 'exclusive contracts' with physicians or groups but does not name these groups as in past by-laws. This could result in exclusion of established independent practices that have long provided services if such contracts were implemented. It could allow them to limit which groups are part of their 'service line,' or close existing service contracts or change them from credentialed established physicians currently providing the current service in the respective departments. This from the same group opposed to reversing the CON law which could allow these practitioners to build their own facilities to practice in? 2) The second area of concern suggests the Board of Trustees in the new by-laws has the authority to 'waive' for any reason by-laws when they feel such action is necessary. I expect and understand the ability and need to 'amend' bylaws, but unilaterally 'waive' them is concerning. 3) The third area of concern of the new by-laws is limiting physician involvement (or increasing administration involvement) in both electing department/section chairs, and the credentialing and peer review process. Physician have long governed themselves and doing so have provided excellent service and care to the hospitals and communities they serve. It appears that the corporations new by-laws, aim to limit physician involvement in this process or at	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			least significantly increase involvement from the administration - which should not occur at the expense of limiting physicians involvement.	
	7/24/16	20r) Robert Erdin, OrthoCarolina	I am opposed to the recent changes in hospital bylaws which have been implanted at Novant at Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk, skewing the governance of medical practice. I am deeply concerned about the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish (ortho, gen surgery, cardiology, etc.) eliminating my ability to practice. These changes, in a state that has CON laws, would mean that I, or one of my partners, would have to leave the area in order continue working with no other option. This could eliminate the ability of citizens(patients) to receive appropriate care locally. These and many other recent changes are very detrimental to the public good and I would please ask for your help. Thank you, Dr. Robert Erdin	
	7/25/16	20s) Patricia McHale, OrthoCarolina patricia.mchale@orthocarolina.com	I am opposed to the recent changes in hospital bylaws which have been instituted at Novant - Forsyth. These changes put the practice of medicine (in my case Orthopedic Surgery) at serious risk. Areas of concern include the ability for physician privileges to be eliminated without a peer physician on the hospital staff being involved. Another area of concern is that administration now has the ability to close any 'service line' they wish to (i.e.Orthopaedic Surgery), eliminating my ability to practice in that area. This, in a state that has CON laws, would mean that the proovder would have to leave the area in order continue working. This also limits the patient's choice as to which provider he/she prefers, which can adversely affect patient care. This could end up harming the hospital; if the facility takes a provider/service line out, the patient may choose to follow the provider to a different facility. These and many other recent changes are very detrimental to the public good and I would please ask for your help. Thank you, Dr. Patricia McHale, Fellow of the American Academy or Orthopaedic Surgery, Member of the AAOS and NCOA.	
	7/30/16	20t) William Satterfield, OC winston	The bylaws changes at novant health care Forsyth hospital in Winston Salem are prohibitive to independent medical physicians. The ability for a physician to be stripped of privileges with no peer review is not acceptable and unheard of in medicine. Further, the hospital has the right to eliminate service lines threatens all those not employed by the hospital. These changes were rammed through by the hospital influencing their own physicians to vote for them, and are not reflective	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			of the physicians who practice in the hospital. All outpatient physicians who don't work at the hospital anymore voted for these changes under hospital influence. As the hospitals control more and more the private practice physician can no longer stay viable. These changes should be overturned as they prohibit fair and equal practice and encourage large hospitals to eliminate any competition, frankly they should be viewed as antitrust issues. Thanks.	
	8/01/16	20u) Jay Singleton,	These bylaw changes are cloaked as a means for hospitals to better serve there physicians and oversee operations. In essence it is a tightening of the stranglehold they already have over NC physicians. Hospital privileges are tied to every aspect of a physicians practice. Without privelages surgeons can't do surgery, and primary care docs cannot admit patients. Many medical boards require that doctors have privelages. After over a decade of training and years of service, a doctor can find his/her self without a job or medical license with millions of dollars of debt unless they toe the line set forth by purposefully ambiguous bylaws that they must agree to. Hospital administrators could use these bylaws to extort physicians into doing anything they want. The stakes would be too high to speak up and there would be little legal recourse to help us fight. Less control. More free will. Monopolies=dictatorship.	
	8/01/16	20v) Gregory Temas, docgpt@Aol.com	Leave the current language as is. Too many hospitals are relinquishing independent physicians of staff appointments and putting in either employed physicians, or even non-physicians, so they can push their agenda through medical committees without any resistance. Medicine is an art that pays careful attention to detail. Hospital administrators, despite claiming non-profit status, have become increasingly focused on profits as they buy out other hospitals, increase their pay and hire incredible numbers of 'assistants'. Physicians typically look at the impacts of quality of care over profits. The NCDHHS needs to assure that independent physicians play a major and key role in deciding the language of Hospital by-laws to prevent their exclusion from hospital staff. Thank you.	
