November 8, 2018

Submitted Electronically (rrc.comments@oah.nc.gov)

North Carolina Rules Review Commission
1711 New Hope Church Rd.
Raleigh, NC 27609

Dear Commissioners:

On behalf of Medicaid providers rendering a significant portion of Medicaid services in North Carolina, the North Carolina Healthcare Association, North Carolina Medical Society, and the Association for Home and Hospice Care of North Carolina jointly submit these written comments. Our provider associations oppose the versions of 10A NCAC 22F .0301 and 10A NCAC 22J .0106 that the Rules Review Commission is scheduled to review at its November 15, 2018 meeting. Pursuant to 26 NCAC 05 .0103(b), these comments set forth how the rules fail to comply with the statutory grounds for the Rules Review Commission's review set forth in N.C. Gen. Stat. § 150B-21.9.

Our provider associations represent a broad swath of Medicaid providers, including hospitals, health systems, physicians, physician assistants, hospices, and home health agencies. Descriptions of our associations are attached. Our associations have an interest on behalf of all Medicaid providers in ensuring that the Medicaid rules are promulgated in a way that conforms with the Administrative Procedure Act ("APA") and that ensures a functional and sustainable Medicaid program.

We have previously provided the North Carolina Department of Health and Human Services' Division of Health Benefits ("DHB"), formerly the Division of Medical Assistance ("DMA") (collectively referred to as "DHHS"), compromise language to address our concerns with 10A NCAC 22J .0106 and have also made suggestions to DHHS on how to refine and improve 10A NCAC 22F .0301. We are attaching a copy of our proposed compromise language for 10A NCAC 22J .0106 to this letter, and we would ask the Commission and its staff counsel to review it.

As written, 10A NCAC 22F .0301 and 10A NCAC 22J .0106 do not meet <u>any</u> of the criteria set forth in N.C. Gen. Stat. § 150B-21.9. Specifically, these rules:

1. are outside of the authority delegated to DHHS by the General Assembly;

2. are unclear and ambiguous;

3. are not reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency; and

4. were not adopted in accordance with the rulemaking requirements of the APA.

I. THE RULES ARE OUTSIDE OF THE AGENCY'S DELEGATED AUTHORITY.

In the context of the two rules promulgated by DHHS, the scope of the authority delegated by the General Assembly must be determined not only by reference to whatever general enabling provisions may exist, but also by reference to the APA itself. The APA limits "the authority delegated to the agency." If the APA expressly prohibits a certain type of rule, then agencies do not have statutory authority to adopt that type of provision. A rule cannot be simultaneously authorized and prohibited by the General Assembly. To the extent statutes were to appear at odds with one another in that regard, they must be interpreted and applied in accordance with standard principles of construction. This would require giving priority to legislation specifically prohibiting the type of rule at issue, not to a general enabling provision that does not specifically address the prohibited rule. Therefore, in order to determine whether a proposed rule is authorized by law, the Commission must also squarely confront APA provisions that place restrictions on agency authority.

In attempting to justify previous versions of 10A NCAC 22F.0301 and 10A NCAC 22J.0106, the agency has referred the Commission to N.C. Gen. Stat. § 108A-54.1B, insisting that its language authorizes DHHS's rules. Properly understood, N.C. Gen. Stat. § 108A-54.1B(a) merely provides the agency with the general authority to adopt regulations relevant to the programs overseen by DHHS. Although, initially, the first clause would appear to give the agency the authority to "define . . . federal laws and regulations," state administrative agencies cannot define federal laws and regulations. U.S. Const. Art. VI cl. 2.

In any event, N.C. Gen. Stat. § 108A-54.1B does not authorize the agency to adopt rules that conflict with the APA. It contains no language that would render the APA's prohibitions inapplicable. If the General Assembly intends to exempt an agency from the APA's rulemaking requirements, it does so explicitly as an exemption in the APA. *See* N.C. Gen. Stat. § 150B-1(d).

