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10A NCAC Reference	Summary	Description of Concerns	Statutory Grounds for Objection
22F.0301	[2] The rule states that provider abuse "includes" various things. This language could be interpreted as giving DMA unlimited authority to characterize a provider's conduct as abuse even if that conduct is not actually described in the	[1] This rule in general goes far beyond the federal definitions of "abuse" in 42 C.F.R. § 455.2. DMA's expansion of the definition violates N.C.G.S. § 150B-19(3) because it serves to "[i]mpose[] criminal liability or a civil penalty for an act or omission, including the violation of a rule," without there being "a law specifically authoriz[ing] the agency to do so." <i>Abuse</i> is a term of art that, if found to have occurred, can trigger "lock-out" of the provider from participation in the Medicaid program under 42 C.F.R. § 431.54(f). DMA cannot simply characterize anything it finds distasteful as "abuse," as this constitutes the imposition of a penalty for conduct that is not penalized under federal or state law. [2] The rule is (at best) not clear, and depending on how an ambiguity is resolved, it may violate statutory limitations on the scope of DMA's power to create penalties. The rule's leading sentence states that provider abuse "includes" the items listed in its various subparagraphs. This language could be interpreted as giving DMA unlimited authority to characterize a provider's conduct as abuse even if that conduct is not actually described in the rule. In other words, the risk is that readers will construe the word "includes" as "includes <u>but is not limited to.</u> " If this language were to be interpreted as saying abuse "includes <u>only</u> " the types of conduct listed, the ambiguity would be resolved. However, without language making that limitation obvious, the rule is unlawful because (i) it gives DMA unchecked discretion over what constitutes "abuse," thus exceeding DMA's statutory authority and breaching the limitations imposed by N.C.G.S. § 150B-21.9(a)(2).	"expressly authorized by federal or State law." N.C.G.S. § 150B-19.1(a)(1). The rule "[i]mposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, [without] a
22F.0301(3)	including, within the definition of "provider abuse," the act of billing for services provided by someone who "does not meet the requirements set out	[1] N.C.G.S. § 108A-54.2, which governs Clinical Coverage Policies ("CCPs"), was amended years ago to ensure that CCPs are only given the effect of rules with respect to assessment of conditions. The statute does not permit DMA to embed training requirements or additional provider qualifications into CCPs and have such requirements regarded as rules. Because N.C.G.S. § 150B-21.6 prohibits DMA from incorporating unpromulgated materials into its rules by reference, paragraph (3) is unlawful. The CCPs are neither a rule adopted by DMA, id. § 150B-21.6(1), nor a "code, standard, or regulation" adopted by another agency. Id. § 150B-21.6(2). See also id. § 150B-18 (prohibiting the enforcement of agency directives that are neither promulgated as a rule nor within the exceptions to rulemaking). [2] In addition, the paragraph remains dramatically overbroad. In a hospital setting, for example, a wide array of Medicaid-covered services may be provided by dozens of different physicians and other practitioners. If it so happens that one of those physicians has not yet completed the enrollment or credentialing process, the innocent filing of a claim for the hospital services could be rendered "fraudulent" or "abusive" by the proposed language. Among other reasons, this is because the phrase "person who does not meet the requirements set out in the Medicaid State Plan or Clinical Coverage Policies" does not recognize the intentionality elements of the federal definitions.	law." N.C.G.S. § 150B-19.1(a)(1). Is not "necessary to serve the public interest."

the requirement." N.C.G.S. § 150B-19(6).

