May, Amber Cronk

From: Matthew Jordan Cochran <mjc@ocrlaw.com>
Sent: Thursday, September 13, 2018 5:56 PM
To: rrc.comments
Cc: May, Amber Cronk; Niehaus, Virginia
Subject: [External] Comments to Proposed Rules [32 N.C. Reg. 1258–68]

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Dear Rules Review Commission and Counsel:

Please accept this message as my preliminary comments/objections to 10A N.C.A.C. 22F.0301 and 10A N.C.A.C. 22J.0106. Thus far, it does not appear that any objection letter to the agency has been posted on the Commission's website despite the forthcoming objections indicated in the draft minutes from the August 16, 2018 meeting. In addition, I have neither received nor independently located any revised rules produced by the agency following that meeting. Therefore, my understanding is that no such revisions have been produced to date. I respectfully request that the Commission allow me to submit final comments once the agency has circulated revised rules.

I. What is "the authority delegated to the agency by the General Assembly"?

The Administrative Procedure Act ("APA") requires the Commission to determine whether a proposed rule "is within the authority delegated to the agency by the General Assembly." N.C.G.S. § 150B-21.9(a)(1). It is the APA—all of it, not just the four subparagraphs of section 150B-21.9(a)—that determines the outermost limit of what the Commission may regard as "the authority delegated to the agency." If the APA expressly prohibits a certain type of regulatory provision, then administrative agencies do not have statutory authority to adopt that type of provision. A proposed 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 regulatory feature.

In the context of the two rules proposed by the NCDHHS's Division of Health Benefits ("DHB"), formerly the Division of Medical Assistance ("DMA"), 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. Over the past several months, the agency has referred the Commission to N.C.G.S. § 108A-54.1B, insisting that its language authorizes numerous objectionable rules. It does not. Here is the relevant language of that statute:

> The Department is expressly authorized to adopt temporary and permanent rules to implement or define the federal laws and regulations, the North Carolina State Plan of Medical Assistance, and the North Carolina State Plan of the Health Insurance Program for Children, the terms and conditions of eligibility for applicants and recipients of the Medical Assistance Program and the Health Insurance Program for Children, audits and program integrity, the services, goods, supplies, or merchandise made available to recipients of the Medical Assistance Program and the Health Insurance Program for Children, and reimbursement for the services, goods, supplies, or merchandise made available to recipients of the Medical Assistance Program and the Health Insurance Program for Children.

N.C.G.S. § 108A-54.1B(a). Before accepting 108A-54.1B as a panacea for the overreaches DHB seeks to enshrine in the Administrative Code, the Commission should observe what that statute says and what it does not say. Moreover, that statute is only part of the equation. 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.

First I will take the liberty of restating N.C.G.S. § 108A-54.1B(a) so as to make its meaning clearer. Here is my gently paraphrased version of its text:

> The Department is expressly authorized to adopt temporary and permanent rules [for these purposes:]
> (1) to implement [applicable] federal laws and regulations;
> (2) to implement the North Carolina State Plan of Medical Assistance;
> (3) to implement the North Carolina State Plan of the Health Insurance Program for Children;
> (4) to define the terms and conditions of eligibility for applicants and recipients of the Medical Assistance Program and the Health Insurance Program for Children;
> (5) to define and implement [the Department's] audit and program integrity [functions];
> (6) to define the services, goods, supplies, or merchandise made available to recipients of the Medical Assistance Program and the Health Insurance Program for Children; and
> (7) to implement reimbursement for the services, goods, supplies, or merchandise made available to recipients of the Medical Assistance Program and the Health Insurance Program for Children.

This language merely provides the agency with the *general* authority to adopt regulations relevant to the programs overseen by the Department. Despite what the first clause of the subparagraph might suggest, state administrative agencies cannot "*define* . . . federal

laws and regulations." That is impossible both factually and legally. It would be contrary to widely accepted canons of construction to give this statute such an absurd meaning. *See, e.g.*, *Hobbs v. Moore Cty.*, 267 N.C. 665, 671, 149 S.E.2d 1, 5 (1966) ("If possible, the language of a statute will be interpreted so as to avoid an absurd consequence. A statute is never to be construed so as to require an impossibility if that result can be avoided by another fair and reasonable construction of its terms."). So the statute's wording does not (and could not) empower the state's Medicaid agency to "define" federal laws and regulations.