The APA contains numerous provisions that limit an agency's authority. For example, the APA prohibits an agency from adopting a rule that "[i]mposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, unless *a law* specifically authorizes the agency to do so or *a law* declares that violation of the rule is a criminal offense or is grounds for a civil penalty." N.C. Gen. Stat. § 150B-19(3) (emphasis added). Additionally, the APA prohibits DHHS from incorporating unpromulgated materials into its rules by reference unless it is adopted as a rule by the agency or it is a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association. *Id.* § 150B-21.6; *see also id.* § 150B-18. Finally, the General Assembly forbids the agency to adopt any rule that "[a]llows the agency to waive or modify a requirement set forth in a rule unless a rule establishes specific guidelines the agency must follow in determining whether to waive or modify the requirement." *Id.* § 150B-19(6).

The overreaching provisions of both rules expose providers to civil liability for unintentional errors without authority to do so in violation of N.C. Gen. Stat. § 150B-19(3). Both rules penalize lawful acts and omissions. As a result, the rules are outside the agency's authority as circumscribed by N.C. Gen. Stat. § 150B-19(3) and are therefore objectionable under N.C. Gen. Stat. § 150B-21.9(a)(1).

For example, 10A NCAC 22F.0301(10) penalizes providers who do not notify DHHS "within 30 calendar days of learning of *any adverse action* initiated against any required license, certification, registration, accreditation, or endorsement of the provider or any of its officers, agents, or employees" (emphasis added). Suppose the provider is a hospital with many hundreds of employees for whom a valid drivers' license is a job "requirement." Suppose further that one of those employees is charged with a traffic offense that triggers the suspension or revocation of their drivers' license. If the provider fails to notify DHHS of this promptly after learning about it, it has violated paragraph (10).[1]

Similarly, 22J .0106's attempt to bar providers from billing patients for services not covered by Medicaid is not authorized by N.C. Gen. Stat. § 108A-54.1B(a). Billing patients for services provided when they do not have any other coverage is a transaction that is completely outside of the agency's purview. N.C. Gen. Stat. § 108A-54.1B, upon which DHHS has relied for the proposition that it is authorized to create "conditions" for participating as a Medicaid provider, does not contain that authority. Instead, it says DHHS can determine "the terms and conditions of *eligibility* for applicants and recipients." *Id.* § 108A-54.1B(a) (emphasis added). This rule cannot possibly satisfy the standard set forth in N.C. Gen. Stat. § 150B-21.9(a)(1) and remains objectionable.

22F .0301 attempts to incorporate unpromulgated materials, including Clinical Coverage Policies. DHHS's reference to Clinical Coverage Policies appear to refer to the "medical coverage policy" concept embedded in N.C. Gen. Stat. § 108A-54.2. Under state law, medical coverage policy is defined as "those policies, definitions, or guidelines utilized to evaluate, treat, or support the health or developmental conditions of a recipient so as to determine eligibility, authorization or continued authorization, medical necessity, course of treatment and supports, clinical outcomes, and clinical supports treatment practices for a covered procedure, product, or service." N.C. Gen. Stat. § 108A-54.2(b). Medical coverage policies, as defined under this provision, are exempted from the APA's rulemaking requirements. N.C. Gen. Stat. § 150B-1(d)(9). As a result, the scope is important. Essentially, these policies are only given the effect of rules with respect to assessment of conditions. To the extent any policy deviates from the above language in its scope or function, it is not exempt from rulemaking because it no longer meets the statutory definition of "medical coverage policy." As written, many of the Clinical Coverage Policies go beyond the definition of medical coverage policy Therefore, DHHS's incorporation of these materials into 22F .0301 is a violation of the APA.

Finally, 22F .0301 improperly gives the agency discretion to determine what constitutes abuse without providing any specific guidelines. Because the word "includes" can be interpreted

1 As another example, 22F .0301(17) declares that it is abuse to fail to notify DHHS of "any change in information contained in the Medicaid provider enrollment application within 30 calendar days of the event triggering the reporting obligation." Suppose a longtime Medicaid provider merges with another company or simply "rebrands" itself, resulting in an eventual changing of numerous employee e-mail addresses. If any e-mail address listed in the provider's Medicaid enrollment application no longer matches its owner's e-mail address and the provider does not timely notify the agency, the provider would have committed abuse.

as signaling a non-exclusive list, the rule violates N.C. Gen. Stat. § 150B-19(6). As explained above, that statute prohibits rules that depend upon unguided agency discretion for their interpretation and enforcement. A rule that attempts to define "abuse" using an open-ended list is logically incapable of satisfying N.C. Gen. Stat. § 150B-19(6) and is therefore outside of the agency's authority.