	8/08/16	20w)	As a private practicing physician in an area that is dominated by 2 large health care organizations, I feel that these proposed changes to bylaws are directed against private practicing physicians in the area. There seems to be an organized effort to reduce any competing private practices. This is especially concerning given the fact that my practice can only performed in 1 hospital in town. I fully support the concerns voiced in email generated by the NC OB/Gyn Society.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
21) 10A NCAC 13B .3706 – Organization and Responsibilities of the Medical Staff	8/08/16	Conor Brockett, North Carolina Medical Society cbrockett@ncmedsoc.org	The Medical Care Commission ('Commission') originally classified Rule .3706 as 'necessary without substantive public interest.' The North Carolina Medical Society ('NCMS') objects to the rule as unclear and ambiguous, and requests the Commission reclassify it as 'necessary with substantive public interest.' Rule .3706 is yet another Commission rule that addresses at least one aspect of medical staff organization. Paragraph (b) describes the roles and responsibilities of executive committees and requires each medical staff to have one. Paragraph (d) lists some core medical staff functions, and paragraph (c), acknowledging the reality that a medical staff often carries out its operations in committee environments, establishes basic record keeping requirements for 'proceedings of medical staff committees.' But in addition to this generic idea and acknowledgement of 'medical staff committees,' paragraph (e) of Rule .3706 goes farther: 'There SHALL BE medical staff and DEPARTMENTAL MEETINGS for the purpose of reviewing the performance of the medical staff, departments or services, and reports and recommendations of medical staff and MULTI-DISCIPLINARY COMMITTEES.' (Emphasis added.) NCMS has been unable to locate any other provision in the Commission's rules that mentions departmental meetings or multi-disciplinary committees at all, let alone a description comparable to paragraph (b)'s articulation of the role and functions of a medical staff executive committee. The rule's mandate that the medical staff have departmental and multi-disciplinary committees generates ambiguity and confusion over how a medical staff should be organized. Does paragraph (e) require a medical staff to incorporate these additional committee types into the organizational structure described in its bylaws? A very general purpose is given for 'departmental meetings,' but what is the purpose of a multi-disciplinary committee? Who is eligible and required to attend departmental meetings? Who is eligible to serve on multi-disciplinary committees? Finally, Rule .3706 is unclear and ambiguous in that paragraph (d) enumerates eight functions that 'shall be performed by the medical staff[.]' Upon first read, the phrase seems to clearly empower the medical staff with the authority and responsibility for carrying out these functions. However, there is no rule provision that addresses whether these same functions are delegable – voluntarily or involuntarily – by the medical staff. In other words, the rule does not explicitly state whether the medical staff is SOLELY responsible for each of the enumerated functions, or whether responsibility for a given function may be ceded in whole or in part. For example, credentialing review, .3706(d)(1), has traditionally been a responsibility of the medical staff. But NCMS understands that some facilities are enacting policies unilaterally to remove control over credentialing processes	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			from the medical staff. The current rule is ambiguous as to whether such an arrangement or action is permissible. For all of these reasons, the Commission should reconsider its original determination and classify Rule .3706 as necessary with substantive public interest.	
22) 10A NCAC 13B .3707 – Medical Orders	8/08/16	22a)	Support for North Carolina Hospital Association proposal or other action to amend this rule 10A NCAC 13B.3707 to be consistent with CMS' Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2) about nonmedical staff orders, which provides that: 'other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations.'	
	8/08/16	22b) Mike Vicario, NCHA mvicario@ncha.org	NCHA objects to the10A NCAC 13B .3707 MEDICAL ORDERS requirement that 'medical orders be issued only from members of the medical staff.' In the past most physicians in the community had hospital privileges. While hospitalists are prevalent in many settings now, patients of primary care providers still need certain diagnostic and therapeutic services of a hospital. While the care delivery model has changed, it is in the best interest of patient safety that these NC licensed physicians be able to order these services from the hospital for their patients, once hospital has verified the authenticity of the order and current licensure of the physician. The Centers for Medicare and Medicaid Services has recognized this need, and has modified their Interpretive Guidelines to address this issue as seen in their Interpretive Guidelines at §§482.23(c)(1), (c)(1)(i) and (c)(2): ….'other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations.' The NC rule is more restrictive than the Condition of Participation. We suggest a revision to the NC Regulation, requiring that practitioners 'write orders for diagnostic or therapeutic studies or for the preparation and administration of drugs and biologicals in accordance with CMS Regulation and Conditions of Participation.' We believe this change would provide consistency while enabling physicians and hospitals to continue to provide safe and effective care.	
	8/08/16	22c) David Parks, New Hanover Regional Medical Center david.parks@nhrmc.org	New Hanover Regional Medical Center suggests revisions to 10A NCAC 13B .3707 MEDICAL ORDERS requirement that medical orders be issued only from members of the medical staff. The current language of the rule makes an exception only for patients 'who are under the continuing care of an out-of-state physician but are	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			temporarily located in North Carolina…' after the hospital has verified the authenticity of the order and current licensure of the physician in the other state. (10A NCAC 13B.3707(f)) The verification procedures are an appropriate method for insuring quality and safety for patients. Without changing the requirement of the hospital to verify that the order is current and that the ordering physician is licensed to prescribe or order the treatment, the rules commission should extend this same criteria to any physician not on the medical staff who is ordering the test or treatment, not just those who are out-of-state caring for a patient temporarily located in North Carolina. This change is consistent with the current realities in healthcare delivery. The vast majority of family practice and internal medicine physicians in primary care practice are no longer on medical staff at a hospital. Instead, hospitalists have filled this role of admitting and caring for the patients admitted for inpatient care. For a patient's primary care physician to order labs, x-rays, or outpatient treatment (blood, special IV meds, etc.), hospitals need to be able to verify his/her license, and proceed with following the order, even if the provider is not on the hospital medical staff. Due to the cost and time requirements of participating on a hospital medical staff, it is not practical for these primary care physicians to be on a hospital medical staff in order to send their patients for testing and treatment within the scope of their practice. The Centers for Medicare and Medicaid Services have addressed this issue in their Interpretive Guidelines stating: ….'other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations.' We understand NCHA may have also submitted comments with recommended language similar to the following, which we too would support and recommend. A revision to the NC Regulation requiring practitioners to 'write orders for diagnostic or therapeutic studies or for the preparation and administration of drugs and biologicals in accordance with CMS Regulation and Conditions of Participation' would provide consistency while enabling physicians and hospitals to continue to provide safe and effective care.	