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22F.0301(4)	[1] The language of this paragraph is impermissibly vague. [2] DMA exceeds its authority by including, within the definition of "provider abuse," the failure to observe "accepted medical standards for the community," which are not set forth in law or rule and thus unable to serve as the basis for any regulatory penalty.	[1] This paragraph lists, as a form of abuse, "failure to provide and maintain within accepted medical standards for the community, as set out in 10A NCAC 25A .0201, including (a) quality of care; or (b) medically necessary care and services." This language is missing something—e.g., a direct object. In other words, what must the provide and maintain"? Subparagraphs (a) and (b) do not resolve that issue. This subparagraph is thus objectionable as unclear and/or ambiguous. [2] Unfortunately, the rule referenced in this paragraph (10A NCAC 25A.0201) does not "set out" any "accepted medical standards for the community." It simply says, "[m]edical necessity is determined by generally accepted North Carolina community practice standards as verified by independent Medicaid consultants." It is clear that these "community practice standards" are not "adopted" as that term is defined by N.C.G.S. § 150B-2(1b). As a result, paragraph (4) is impermissible because it attempts impose standards that are neither enacted as law or adopted as rule, thus violating N.C.G.S. § 150B-21.6(2) as well as N.C.G.S. § 150B-19(3).	Is not "within the authority delegated to the agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not "expressly authorized by federal or State
22F.0301(5)	participation agreement. [2] DMA includes, within the definition of "provider abuse," the "failure to comply	[1] DMA's reference to the "Provider Administrative Participation Agreements" is clearly unlawful. N.C.G.S. § 150B-21.6 prohibits DMA from incorporating these sorts of unpromulgated materials into its rules by reference. The agreements are neither a rule adopted by DMA, <i>id.</i> § 150B-21.6(1), nor a "code, standard, or regulation" adopted by another agency. <i>Id.</i> § 150B-21.6(2). In fact, they are not "adopted" at all as that term is defined in N.C.G.S. § 150B-2(1b). The rule's attempt to ascribe the force of law to the provider agreement thus also violates N.C.G.S. 150B-18, f which prohibits the agency from seeking to implement or enforce anything that "has not been adopted as a rule in accordance with this Article [2A]." Moreover, the agreements themselves can and should govern the consequences of their breach. [2] The concept of "requirements of certification" is not defined and is impermissibly ambiguous and unclear. Moreover, it is an overreach to characterize as abusive any failure to "comply" with one of the vast host of such "requirements" regardless of whether that failure would also fall within the actual federal definition of "abuse" in 42 C.F.R. § 455.2. Every administrative slip-up is not "abuse."	Is not "within the authority delegated to the agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not "expressly authorized by federal or State law." N.C.G.S. § 150B-19.1(a)(1). Agency has not "[sought] to reduce the burden upon those who must comply with the rule." N.C.G.S. § 150B-19.1(a)(2). Does not comply with N.C.G.S. Chapter 150B, Article 2A, Part 2. N.C.G.S. §§ 150B-21.2(a), -21.9(a)(4). Is not "clear and unambiguous," N.C.G.S. § 150B-21.9(a)(2), and "[a]llows the agency to waive or modify a requirement set in a rule [without] a rule establish[ing] specific guidelines the agency must follow in determining whether to waive or modify