II. THE RULES ARE UNCLEAR AND AMBIGUOUS.

Numerous elements of DHHS's rules feature terms that are incapable of definition or whose meaning is ambiguous. As a result, the rules are objectionable under N.C. Gen. Stat. § 150B-21.9(a)(2) because they are not "clear and unambiguous."

For example, 22F .0301(6) includes within the definition of "abuse," the "failure to comply with requirements of certification." This language is unclear, ambiguous, and overbroad. Does this phrase refer, for example, to the requirements for board certification available to physicians in various fields of specialization? If so, the rule exceeds DHHS's authority as restricted by N.C. Gen. Stat. § 150B-19(3) because it unilaterally penalizes something that is not already illegal or penalized—namely, the loss of board certification, which is something that is completely voluntary for physicians. If the rule does not refer to board certification requirements, it should specify accordingly.

10A NCAC 22J .0106 is also unclear. For example, paragraph (a) states that a provider can "refuse" to "accept a patient as a Medicaid patient," but paragraph (b) states that a provider will be "deemed to have accepted" such a patient if the provider submits a claim to Medicaid for the services provided—regardless of whether those services are actually covered. This is contradictory or, at best, unclear. How can a provider both "refuse to accept" a patient as a Medicaid patient, as suggested by paragraph (a), and be "deemed to have accepted" such a patient under paragraph (b)? The rule does not resolve that question.

In addition, the language of paragraph (c) is unclear and ambiguous because the act of "billing" is not defined. This is problematic because, depending on how DHHS interprets this language in a particular instance, certain activities might be deemed to violate this rule despite their being mandated by other regulations. For example, the "Patient's Bill of Rights" in 10A NCAC 13B .3302 requires the provider, upon request by the patient, to issue a bill to the patient and explain it in detail. Unfortunately, paragraph (c) of 22J .0106 does not distinguish between the Bill of Rights scenario and others in which the hospital bill is provided to the patient.

Also, many providers frequently issue bills to patients in the context of assisting those patients in qualifying for the provider's charity-care (or financial assistance) programs. Charity-related procedures are governed by a variety of authorities and documents including federal tax law and the provider's community-needs assessment. Modifying those procedures in order to ensure compliance with this rule would create a substantial economic impact across the state, as significant resources are required in order to develop those structures within each provider's system. Furthermore, copies of bills are frequently issued to provide the patient with documentation of expenses, proof of which is required to satisfy that patient's Medicaid "deductible" in future situations. Unfortunately, as written, paragraph (c) would not prevent DHHS from unlawfully

penalizing a provider for issuing a bill or statement of charges to patients even in these sorts of situations.

For comparison, it is useful to recall the Commission's recent objections to other rules on clarity/unambiguity grounds. For example, in its August 21, 2018 objection letter to the Board of Elections and Ethics Enforcement, the Commission objected on clarity/unambiguity grounds no fewer than 38 separate times. Here are a couple of examples:

08 NCAC 10B .0102	Unclear/Ambiguous	The Commission found this Rule to be ambiguous as written as it includes language such as "other approved communications devices", "other necessary identifiers", "necessary mechanisms", "correctly", "good working order", "continual adequate", "proper", and "official timepiece" without providing any additional information as to the meaning of these terms.
08 NCAC 10B .0103	Unclear/Ambiguous	The Commission found this Rule to be ambiguous as written as it includes language such as "clearly", "fail-safe", "adequate", "proper", "other approved record", "secure", and "properly" without providing any additional information as to the meaning of these terms.

If phrases like "necessary mechanisms" and "other approved record" are unclear or ambiguous, then it follows that the phrase "requirements of certification" is also unclear or ambiguous (or both). Until DHHS eliminates these types of vague references or provides wording that makes their meanings clearer, 10A NCAC 22F.0301 and 10A NCAC 22J .0106 will remain objectionable under N.C. Gen. Stat. § 150B-21.9(a)(2).