	8/08/16	22d)	- Outdated language with 'hard copy print out for order of patient charts' – allow for updated language around EMRs, such as 'in a computer or data processing system…'	
23) 10A NCAC 13B .3801 – Nurse Executive	8/08/16		With the total quality program is it required that nursing schedules meetings every 60 days to evaluate quality and efficiency of nursing services?	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
24) 10A NCAC 13B .3902 - Manager	8/05/16	24a) Jan Baucom , Caromont Health - Caromont Regional Medical Center jan.baucom@caromonthealth.org	CaroMont Regional Medical Center Health Information Management Department 2525 Court Drive Gastonia, NC 28054 August 4, 2016 TO: The North Carolina Medical Care Commission 2701 Mail Service Center Raleigh, NC 27699-2701 FROM: Jan Baucom, RHIA, CCS Director HIM/Medical Records CaroMont Regional Medical Center jan.baucom@caromonthealth.org Phone: 704-834-2113 SUBJECT: Comment: 10A NCAC 13B .3902 MANAGER CaroMont Regional Medical Center, located in Gastonia, NC, wishes to comment on 10A NCAC 13B .3902(a) regarding the MANAGER of the medical records service in hospitals. Our comments are in anticipation of rule changes currently being reviewed according to the DHSR Rule Review Schedule per G.S. 150B-21.3A, with initial agency determination of rules affecting hospitals in May 2016 and final agency determination in February 2017. We request a change to 10A NCAC 13B .3902 (a) MANAGER regarding the qualifications of the manager. Currently, this section states: (a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record administrator or an accredited records technician, the facility shall retain a person with these qualifications on a part-time or consulting basis. Background of the Rule The designated qualifications for manager of medical records services are certification titles granted through the American Health Information Management Association (AHIMA) to individuals who have successfully completed required educational requirements and have passed a rigorous certification exam. Effective January 1, 2000, AHIMA changed the title from Registered Record Administrator (RRA) to Registered Health Information Adminsitrator (RHIA), and from Accredited Record Technician (ART) to Registered Health Information Technician (RHIT). Candidates eligible to take the RHIA certification exam have completed academic requirements at the baccalaureate or master's level of a Health Information Management (HIM) program accredited by the Commission on Accreditation for Health Informatics and Information Management Education (CAHIIM). Candidates eligible to take the RHIT certification exam have completed academic requirements at the associate's degree level of an HIM program accredited by CAHIIM. Individuals who earn these certifications must maintain their credentials through continuing education units obtained in specific domains required by AHIMA which must be reported every two years. Rationale For The Rule Change Request for the change is to update these titles consistent with industry and professional standards of the credentialed individuals who manage the medical records service in hospitals in North Carolina. Proposed Rule Change 10A NCAC 13B	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			.3902 MANAGER (a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record health information administrator or an registered health information accredited records technician, the facility shall retain a person with those qualifications on a part-time or consulting basis. (b) The manager of the medical records service shall advise, administer, supervise and perform work involved in the development, analysis, maintenance and use of medical records and reports. (c) When the manager is employed on a part-time or consulting basis, he or she shall organize the department, train the regular personnel and make periodic visits to the facility. The manager shall evaluate the records and the operation of the service and document the visits by written reports. A written contract specifying his or her duties and responsibilities shall be kept on file and made available for inspection by the Division's surveyor. (d) The manager of the medical records service shall maintain a system of identification and filing to facilitate the prompt location of medical records of any patient. (e) The manager of the medical records service shall store medical records in such a manner as to provide protection from loss, damage, and unauthorized access. History Note: Authority G.S. 131E-79 RRC Objection due to lack of Statutory Authority Eff. July 13, 1995. Eff. January 1, 1996. Thank you for your consideration of this rule change. Please feel free to contact me if you have questions or request additional information. Sincerely, Jan Baucom, RHIA, CCS Director HIM/Medical Records (electronically signed)	
	8/05/16	24b) Jan Baucom , Caromont Health - Caromont Regional Medical Center jan.baucom@caromonthealth.org	NOTE: Please disregard previous comment, resubmitted with revised formatting from copy/paste. CaroMont Regional Medical Center Health Information Management Department 2525 Court Drive Gastonia, NC 28054 August 4, 2016 TO: The North Carolina Medical Care Commission 2701 Mail Service Center Raleigh, NC 27699-2701 FROM: Jan Baucom, RHIA, CCS Director HIM/Medical Records CaroMont Regional Medical Center jan.baucom@caromonthealth.org Phone: 704-834-2113 SUBJECT: Comment: 10A NCAC 13B .3902 MANAGER CaroMont Regional Medical Center, located in Gastonia, NC, wishes to comment on 10A NCAC 13B .3902(a) regarding the MANAGER of the medical records service in hospitals. Our comments are in anticipation of rule changes currently being reviewed according to the DHSR Rule Review Schedule per G.S. 150B-21.3A, with initial agency determination of rules affecting hospitals in May 2016 and final agency determination in February 2017. We request a change to 10A NCAC 13B .3902 (a) MANAGER regarding the qualifications of the manager. Currently, this section states: (a) The medical records service	

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			manager of the medical records service shall store medical records in such a manner as to provide protection from loss, damage, and unauthorized access. History Note: Authority G.S. 131E-79 RRC Objection due to lack of Statutory Authority Eff. July 13, 1995. Eff. January 1, 1996. Thank you for your consideration of this rule change. Please feel free to contact me if you have questions or request additional information. Sincerely, Jan Baucom, RHIA, CCS Director HIM/Medical Records (electronically signed)	
	8/08/16	24c)	(a) Update term – qualified medical records 'manager' to 'leader' or 'expert'	
25) 10A NCAC 13B .3903 – Preservation of Medical Records	6/23/16	25a)	10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS (d) The hospital shall give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility. COMMENT: REQUIRING AT LEAST TWO FORMS OF NOTIFICATION BEFORE DISTRUCTION OF RECORDS THAT HAVE BEEN RETAINED AFTER THE REQUIRED PERIOD IS OVERBURDENSON, COMPLEX AND EXPENSIVE. IT ALSO SETS UP AN UNREALISTIC EXPECTATION IN THE PUBLIC THAT THEY WILL BE PERSONALLY NOTIFIED IF THE AGENCY EVER DESTROYS THEIR OLD PAPER-BASED MEDICAL RECORD.	