Nor does this general enabling statute authorize the agency to adopt rules that conflict with the APA. It contains no language that would render the APA inapplicable (e.g., "notwithstanding anything in the Administrative Procedure Act to the contrary, the Department may adopt whatever rules it wants"). As a result, it is also necessary to consider the APA itself and the limitations it imposes on the rulemaking process both procedurally and substantively. There are many such provisions in the APA, but this message will focus on a handful that are relevant to the rules proposed by DHB.

The first pertinent curtailment of agency authority put in place by the General Assembly reads as follows:

> An agency may not adopt 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.G.S. § 150B-19(3) (emphasis added). By this provision General Assembly has prohibited the agency from creating penalties for actions that are not already penalized by law. The agency cannot use a rule to reclassify otherwise innocent or inoffensive actions so as to penalize the person committing those actions unless there is a law "specifically authoriz[ing] the agency to do so." *Id.* Therefore, N.C.G.S. § 150B-19(3) informs us that an agency's imposition of penalties for otherwise lawful conduct is specifically *not* "within the authority delegated to the agency by the General Assembly" for purposes of N.C.G.S § 150B-21.9(a)(1).

An additional restriction the General Assembly has placed on agency authority is found in N.C.G.S. § 150B-21.6, which prohibits DMA from incorporating unpromulgated materials into its rules by reference unless certain conditions are met:

> An agency may incorporate the following material by reference in a rule without repeating the text of the referenced material:
> (1) Another rule or part of a rule adopted by the agency.
> (2) All or part of a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association.

N.C.G.S. § 150B-21.6. This provision exists to ensure that any materials to which the agency seeks subject the regulated public were already enacted by a legislature or subjected to rulemaking procedures and requirements like those embedded in the APA. Any proposed rule that seeks to govern the public through provisions that are themselves neither enacted or formally promulgated violates the above-referenced statute and thus cannot be considered "within the authority delegated to the agency by the General Assembly" as required by N.C.G.S § 150B-21.9(a)(1).

A similar, more general restriction on the scope of agency authority states as follows:

> This Article [2A of Chapter 150B] applies to an agency's exercise of its authority to adopt a rule. A rule is not valid unless it is adopted in substantial compliance with this Article. An agency shall not seek to implement or enforce against any person a policy, guideline, or other interpretive statement that meets the definition of a rule contained in G.S. 150B-2(8a) if the policy, guideline, or other interpretive statement has not been adopted as a rule in accordance with this Article.

N.C.G.S. § 150B-18. This statute prohibits agencies from seeking to implement or enforce anything that "has not been adopted as a rule in accordance with . . . Article [2A]." *Id.* A proposed rule that attempts to enforce unpromulgated guidelines or other extraneous materials against the public is quite obviously *not* "within the authority delegated to the agency by the General Assembly." N.C.G.S § 150B-21.9(a)(1).

In addition, the General Assembly has forbidden the agency to adopt any rule that "[a]llows the agency to waive or modify a requirement set in a rule unless a rule establishes specific guidelines the agency must follow in determining whether to waive or modify the requirement." N.C.G.S. § 150B-19(6). Any proposed rule that arrogates to agency the power to act in its absolute, unguided discretion in enforcing that rule is therefore outside of the authority delegated to that agency by the General Assembly for purposes of N.C.G.S § 150B-21.9(a)(1).

For the convenience of the reader, rather than setting forth these principles repeatedly, the remainder of this message will refer back to the above discussion to the extent N.C.G.S § 150B-21.9(a)(1) is applied in scrutinizing DHB's proposed rules.

II. 10A N.C.A.C. 22F.0301

Many of the objectionable features of 10A N.C.A.C. 22F.0301 have been explained in prior comments including those I distributed to the Commission during its August 16, 2018 meeting—which comments are incorporated by reference in this message as if completely set forth. I therefore first refer the Commission to those written comments for an overview of the specific defects involved. The agency asserts (i) that N.C.G.S. § 108A-54.1B authorizes it to define "abuse" as broadly as it wishes and (ii) that the agency is powerless to police the Medicaid program unless each and every error by a provider constitutes "abuse." Neither is true.