III. THE RULES ARE NOT REASONABLY NECESSARY TO IMPLEMENT OR INTERPRET STATE LAW OR FEDERAL LAW OR REGULATION.

Numerous portions of the Medicaid rules before the Commission overlap with and duplicate requirements already promulgated by DHHS or the federal Medicaid agency or enacted by the General Assembly or Congress. As a result, the rules are objectionable under N.C. Gen. Stat. § 150B-21.9(a)(3) because their provisions are not "reasonably necessary" to implement any applicable law or federal regulation. In fact, the offending portions of the rules are not necessary at all.

For 22F .0301, federal regulations already define abuse as "provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care." 42 C.F.R. § 455.2. In some of its newly added provisions, DHHS incorporates into the definition of abuse violations of federal laws such as the Americans with Disabilities Act and Section 1557 of the Affordable Care Act. These federal laws have their own robust enforcement mechanisms. The inclusion of these federal laws as acts of abuse is overreaching and sets up the likelihood of duplicative and inconsistent enforcement.

For 22J .0106, applicable federal regulations already prohibit balance-billing of Medicaid patients for covered services. *See* 42 C.F.R. § 447.15 (requiring providers to accept Medicaid

payment as "payment in full"). Therefore, even ignoring the agency's lack of authority for the prohibitions and requirements contained in proposed paragraphs (a) through (d), paragraph (e) of DHHS's rule overlaps with and is duplicative of 42 C.F.R. § 447.15 and is not "reasonably necessary" to implement any applicable law or federal rule. Accordingly, these rules are objection-objectionable under N.C. Gen. Stat. § 150B-21.9(a)(3).

IV. THE RULES WERE NOT ADOPTED IN ACCORDANCE WITH THE APA.

The version of 10A NCAC 22F .0301 published for the November 15, 2018 Committee meeting is dramatically different from the text published in the North Carolina Register in January of this year. The language is also quite different from the rule as it has existed to this point. The differences, moreover, are substantial, imposing tremendous regulatory and compliance burdens on providers.

The current version of 22F .0106 adds fifteen new types of abuse in addition to the five in the existing rule. For example, paragraph (15) defines program abuse as including the submission of merely "inaccurate" or merely "incomplete" claims. Millions of Medicaid claims are filed each year. Many of these claims routinely require a significant degree of back-and-forth between the provider and the agency to address various technical deficiencies or coding errors. The Medicaid agency already has a valid and appropriate mechanism for dealing with erroneous claims—namely, *denial* of those claims. The proposed rule, however, turns each error into an instance of "abuse," which could result in a provider's suspension or termination. This change has a sweeping and cost-intensive impact on providers and the regulated public. Even if it were the only change proposed for this rule, this paragraph alone would require republication of this rule.

Additionally, because of these rules' substantial economic impact, and because the rules are "not identical to a federal regulation that the agency is required to adopt," the APA requires a fiscal note approved by the Office of State Budget and Management. N.C. Gen. Stat. § 150B-21.4(b1). However, the agency did not follow those procedures in its proposed readoption of these rules.

The fiscal analysis is not only for the benefit of the regulated public. Medicaid is a federal-state program. Even though the two rules before the Commission go beyond federal requirements, the federal partner (CMS) can scrutinize the state agency's enforcement of these two rules and demand from DHHS a return of the federal matching funds for DHHS's failure to enforce these requirements. *See, e.g.*, HHS Office of Inspector General, *New York Claimed Federal Reimbursement for Some Assertive Community Treatment Services That Did Not Meet Medicaid Requirements* 6–7 (Oct. 2018). The seeming expansion of these Medicaid rules and their potential costs for both providers and the state warrant a fiscal analysis.

Because N.C. Gen. Stat. § 150B-21.4 is located in Part 2 of Article 2A, and because DHHS did not follow its requirements, the Commission should object to these rules. *See* N.C. Gen. Stat. § 150B-21.9(a)(4) (stating that "[t]he Commission must determine whether a rule . . . was adopted in accordance with Part 2 of this Article").

* * *

The proposed rules are not within the authority delegated to DHHS by the General Assembly. They contain language that is not clear or is ambiguous. They are not "reasonably necessary" to protect providers and beneficiaries or to further any lawful objective. These rules were not promulgated in substantial compliance with Part 2 of Article 2A of the APA, despite the substantive changes they contain. For all of the foregoing reasons, on behalf of our provider associations and our member Medicaid providers, we request that the Commission object to 10A NCAC 22F .0301 and 10A NCAC 22J .0106 as currently written by DHHS.