	7/27/16	25b) Mike Vicario, NCHA mvicario@ncha.org	NCHA objects to the current rule 10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORD and requests removal of the requirement under section (d) that the hospital 'give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility.' Background of the Rule Authority for the rule is taken from Article 1C, Reporting by physicians and hospitals of wounds, injuries and illnesses; 131E-79, Rules and Enforcement, and 131E-97, Confidentiality of patient information. The statute, however, does not speak to the preservation of or process for destruction of obsolete medical records. (It should also be noted that 131E-97 (a) clarifies that medical records are not public records as defined by Chapter 132 of the General Statutes.) Rationale For The Rule Change North Carolina has the	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			second longest medical record retention requirement in the country at 11 years or until the patient's 30th birthday, according to Healthit.gov. However, even after holding an obsolete medical record for 11 years or more, an additional 'notification' requirement must be met prior to the destruction of the record. - Unlike other southeastern states, North Carolina requires patient notification upon intended destruction of an obsolete medical record, even beyond the expiration of the retention period. - One hospital system provided an expense breakdown of the cost of compliance for retrieval, notification and destruction of obsolete medical records. About 38,644 cubic feet of storage is currently being rented for storage of approximately 11 years worth of former patients' records. Fees for pulling records, and for moving and destroying them are an estimated $96,610. In addition, the estimated cost of notifying patients and representatives in accordance with that regulation is $352,404. - Hospitals have indicated that they retain records indefinitely because they cannot locate a patient they served 11 or more years ago or because of the difficulty in documenting compliance with the 'written notice' notification. (The regulation does not discuss which type of mailing is to be used or how to document compliance.) One hospital indicated that, after 11 years, a high percentage of the patients will have moved, and numerous notification letters would be returned for an invalid address, frustrating notification attempts. Efforts to reach patient representatives are also complicated by the requirements, and in some cases the information is not maintained on file. - One option studied by a hospital system with a new electronic health record system involves a software application to enable the new EHR to map, store, and organize old electronic medical records for individual retrieval. Another is to continue service contracts for the old record systems, as well as for any remaining paper records. Both options are expensive, and the need for them is exacerbated by the regulation's lengthy retention and dual notification requirements. - The current rule is not comparable to current Medicare policy and regulations, which requires the medical record to be retained for 5 years and which also does not have a requirement to inform former patients of the impending destruction of obsolete hospital records. - Hospitals are aware of the need to retain the records of children and adolescents for longer periods of time, as well as those potentially involved in legal matters. Additional Benefits of Rule Change All North Carolina hospitals would benefit from the elimination of the requirement to notify the public of impending destruction of medical records. They would be empowered to establish a process for record destruction once individual records have reached the required (11 year) minimum storage. However, due to continued uncertainty in determining whether the regulation would be	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			met, the destruction of obsolete records must now be processed on a case-by-case basis. Effect Of Rule Change On Other Rules Or Existing Practices Nursing Homes and other facilities have separate regulations governing retention of medical records. The North Carolina Medical Care Commission is currently reviewing 10A NCAC 13D .2402, PRESERVATION OF MEDICAL RECORDS for nursing homes. Those Likely To Be Affected By The Rule Change All licensed hospitals in North Carolina. Thank you for your consideration and please feel free to contact me if you have questions or need further information.	
	8/05/16	25c) Jan Baucom, Caromont Health - Caromont Regional Medical Center jan.baucom@caromonthealth.org	CaroMont Regional Medical Center Health Information Management Department 2525 Court Drive Gastonia, NC 28054 August 4, 2016 TO: The North Carolina Medical Care Commission 2701 Mail Service Center Raleigh, NC 27699-2701 FROM: Jan Baucom, RHIA, CCS Director HIM/Medical Records CaroMont Regional Medical Center jan.baucom@caromonthealth.org Phone: 704-834-2113 SUBJECT: Comment: 10A NCAC 13B .3902 MANAGER CaroMont Regional Medical Center, located in Gastonia, NC, wishes to comment on 10A NCAC 13B .3902(a) regarding the MANAGER of the medical records service in hospitals. Our comments are in anticipation of rule changes currently being reviewed according to the DHSR Rule Review Schedule per G.S. 150B-21.3A, with initial agency determination of rules affecting hospitals in May 2016 and final agency determination in February 2017. We request a change to 10A NCAC 13B .3902 (a) MANAGER regarding the qualifications of the manager. Currently, this section states: (a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record administrator or an accredited records technician, the facility shall retain a person with these qualifications on a part-time or consulting basis. Background of the Rule The designated qualifications for manager of medical records services are certification titles granted through the American Health Information Management Association (AHIMA) to individuals who have successfully completed required educational requirements and have passed a rigorous certification exam. Effective January 1, 2000, AHIMA changed the title from Registered Record Administrator (RRA) to Registered Health Information Adminsitrator (RHIA), and from Accredited Record Technician (ART) to Registered Health Information Technician (RHIT). Candidates eligible to take the RHIA certification exam have completed academic requirements at the baccalaureate or master's level of a Health Information Management (HIM) program accredited by the Commission on Accreditation for Health Informatics and Information	Note: she comments on Rule .3902 but submitted it for Rule .3903. This is not our error in putting this comment here. She is referring to another rule. The same comment was submitted for the rule she is commenting on.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			Management Education (CAHIIM). Candidates eligible to take the RHIT certification exam have completed academic requirements at the associate's degree level of an HIM program accredited by CAHIIM. Individuals who earn these certifications must maintain their credentials through continuing education units obtained in specific domains required by AHIMA which must be reported every two years. Rationale For The Rule Change Request for the change is to update these titles consistent with industry and professional standards of the credentialed individuals who manage the medical records service in hospitals in North Carolina. Proposed Rule Change 10A NCAC 13B .3902 MANAGER (a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record health information administrator or an registered health information accredited records technician, the facility shall retain a person with those qualifications on a part-time or consulting basis. (b) The manager of the medical records service shall advise, administer, supervise and perform work involved in the development, analysis, maintenance and use of medical records and reports. (c) When the manager is employed on a part-time or consulting basis, he or she shall organize the department, train the regular personnel and make periodic visits to the facility. The manager shall evaluate the records and the operation of the service and document the visits by written reports. A written contract specifying his or her duties and responsibilities shall be kept on file and made available for inspection by the Division's surveyor. (d) The manager of the medical records service shall maintain a system of identification and filing to facilitate the prompt location of medical records of any patient. (e) The manager of the medical records service shall store medical records in such a manner as to provide protection from loss, damage, and unauthorized access. History Note: Authority G.S. 131E-79 RRC Objection due to lack of Statutory Authority Eff. July 13, 1995. Eff. January 1, 1996. Thank you for your consideration of this rule change. Please feel free to contact me if you have questions or request additional information. Sincerely, Jan Baucom, RHIA, CCS Director HIM/Medical Records (electronically signed)	