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22F.0302(c)	DMA exceeds its statutory and regulatory authority by seeking to suspend or terminate a provider upon a determination that "provider abuse" has occurred.	The final sentence of paragraph (c) exceeds DMA's authority by indicating that one or more of the "administrative actions" listed in 10A N.C.A.C. 22F.0602 can be triggered by a finding of abuse. Unfortunately, the referenced rule recites forms of action that are not permitted in the context of mere abuse, including suspension of the provider pursuant to 42 C.F.R. § 455.23. [See comments contained in this document concerning the proposed 10A N.C.A.C. 22F.0602.] The federal regulations cited following this rule's text do not support suspension or termination of a provider except as follows: (i) a credible allegation of fraud under 42 C.F.R. § 455.23; (ii) the provider's making of false statements or certain incomplete statements when applying to enroll per 42 C.F.R. § 455.416; and (iii) the provider's failure to make certain disclosures under 42 C.F.R. § 455.106. None of these concerns mere "abuse." The other federal regulations cited in the History Note simply have nothing to do with suspension or termination of a provider. In addition, the North Carolina statutes cited do not support suspension or termination in "abuse" situations at all. Moreover, N.C.G.S. § 108C-5 only authorizes payment suspensions for two situations: (i) provider fraud as defined by 42 C.F.R. § 455.23, and (ii) recoupment of an unpaid overpayment that has become final. Neither is triggered by mere "abuse."	interpret an enactment of the General Assembly, or of Congress, or a regulation
22F.0602(a)	The paragraph would grant DMA unfettered discretion regarding whether and when to impose penalties or other actions on a provider. Its language is not clear and is ambiguous, and it serves to expand DMA's powers to an unlawful extent.	[1] Paragraph (a) of the rule states that DMA "may" impose various "administrative actions" against providers. Unfortunately, the word "may" arrogates to DMA the power to act in its absolute, unguided discretion. [2] This paragraph also indicates DMA can impose these actions "in any particular order." This results in an unclear and ambiguous rule. For instance, can DMA terminate someone and <i>then</i> suspend them? Can DMA issue a warning letter followed immediately (without further warning) by placement of the provider on "prepayment review"? The current wording of this rule would, for example, allow DMA to "negotiat[e] a financial settlement with the provider" only to proceed immediately thereafter with suspension of that provider notwithstanding the settlement. The net effect of this design is lack of clarity and the elevation of DMA's authority and discretion to a level exceeding that which it is granted by law.	a rule establish[ing] specific guidelines the agency must follow in determining whether to waive or modify the requirement." N.C.G.S. § 150B-19(6). Is not "within the authority delegated to the agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not "expressly authorized by federal or State
22F.0602(a)(2)	provider as an "administrative action" to be taken by DMA in cases of program abuse. It is either redundant and thus	Presumably the authority for this subparagraph is 42 C.F.R. § 431.54(f). However, if that is the case, these suspension provisions are duplicative of those contained the "provider lock-out" rule at 10A NCAC 22F.0603. This renders the subparagraph objectionable as redundant and likely to create confusion. There does not appear to be any separate authority for imposing such a sanction in a mere "abuse" case. 42 C.F.R. § 455.23 does not permit suspension of the provider except in situations of <i>fraud</i> . Meanwhile, 42 C.F.R. § 1002.3 authorizes agencies to take the same actions against a provider that the CMS Secretary could take to "exclude" a provider pursuant to 42 U.S.C. §§ 1320a-7, 1320a-7a, or 1395cc(b)(2). Those sections of the Social Security Act, however, do not give the agency <i>carte blanche</i> to exclude providers in a manner inconsistent with the specific protocol set forth in 42 C.F.R. § 455.23 (suspension due to credible allegation of fraud) and 42 C.F.R. § 431.54(f) (provider lock-out in cases of abuse). As for N.C.G.S. § 108C-5, the statute only authorizes payment suspensions for two situations: (i) provider fraud, with specific reference to the federal rule just mentioned; and (ii) recoupment of an unpaid overpayment that has become final. Neither of those is triggered by mere "abuse."	Is not "within the authority delegated to the agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not