Sincerely,

Linwood Jones
North Carolina Healthcare Association
Senior Vice President & General Counsel

/s Chip Baggett

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Association for Home and Hospice Care of North Carolina
President and CEO

CC: Ryan Eppenberger, DHB Rulemaking Coordinator;
Joel Johnson, DHHS Assistant General Counsel

Provider Associations

The North Carolina Healthcare Association ("NCHA") is a statewide trade association representing 130 hospitals and health systems in North Carolina. The NCHA is an advocate before the General Assembly, the courts, and executive agencies on issues of interest to hospitals and the patients they serve. Virtually all of the NCHA's member hospitals participate in the Medicaid program.

The North Carolina Medical Society ("NCMS") is the largest physician organization in North Carolina, representing over 10,000 licensed physicians, physician assistants, medical interns and residents, medical students, and retired physicians. NCMS unifies doctors across North Carolina in all specialties and work settings on issues related to the physician-patient relationship, health and insurance regulation, and patient safety. More specifically, NCMS and its member physicians and physician assistants devote significant advocacy resources to promote the efficient and sustainable operation of North Carolina's Medicaid program.

The Association for Home and Hospice Care of North Carolina ("AHHC") is a comprehensive association, representing the full continuum of home care, private duty, companion-sitter, skilled home health care, hospice and palliative care (both outpatient and inpatient), and Program for All-inclusive Care for the Elderly ("PACE") providers. AHHC represents more than 825 licensed agencies serving patients in all 100 North Carolina counties.

Provider Compromise Proposal for 10A NCAC 22J .0106

10A NCAC 22J .0106 BILLING OF PATIENTS FOR MEDICAID-COVERED SERVICES

(a) When a patient has Medicaid coverage for the services provided to that patient, the provider may elect to forego Medicaid reimbursement and bill the patient for those services if the provider informs the patient that the provider will not bill Medicaid for those services but will instead charge the patient for those services.

(b) A provider may also bill a Medicaid recipient in the following situations:

(1) for allowable deductibles, co-insurance, or co-payments as specified in the Medicaid State Plan or federal law; or

(2) the patient is 65 years of age or older and is enrolled in the Medicare program at the time services are provided but has failed to supply a Medicare number as proof of coverage; or

(3) the patient is not eligible for Medicaid as defined in the Medicaid State Plan or is eligible only for Medicaid benefits that do not cover the types of services provided.

(c) If Medicaid does not pay a provider's claim because the billed service is determined not to be medically necessary in accordance with the Medicaid State Plan or applicable clinical coverage policy promulgated pursuant to G.S. 108A-54.2(b), the provider shall not bill the patient unless, before the service was provided, the provider informed the patient that the patient may be billed for services not paid by Medicaid due to lack of medical necessity.

(d) A provider that bills Medicaid for services covered and reimbursed by Medicaid agrees to accept Medicaid payment, plus any authorized deductible, co-insurance, co-payment, and third party payment, including workers' compensation, as payment in full for all Medicaid covered services provided. A provider shall not deny services to any Medicaid patient on account of the individual's inability to pay a deductible, co-insurance, or co-payment amount as specified in the Medicaid State Plan. An individual's inability to pay shall not eliminate his or her liability for the cost sharing charge. Notwithstanding anything contained in this paragraph, a provider may actively pursue recovery of third party funds that are primary to Medicaid.

(e) When a provider bills a patient for its services and the patient is later found to be eligible for Medicaid benefits that cover the services provided, the provider may seek reimbursement from Medicaid. Upon receipt of Medicaid reimbursement for those services, the provider shall refund to the patient all money paid by the patient for those services with the exception of any third party payments or cost sharing amounts as described in the Medicaid State Plan.

(f) Notwithstanding anything in this rule to the contrary, this rule applies only when services are provided to a patient whose Medicaid benefits cover the types of services provided. Nothing in this rule prohibits a provider from transmitting copies of bills or statements to a patient when requested by the patient or to assist the patient in obtaining or determining eligibility for Medicaid or other coverage or assistance. For purposes of this rule, the term "services" includes medical products.