	8/05/16	25d) Jan Baucom , Caromont Health - Caromont Regional Medical Center jan.baucom@caromonthealth.org	CaroMont Regional Medical Center Health Information Management Department 2525 Court Drive Gastonia, NC 28054 August 4, 2016 TO: The North Carolina Medical Care Commission 2701 Mail Service Center Raleigh, NC 27699-2701 FROM: Jan Baucom, RHIA, CCS Director HIM/Medical Records CaroMont Regional Medical Center jan.baucom@caromonthealth.org Phone: 704-834-2113 SUBJECT: Comment: 10A NCAC 13B .3903 PRESERVATION OF MEDICAL	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			RECORDS CaroMont Regional Medical Center, located in Gastonia, NC, wishes to comment on 10A NCAC 13B .3903(d) regarding the PRESERVATION OF MEDICAL RECORDS requirements for hospitals. Our comments are in anticipation of rule changes currently being reviewed according to the DHSR Rule Review Schedule per G.S. 150B-21.3A, with initial agency determination of rules affecting hospitals in May 2016 and final agency determination in February 2017. We request an amendment to 10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS to remove the requirement under section (d) that hospitals 'give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility.' Background of the Rule Authority for the rule is taken from Article 1C, Reporting by physicians and hospitals of wounds, injuries and illnesses; 131E-79, Rules and Enforcement, and 131E-97, Confidentiality of patient information. The statute, however, does not speak to the preservation of or process for destruction of obsolete medical records. (It should also be noted that 131E-97 (a) clarifies that medical records are not public records as defined by Chapter 132 of the General Statutes.) Rationale For The Rule Change North Carolina has the second longest medical record retention requirement in the country at 11 years or until the patient's 30th birthday, according to Healthit.gov. However, even after holding an obsolete medical record for 11 years or more, an additional 'notification' requirement must be met prior to the destruction of the record. - North Carolina requires patient notification upon intended destruction of an obsolete medical record, even beyond the expiration of the retention period. - CaroMont Regional Medical Center retains records indefinitely because of the difficulty which would be encountered to locate patients we served 11 or more years ago or because of the difficulty in documenting compliance with the 'written notice' notification. (The regulation does not discuss which type of mailing is to be used or how to document compliance.) We have records back to the beginning of our facility, in the early 1930's, and many of the patients treated prior to 11 years ago are deceased, moved from this area or to a new address in this area, married or remarried with different current names. We believe a high percentage of notification letters, if mailed to the address provided during these years (1930's through 2005), would be returned undeliverable. Efforts to reach patient representatives would also be complicated by the requirements, and in some cases the information is not maintained on	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			file, since patient representatives can change for individuals through the course of their lives. Storage of these records from the 1930's has caused us to spend millions of dollars over the past years microfilming these records. We believe financial resources could better be served on direct patient care or other services that provide patient-centered value, rather than storage or conversion to a microfilm medium. Even with electronic records, implemented in the past 12 years at our facility, the cost of electronic storage will be expensive to maintain and we will experience the same difficulty meeting requirements for individual patient notification prior to destruction. - The current rule is not comparable to current Medicare policy and regulations, which requires the medical record to be retained for 5 years and which also does not have a requirement to inform former patients of the impending destruction of obsolete hospital records. - We are aware of the need/requirement to retain the records of children and adolescents for longer periods of time, and request no changes to this section, as well as for record potentially involved in legal matters. Additional Benefits of Rule Change All North Carolina hospitals would benefit from the elimination of the requirement to notify the public of impending destruction of medical records. They would be empowered to establish a process for record destruction once individual records have reached the required (11 year) minimum storage. However, due to continued uncertainty in determining whether the regulation would be met, the destruction of obsolete records must now be processed on a case-by-case basis. Effect Of Rule Change On Other Rules Or Existing Practices Nursing Homes and other facilities have separate regulations governing retention of medical records. The North Carolina Medical Care Commission is currently reviewing 10A NCAC 13D .2402, PRESERVATION OF MEDICAL RECORDS for nursing homes. Those Likely To Be Affected By The Rule Change All licensed hospitals in North Carolina. CaroMont Regional Medical Center requests and supports the following Proposed Change to 10A NCAC 13B .3903: 10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS (a) The manager of medical records service shall maintain medical records, whether original, computer media, or microfilm, for a minimum of 11 years following the discharge of an adult patient. (b) The manager of medical records shall maintain medical records of a patient who is a minor until the patient's 30th birthday. (c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records shall be stored in a business offering retrieval services for at least 11 years after the closure date. (d) DELETE THIS SECTION. (d) The manager of medical records may authorize the microfilming of medical records.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			Microfilming may be done on or off the premises. If done off the premises, the facility shall provide for the confidentiality and safekeeping of the records. The original of microfilmed medical records shall not be destroyed until the medical records department has had an opportunity to review the processed film for content. (e) Nothing in this Section shall be construed to prohibit the use of automation in the medical records service, provided that all of the provisions in this Rule are met and the information is readily available for use in patient care. (f) Only personnel authorized by state laws and Health Insurance Portability and Accountability Act regulations shall have access to medical records. Where the written authorization of a patient is required for the release or disclosure of health information, the written authorization of the patient or authorized representative shall be maintained in the original record as authority for the release or disclosure. (g) Medical records are the property of the hospital, and they shall not be removed from the facility jurisdiction except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review. History Note: Authority G.S. 90-21.20B; 131E-79; 131E-97; Eff. January 1, 1996; Amended Eff. July 1, 2009. Thank you for your consideration of this rule change. Please feel free to contact me if you have questions or request additional information. Sincerely, Jan Baucom, RHIA, CCS Director HIM/Medical Records (electronically signed)	
	8/08/16	25e)	In support of changing the administrative code regarding requirements to provide individual notice to patients to destroy records. Advocate elimination of the requirement to give public and individual notice for destruction of medical records for hospitals.	