A. Statutory authority

Although N.C.G.S. § 108A-54.1B does permit the agency to "adopt temporary and permanent rules" for various purposes including the policing of Medicaid providers through "audit and program integrity [functions]," the statue does not override the provisions of the APA. As explained below, the rule does not comply with many of the APA's restrictions on agency authority and therefore is *not* "within the authority delegated . . . by the General Assembly" for purposes of N.C.G.S § 150B-21.9(a)(1).

The overbroad provisions of 10A N.C.A.C. 22F.0301 transgress the boundaries imposed on agency authority by N.C.G.S. § 150B-19(3) by bringing within the definition of "abuse" an innumerable host of possible infractions or errors for which the law does not impose any criminal liability or civil penalty. The question of whether a provider's conduct constitutes "abuse" is consequential because abuse (if found to have occurred) negatively impacts the provider's participation in the Medicaid program. As a result, the applicable federal Medicaid regulation is quite focused in its scope, defining 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 (emphasis added). In contrast, the proposed rule takes no interest in whether the provider's conduct is intentional versus merely accidental, or repeated versus incidental and isolated. Nor does the rule contemplate whether the provider's conduct actually "result[s] in unnecessary cost to the Medicaid program"—or *any* cost to the Medicaid program, for that matter.

For example, 10A N.C.A.C. 22F.0301(5) broadly penalizes providers who default on any number of ministerial requirements contained in their Provider Administrative Participation Agreement (or "PAPA"). It is useful to review the generic PAPA presented on the NCTracks website. *See* NCDHHS Provider Administrative Participation Agreement (Jul. 1, 2013), http://bit.ly/2CQNBeE. Here are a couple of examples of the sorts of things that constitute breach of such an agreement:

- PAPA ¶ 4.b. – The provider's failure to notify the agency of "any adverse action initiated against any required license . . . of its officers, agents, or employees" within 30 calendar days.
- PAPA ¶ 6.a.iv. – The provider's failure to notify the agency in writing of "any change in address, telephone number, or email" within 30 calendar days.

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 hospital fails to notify DMA of this promptly after learning about it, it has breached "the terms and conditions" of the PAPA within the meaning of 10A N.C.A.C. 22F.0301(5). Similarly, suppose a longtime Medicaid provider merges with another company, 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 doesn't timely notify the agency, the provider has again breached "the terms and conditions" of the PAPA for purposes of this proposed rule.

While the PAPA's various requirements may serve some useful function, not all conduct that incidentally violates that agreement is subject to criminal liability or civil penalty under existing law. No "law" states that the failure to provide the above-described notices "is a criminal offense or is grounds for a civil penalty." N.C.G.S. § 150B-19(3). Even the federal regulation on point would not countenance adverse action against a provider for such oversights, as they cause neither "unnecessary cost to the Medicaid program" nor reimbursement for unnecessary or sub-standard services. 42 C.F.R. § 455.2. As a result, the agency is not permitted to impose a penalty on a provider for such "act[s] or omission[s]." And let there be no mistake: the proposed rule *does* impose a "civil penalty" within the meaning of N.C.G.S. § 150B-19(3). This is because abuse triggers a host of adverse actions against the provider that can include suspension of payments, pre-payment review of claims, and other penalizations. *See* 10A N.C.A.C. 22F.0602.

Paragraph (5) of the proposed rule is also outside the authority delegated by the General Assembly due to the restrictions placed on that authority by N.C.G.S. § 150B-21.6. The PAPA is neither a rule adopted by DHB, *id.* § 150B-21.6(1), nor a "code, standard, or regulation" adopted by another agency. *Id.* § 150B-21.6(2). In fact, it is not "adopted" at all as that term is defined in N.C.G.S. § 150B-2(1b). Moreover, the PAPA has not been subjected to review pursuant to the APA. DHB's attempt to enforce the PAPA's terms and conditions against the regulated public exceeds the limitations imposed by N.C.G.S. § 150B-21.6. Similarly, the proposed rule's attempt to ascribe the force of law to the PAPA violates N.C.G.S. § 150B-18, which prohibits the agency from seeking to implement or enforce anything that "has not been adopted as a rule in accordance with . . . Article [2A of the APA]."