	8/08/16	25f)	- Update with electronic medical record language.	
26) 10A NCAC 13B .4002 – Staffing	8/08/16		(b) 'Director of Ambulatory Care Services' – suggestion to use more generic term. CMS changes to language around requiring one leader of outpatient services.	
27) 10A NCAC 13B .4003 – Policies and Procedures	8/08/16		(a) Clarification on which policies need medical staff approval; Not all outpatient services policies are related to medical staff (b)(1) – what is meant by policy on patient access to outpatient services. Should this statement be deleted?	
28) 10A NCAC 13B .4005 – Medical Records	8/08/16		(a) There is not one 'manager of outpatient services'. EMR language is needed.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
29) 10A NCAC 13B .4103 – Provision of Emergency Services	8/08/16		(a) 'Any of any facility' doesn't make sense	
30) 10A NCAC 13B .4104 – Medical Director	8/08/16		- Clarification for whether 'emergency privileges' are considered for disasters, while 'temporary privileges' are for urgent patient care needs such as covering weekends or holidays. - Is it necessary for the credentialing committee to approve this if it's coming through the full medical executive committee or governing body? - Please add clarification with intent on this wording.	
31) 10A NCAC 13B .4105 – Nursing	8/08/16		- Change 'reception' to 'triage'	
32) 10A NCAC 13B .4106 – Policies and Procedures	8/08/16		(2) This list should be reviewed for applicability in 2016 and beyond. Why would these conditions be singled out at this time versus others? - Recommend we don't have management of patient policies (eliminate 2&5). - Finding out these topics some are generic for whole hospital but some are specific to certain areas - Please review for a more up-to-date approach (11) Use more current terminology/expectations	
33) 10A NCAC 13B .4107 - Emergency Records	8/08/16		(a) change 'register' to 'log' (b)(7) change 'family' to 'support person'	
34) 10A NCAC 13B .4108 – Observation Beds	8/08/16		Review for necessity	
35) 10A NCAC 13B .4201 – Organization	8/08/16		(d) 'change to …needs as determined by facility leaders.'	
36) 10A NCAC 13B .4301 – Organization Maternal Services	8/08/16		(b)(10) Would a transfer agreement be required if the facility is unable to provide the level of care required?	
37) 10A NCAC 13B .4302 Medical Staff Maternal Services	8/08/16		(a) Include language allowing for the possibility of an MD unattended birth. (MD notified and baby is born before 30 min of when MD arrived?)	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
38) 10A NCAC 13B .4305 – Organization of Neonatal Services	8/08/16	38a)	(2) American Pediatric definition: infants 32 weeks or greater or greater than 1500 gm who have physiological immaturity (apnea or inability to feed orally) or who are moderately ill with problems to resolve quickly. Urgent subspecialty care is not an urgent need. (3) Pediatric defines Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity.	
	8/08/16	38b)	(2) American Pediatric definition: infants 32 weeks or greater or greater than 1500 gm who have physiological immaturity (apnea or inability to feed orally) or who are moderately ill with problems to resolve quickly. Urgent subspecialty care is not an urgent need. (3) recommend removing 'Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.' American Pediatric defines Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity.	
39) 10A NCAC 13B .4511 – Medication Administration	8/08/16	39a)	(e) '…nurse executive or her designee.' (c) '…NC Occupational Board or related national registration...' ex: Radiology/Technology Does not have a NC Board.	
	8/08/16	39b)	(e) '…nurse executive or her designee.' - remove the word 'her'	
40) 10A NCAC 13B .4603 – Surgical and Anesthesia Staff	8/08/16	40a) Catharine Cummer, Duke University Health System, Inc. catharine.cummer@duke.edu	Duke University Health System requests an amendment to 10A NCAC 13B .4603 SURGICAL AND ANESTHESIA STAFF to remove the requirement under subsection (5) that the operating room register maintained by a hospital include 'the presence or absence of complications in surgery.' This particular requirement is unnecessary and creates unduly burdensome administrative responsibilities. Complications are already documented in individual patient records as they arise. Neither federal regulations, CMS conditions of participation, nor TJC hospital accreditation standards include this requirement that complications also be separately logged in an operating room register; this makes it inefficient to try to coordinate this state-specific log information into nationally developed electronic health record formats. Moreover, it can be difficult to define the presence or absence of complications in a log, as complications may not be identified until after the patient leaves the operating room or even several days after the procedure, or if complications arise that are not be related to the surgical procedure itself.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
		40b) Catharine Cummer, Duke University Health System, Inc. catharine.cummer@duke.edu	[NO CONFIRMATION RECEIVED OF SUBMISSION OF PREVIOUS COMMENT; PLEASE DISREGARD IF DUPLICATE OF COMMENT ALREADY SUBMITTED] Duke University Health System requests an amendment to 10A NCAC 13B .4603 SURGICAL AND ANESTHESIA STAFF to remove the requirement under subsection (5) that the operating room register maintained by a hospital include 'the presence or absence of complications in surgery.' This particular requirement is unnecessary and creates unduly burdensome administrative responsibilities. Complications are already documented in individual patient records as they arise. Neither federal regulations, CMS conditions of participation, nor TJC hospital accreditation standards include this requirement that complications also be separately logged in an operating room register; this makes it inefficient to try to coordinate this state-specific log information into nationally developed electronic health record formats. Moreover, it can be difficult to define the presence or absence of complications in a log, as complications may not be identified until after the patient leaves the operating room or even several days after the procedure, or if complications arise that are not be related to the surgical procedure itself.	
	8/08/16	40c)	(2) a roster or electronic facility registry of practitioners	
41) 10A NCAC 13B .4605 – Policies and Procedures	8/08/16		2) 'written or electronic evidence of informed consent, in the patient's record before surgery. If prior written or electronic consent was not obtained, the record shall contain a written or electronic explanation of why prior consent was not obtained'	
42) 10A NCAC 13B .4702 – Organization	8/08/16		(e)change 'department heads' to 'leadership' (f) Clarify 'division'	
43) 10A NCAC 13B .4703 - Sanitation and Safety	8/08/16		Recommend adding reference to local county health department monitoring.	
44) 10A NCAC 13B .4801 – Organization	8/08/16		(c) Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation. Regulations are now available online.	
45) 10A NCAC 13B .4805 – Safety	8/08/16		(c)Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation. (e) Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
46) 10A NCAC 13B .4904 – Tests	8/08/16		(b) Consider adding determined by Medical Staff	
47) 10A NCAC 13B .5005 – Cardiac Rehabilitation Program	8/08/16		Is order information in cost still applicable?	
48) 10A NCAC 13B .5102 – Policy and Procedures	8/08/16		(a) 'Written or electronic' (a)(5-7) Add verbiage to indicate that processes will be followed according to manufacturers' recommendation(s)	
49) 10A NCAC 13B .5104 – Environmental Services	8/08/16		Provide it directly or by contract.	
50) 10A NCAC 13B .5105 – Sterile Supply Services	8/08/16		(1-2) 'and/or by manufacturer's guidelines'	
51) 10A NCAC 13B .5202 – Definitions Applicable to Psychiatric or Substance Abuse Services	8/08/16		(a) Each facility department or service shall establish and maintain written infection control policies and procedures change to each facility should have a policy that includes all departments. The current wording implies each department has to have a department specific policy. Larger health systems have moved away from department specific policies unless needed for an exception or special population.	
52) 10A NCAC 13B .5406 – Discharge Criteria for Inpatient Rehabilitation Facilities or Units	8/08/16		(a) 'The facility shall involve the patient, family or support person, staff members and referral sources in discharge planning.'	
53) 10A NCAC 13B .5408 – Comprehensive Inpatient Rehabilitation Program	6/14/16	53a) Don Huston, Cone Health Rehabilitation Center donald.huston@conehealth.com	Under letter (d), I would like to suggest the wording change to the CMS requirement which states the following: The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy. 2. The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
Staffing Requirements			current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.	
	8/02/16	53b) Mike Vicario, NCHA mvicario@ncha.org	The rule has requirements that are problematic for inpatient rehabilitation providers. - 10A NCAC 13B .5414 provides for a facility that is in compliance with a deemed status accreditation body to also be in compliance with Rules .5401 through .5413 of this Section. - This rule includes specific nursing hour per patient day requirements - the CMS Conditions of Participation and the accreditation requirements do not include a specific NHPPD requirement for inpatient rehabilitation.	
54) 10A NCAC 13B .5411 – Physical Facility Requirements/Inpatient Rehabilitation Facilities or Unit	8/08/16		(d)(2) Operable windows – would this be a current/applicable requirement? (d)(6) Too descriptive on furniture requirements such as the mirror requirement.	
55) 10A NCAC 13B .5412 – Additional Requirements for Traumatic Brain Injury Patients	6/14/16	55a) Don Huston, Cone Health Rehabilitation Center donald.huston@conehealth.com	Under item (2), I would suggest rewording to equal the CMS requirement: The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy. 2. The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.	
	7/22/16	55b)	1. Most patients cannot tolerate 4-4.5 hours of therapy, especially upon admission to the service. 2. Providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful. 3. The therapy requirements are not consistent with CMS Conditions of Participation, currently for 3 hours of therapy/day.	

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	8/02/16	55c) Mike Vicario, NCHA mvicario@ncha.org	NCAC 13B .5412 has requirements that are problematic for the following reasons: - most patients cannot tolerate 4 or 4.5 hours of therapy, especially upon admission to the facility. - providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful - the therapy requirements (and perhaps other licensure requirements for the TBI and spinal cord patients) are not consistent with CMS Conditions of Participation requirements for 3 hours of therapy/day. - the CMS Conditions of Participation requirements do not include a specific NHPPD requirement for inpatient rehabilitation. Hospitals are either obliged to ignore the rule and provide therapy that is consistent with patient needs, or provide additional & potentially unnecessary therapy - at their own cost, in order to treat patients with these conditions.	
	8/08/16	55d) Catharine Cummer, Duke University Health System, Inc. catharine.cummer@duke.edu	Duke University Health System, Inc., requests an amendment to 10A NCAC 13B .5412 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS, to remove the requirement under subsection (2) regarding the required hours of rehabilitation therapy services per patient day. We understand that the North Carolina Hospital Association has submitted comments regarding this requirement, and we strongly support and endorse NCHA's comments. The requirement of a minimum 4.5 hours of therapy per day is inconsistent with federal conditions of participation that require 3 hours per day. In fact, many patients cannot readily tolerate 4.5 hours of therapy per day, especially upon admission to a rehabilitation unit. Therefore, providing additional therapy simply because it is required by a state regulation and not because it is clinically indicated, is costly, unreimbursed, and not necessarily beneficial to the patient.	
56) 10A NCAC 13B. 5413 – Additional Requirements for Spinal Cord Injury Patients	6/14/16	56a) Don Huston, Cone Health Rehabilitation Center donald.huston@conehealth.com	Under item (2), I would suggest rewording to the CMS requirement: The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy. 2. The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.	

Rule Citation & Title	Date	Commenter	Comment	Agency Response
	7/22/16	56b)	1. Most patients cannot tolerate 4-4.5 hours of therapy, especially upon admission to the service. 2. Providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful. 3. The therapy requirements are not consistent with CMS Conditions of Participation, currently for 3 hours of therapy/day.	
	8/02/16	56c) Mike Vicario, NCHA mvicario@ncha.org	NCAC 13B .5413 has requirements that are problematic for the following reasons: - most patients cannot tolerate 4 or 4.5 hours of therapy, especially upon admission to the facility. - providing additional therapy is costly and unreimbursed, so if not beneficial to the patient, is wasteful - the therapy requirements (and perhaps other licensure requirements for the TBI and spinal cord patients) are not consistent with CMS Conditions of Participation requirements for 3 hours of therapy/day. - the CMS Conditions of Participation requirements do not include a specific NHPPD requirement for inpatient rehabilitation. Hospitals are either obliged to ignore the rule and provide therapy that is consistent with patient needs, or provide additional & potentially unnecessary therapy - at their own cost, in order to treat patients with these conditions.	