Finally, to the extent that the word "includes" (appearing at the end of the rule's introductory paragraph) is intended by DHB to signal a *non-exclusive* list, the rule violates N.C.G.S. § 150B-19(6). That statute prohibits rules that depend upon unguided agency discretion for their interpretation and enforcement. A proposed rule that attempt to define "abuse" using an open-ended list is logically incapable of satisfying N.C.G.S. § 150B-19(6) and is therefore outside of the agency's authority.

For the foregoing reasons, 10A N.C.A.C. 22F.0301 as proposed by DHB quite clearly fails the statutory authority requirement imposed by N.C.G.S § 150B-21.9(a)(1) and should not be approved by the Commission.

B. Clarity and unambiguity

DHB's proposed rule includes, within the definition of "abuse," the "failure to comply with requirements of certification." 10A N.C.A.C. 22F.0301(5). This phrase is unclear, ambiguous, and overbroad, violating N.C.G.S § 150B-21.9(a)(2).

Does the phrase refer, for example, to the requirements for *board* certification available to physicians in various fields of specialization? If so, the rule exceeds DHB's authority as restricted by N.C.G.S. § 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. To date, however, despite repeated comments challenging this phrase's meaning and validity, neither the DHB advocates who have appeared before the Commission nor any other agency representative has provided an explanation of what the "requirements of certification" are, exactly.

To see just how objectionable the proposed rule is in this regard, 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, surely the phrase “requirements of certification” is also unclear or ambiguous (or both). Until DHB eliminates this language or provides wording that makes its meaning clearer, 10A N.C.A.C. 22F.0301 will remain objectionable under N.C.G.S § 150B-21.9(a)(2).

III. 10A N.C.A.C. 22J.0106

The objectionable aspects of 10A N.C.A.C. 22J.0102 have been explained in prior written comments including those I distributed to the Commission during its August 16, 2018 meeting. Again, I would refer the Commission to those comments (all of which I hereby incorporate by reference into this message) for an overview of the specific objections. In short, this proposed rule serves to penalize providers who erroneously submit a claim to Medicaid for services provided either (i) to patients whose Medicaid coverage does not extend to those services, such as those with only “Family Planning,” or (ii) to patients who are eligible for full Medicaid but whose services are not covered due to lack of medical necessity.

This rule’s attempt to bar providers from billing patients for services not covered by Medicaid is not authorized by N.C.G.S. § 108A-54.1B(a). Nor is that aspect of the rule required in order to comply with federal law or regulation. Furthermore, N.C.G.S. § 150B-19(3) prohibits this rule for the reasons discussed above. DHB cannot prohibit and thereby penalize conduct not barred by law. 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. This proposed rule cannot possibly satisfy the standard set forth in N.C.G.S § 150B-21.9(a)(1) and remains objectionable.

Thank you for your attention to these issues.

Sincerely,
Matthew

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September 13, 2018

Ms. Amber Cronk May
North Carolina Rules Review Commission
Raleigh, North Carolina

Re: 10A NCAC 22J.0106
10A NCAC 22F.0301

Submitted by email: rrc.comments@oah.nc.gov

Dear Ms. May:

On behalf of the North Carolina Healthcare Association (NCHA), please find our comments objecting to the revisions to the following two rules: 10A NCAC 22J.0106 and 10A NCAC 22F.0301. NCHA represents 130 hospitals and health systems in this State, including 26 critical access hospitals and numerous safety net hospitals.

NCHA understands and acknowledges the need in 10A NCAC 22J.0106 to inform Medicaid patients in advance if the provider does not accept the patient as a Medicaid patient and therefore will bill the patient in lieu of billing Medicaid. However, the proposed revisions to the rule go beyond this and put hospitals at risk for not being able to bill the patient due to an inadvertent billing error. It is our understanding that the Division of Health Benefits interprets the rule to prohibit providers from billing a patient who has no Medicaid coverage for the services provided if the patient meets the definition of “a patient accepted as a Medicaid patient.” Under subsection (b), it appears that providers are deemed to have accepted the patient as a Medicaid patient if they file a claim with Medicaid for the services provided.