	8/08/16	56d) Catharine Cummer, Duke University Health System, Inc. catharine.cummer@duke.edu	Duke University Health System, Inc., requests an amendment to 10A NCAC 13B .5413 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS, to remove the requirement under subsection (2) regarding the required hours of therapy services per patient day. We understand that the North Carolina Hospital Association has submitted comments regarding this requirement, and we strongly support and endorse NCHA's comments. The requirement of 4 hours of therapy per day is inconsistent with federal conditions of participation that require 3 hours per day. In fact, many patients cannot easily tolerate 4 hours of therapy per day, especially upon admission to a rehabilitation unit. Therefore, providing additional therapy simply because it is required by a state regulation and not because it is clinically indicated, is costly, unreimbursed, and not necessarily beneficial to the patient.	
57) 10A NCAC 13B.6227 – Electrical Requirements	8/08/16	57a) Catharine Cummer, Duke University Health System, Inc. catharine.cummer@duke.edu	Duke University Health System, Inc. requests an amendment to 10A NCAC 13B .6227 ELECTRICAL REQUIREMENTS, specifically the requirement in section (e)(6) regarding the areas in which isolated power systems are required. The current regulation requires isolated power system not only in 'inhalation anesthetizing locations' but also any 'other areas were patients are intended to have a direct electrical path to the heart muscle.' This requirement is vague and ambiguous, does not reflect national hospital construction standards, and is not consistent with CMS policy and regulations. CMS already requires	

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			hospitals to comply with National Fire Protection Association standards, which fully and appropriately address patient safety needs; to the extent that this regulatory section applies additional requirements for isolated power in 'other areas' that do not arise under existing NFPA standards, it imposes very significant unnecessary expenses on hospitals to comply. Specifically, to the extent that the reference to 'other areas' would include intensive care units, installing isolated power systems costs approximately $50,000 per intensive care bed. Duke therefore proposes the following change: 10A NCAC 13B .6227 ELECTRICAL REQUIREMENTS (e) Receptacles shall be provided as follows: (1) Each operating room and delivery room shall have at least eight 120 volt duplex receptacles; (2) In areas where mobile X-ray equipment is intended to be used, single receptacles marked for X-ray equipment only shall be installed; (3) Neonatal Level I nurseries shall have a minimum of one 120 volt duplex receptacle located on each nursery wall connected to the critical branch of the emergency electrical system in addition to the receptacles for each bassinet required by Section 517-18 of the North Carolina State Building Code Volume IV; (4) Emergency department examination and treatment rooms shall have a minimum of two 120 volt duplex receptacles located convenient to the head of each bed. Trauma rooms shall have a minimum of three 120 volt duplex receptacles convenient to the head of each bed; (5) 120 volt duplex receptacles for general use shall be installed 50 feet (15.2 m.) apart in all corridors and within 25 feet (7.6 m.) of corridor ends; and (6) Inhalation anesthetizing locations [DELETE: and other areas where patients are intended to have a direct electrical path to the heart muscle] shall be equipped with an isolated power system, approved by the authority having jurisdiction including the following requirements: (A) The line isolation monitor shall be visible to attending staff while caring for the patient; (B) No more than one patient may be served by an isolated power system serving emergency power receptacles; (C) Transformers shall not be located over any patient bed location; and (D) Branch circuit wiring for isolated power systems shall have a dielectric constant of less than 3.5.	
	8/08/16	57b) Catharine Cummer, Duke University Health System catharine.cummer@duke.edu	[NO CONFIRMATION OF SUBMISSION OF PREVIOUS COMMENT RECEIVED; IF THIS IS A DUPLICATE OF COMMENT ALREADY SUBMITTED, PLEASE DISREGARD] Duke University Health System, Inc. requests an amendment to 10A NCAC 13B .6227 ELECTRICAL REQUIREMENTS, specifically the requirement in section (e)(6) regarding the areas in which isolated power systems are required. The current regulation requires isolated power system not only in 'inhalation anesthetizing locations' but also any 'other areas were patients are intended to have a direct electrical path to the heart muscle.'	

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			This requirement is vague and ambiguous, does not reflect national hospital construction standards, and is not consistent with CMS policy and regulations. CMS already requires hospitals to comply with National Fire Protection Association standards, which fully and appropriately address patient safety needs; to the extent that this regulatory section applies additional requirements for isolated power in 'other areas' that do not arise under existing NFPA standards, it imposes very significant unnecessary expenses on hospitals to comply. Specifically, to the extent that the reference to 'other areas' would include intensive care units, installing isolated power systems costs approximately $50,000 per intensive care bed. Duke therefore proposes the following change: 10A NCAC 13B .6227 ELECTRICAL REQUIREMENTS (e) Receptacles shall be provided as follows: (1) Each operating room and delivery room shall have at least eight 120 volt duplex receptacles; (2) In areas where mobile X-ray equipment is intended to be used, single receptacles marked for X-ray equipment only shall be installed; (3) Neonatal Level I nurseries shall have a minimum of one 120 volt duplex receptacle located on each nursery wall connected to the critical branch of the emergency electrical system in addition to the receptacles for each bassinet required by Section 517-18 of the North Carolina State Building Code Volume IV; (4) Emergency department examination and treatment rooms shall have a minimum of two 120 volt duplex receptacles located convenient to the head of each bed. Trauma rooms shall have a minimum of three 120 volt duplex receptacles convenient to the head of each bed; (5) 120 volt duplex receptacles for general use shall be installed 50 feet (15.2 m.) apart in all corridors and within 25 feet (7.6 m.) of corridor ends; and (6) Inhalation anesthetizing locations [DELETE: and other areas where patients are intended to have a direct electrical path to the heart muscle] shall be equipped with an isolated power system, approved by the authority having jurisdiction including the following requirements: (A) The line isolation monitor shall be visible to attending staff while caring for the patient; (B) No more than one patient may be served by an isolated power system serving emergency power receptacles; (C) Transformers shall not be located over any patient bed location; and (D) Branch circuit wiring for isolated power systems shall have a dielectric constant of less than 3.5.	