Providers in North Carolina saw 46 million visits from Medicaid patients last year. A significant number of Medicaid patients coming to the hospital (nearly one out of every 8 beneficiaries) have limited coverage – just for family planning services, not actual Medicaid coverage. However, these patients have been issued a Medicaid ID card and present to the hospital with that card. The resulting confusion for hospital registration personnel and billing systems sometimes leads to hospitals billing the Medicaid program inadvertently. These patients are typically uninsured and will likely fall under the hospital’s charity or financial assistance policy. Nevertheless, the patient may still be responsible for some portion of the bill. The hospital should be able to properly bill these patients for the services provided when Medicaid has determined there is no actual Medicaid coverage for these services. The same is true when Medicaid is inadvertently billed for a patient covered under Medicaid but whose treatment or procedure was not covered by Medicaid.

We are aware of no prohibition under federal Medicaid law requiring states to prohibit providers from properly billing the patient in the above situations. We also see no basis of authority for the Division to prohibit patient billing in these limited situations where Medicaid does not cover the patient or the service. Because this rule is not authorized by federal or state law, it is objectionable under N.C.G.S. § 150B-21.9(a)(1) and should not be approved.

Rule 10A NCAC 22F.0301 revises the definition of abuse in the Provider Abuse section of the rules. NCHA supports a strong Medicaid fraud and abuse program to ensure program integrity. However, rules regarding fraud and abuse, including the definition of what constitutes abuse, must be clear and fairly applied. It is unclear from the rule's wording ("Program abuse by providers as used in this Chapter *includes*:") whether the list of 8 areas constituting abuse is exhaustive or a list of examples. Our understanding is that the Department and the Attorney General have the latter interpretation. This broad interpretation leaves too much discretion for the agency to decide what actions constitute abuse, particularly given that civil or criminal penalties may be applied to conduct labeled as abuse. Providers should have fair notice of what conduct the Department considers abusive and subject to penalties. The rule should be revised, at a minimum, to state one of the following:

- Program abuse by providers as used in this Chapter *includes only:*
- Program abuse by providers *means:*[1]
- Program abuse by providers *includes the practices specifically enumerated in this section:*[2]

In addition, item 5 on the list of practices that the Division may determine constitutes abuse is "violation of the Provider Participation Agreement." NCHA has worked with the Department of Health and Human Services and the Attorney General's Office in the past on the wording of the Provider Participation Agreement. The Agreement is broad and covers a number of requirements, including such issues as the time limit on filing a claim and reporting changes in a provider's phone number to the Department. In incorporating the proposed Rule by reference and providing no qualifying materiality standard, the rule potentially subjects providers to discretionary determinations that minor issues and issues not impacting Medicaid program integrity are abusive, thereby invoking potential penalties against providers. Again, providers need fair notice of what the Department considers abuse.

NCHA believes the overbreadth of 10A N.C.A.C. 22F.0301 is not authorized by federal law and is beyond any authority delegated to the agency by the General Assembly, making it objectionable under N.C.G.S. § 150B-21.9(a)(1). In addition, this rule is objectionable under N.C.G.S. § 150B-21.9(a)(2) because it is not "clear and unambiguous" given its open-ended nature.

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[1] See, for example, the federal definition of abuse for Medicaid: 42 CFR 455.2 ("Abuse *means* provider practices…")

[2] See, for example, NY State Medicaid regulations, Title 18, sec. 515.2 ("An unacceptable practice is conduct which constitutes fraud or abuse and *includes the practices specifically enumerated in this subdivision*:

For these reasons, NCHA respectfully objects to the above two rules.

With best regards,

Linwood Jones
Senior Vice President and General Counsel

cc: Ms. Virginia Niehaus, DHB Rulemaking Coordinator
(virginia.niehaus@dhhs.nc.gov)