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22F.0602(a)(3)	an "administrative action" to be taken by DMA in cases of program abuse. This is	This subparagraph is objectionable because other rules (10A N.C.A.C. 22F.0302) indicate that DMA can impose this form of administrative action in the context of a determination of "program abuse." The administrative action listed in this subparagraph is termination. But in the context of provider abuse, applicable federal rules at 42 C.F.R. § 431.54(f) only authorize the agency to "restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time." However, by its own terms, subparagraph (a)(3) of this proposed rule imposes what is in effect a <i>permanent</i> restriction—that is, an indefinite termination. That is not compatible with the "reasonable period of time" language in the federal rule. Lacking some other source of authority for terminating providers in cases of mere "abuse," this subparagraph remains objectionable as exceeding statutory authority.	, ,
22J.0106	In seeking to adopt this rule, DMA did not comply with the APA's fiscal note requirements or its federal law certification requirements.	[Background] Recent developments have given this rule drastic reach. What brings this problem to the forefront is the surge in the number of patients enrolled in the virtually useless "Family Planning" (FP) Medicaid coverage category. The ACA's expansions of FP coverage have resulted in DMA awarding FP to nearly everyone who applies for but is found ineligible for <i>full</i> Medicaid—from infants to octogenarians. As of July of 2018, over 271,000 of the state's 2.06 million Medicaid enrollees (13.1%) are eligible only for FP. See NCDHHS, Medicaid Enrollment by County and Program Aid Category, https://labsoft.co/2vOL9OR . Despite its proliferation, FP only covers a very narrow selection of services. In most respects it is Medicaid in name only; it certainly dose not cover acute inpatient hospital services. Nevertheless, DMA issues a "Medicaid card" to FP recipients, which is then presented to providers of the ability to bill uninsured patients for services that are not covered by those patients' limited Medicaid benefits under the Family Planning eligibility category, and (2) compliance with the rule's provisions in an attempt to preserve the ability to bill uninsured patients will cost North Carolina Medicaid providers in excess of \$1 million dollars in the aggregate. Because of its substantial economic impact, and because the rule "is not identical to a federal regulation that the agency is required to adopt." N.C.G.S. § 150B-21.4(b1) requires a fiscal note approved by the Office of State Budget and Management ("OSBM"). However, the agency did not follow those procedures in its proposed readoption of this rule. Because section 150B-21.4 is located in Part 2 of Article 2A, and because DMA did not follow tis requirements, the Commission must determine whether a rule was adopted in accordance with N.C.G.S. § 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"). [2] DMA did not accurately r	21.9(a)(4).

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22J.0106(a)	The rule as DMA proposes to revise it involves substantive changes and should be required to be published in the N.C. Register for public review and comment.	The N.C. Register pages published in January 2018 noted that this rule was being "readopted without substantive changes." It did not include the text of the rule. The language most recently added to paragraph (a) discusses situations in which providers can be exempt from the obligation to forewarn a patient that they are not Medicaid-eligible for the service being provided. However, this is a <i>substantive</i> change because it refers to medical/clinical criteria as the threshold for determining the availability of that exemption. The provider community should have the opportunity to review the text of the proposed/revised rule and offer additional comment. This commenter has only been in possession of the revised language of this rule since 7/23/2018, when it was forwarded by DMA's Rulemaking Coordinator. In addition, as of the rewriting of this comment on 8/13/2018, the revised language has not been posted on DMA's website (https://medicaid.ncdhhs.gov/get-involved/rules-actions).	Was not "adopted in accordance with Part 2 of [Article 2A of the Administrative Procedure Act]." N.C.G.S. § 150B-21.9(a)(4).
22J.0106(a), (b)	The language of this rule is conflicting and/or unclear as concerns "refusing" and "accepting" a patient as a Medicaid patient.	Paragraph (a) of this rule 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 a patient as a Medicaid patient" if the provider submits a claim to Medicaid for the services provided. This is contradictory or, at best, unclear. Moreover, it fails to consider the practical realities associated with provider billing. Although provider staff interviewing a patient might understand the limitations of FP Medicaid coverage and even annotate the provider's record-keeping system with a remark explaining that the individual has "FP only," downstream billing systems are unlikely to see these notes and may fail to detect the false positive in NCTracks that occurs when checking Medicaid eligibility for a "FP-only" recipient.	Is not "clear and unambiguous." N.C.G.S. § 150B-21.9(a)(2). Agency has not "[sought] to reduce the burden upon those who must comply with the rule." N.C.G.S. § 150B-19.1(a)(2 Does not comply with N.C.G.S. Chapter 150B, Article 2A, Part 2. N.C.G.S. §§ 150 21.2(a), -21.9(a)(4).

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called Medicaid recipients for services rendered that were not and are not actually covered by Medicaid.

means to "bill" the patient. This latent ambiguity is significant because many health systems issue statements of charges to their patients for other reasons.

[1] DMA imposes unlawful conditions on [1] The prohibitions imposed by paragraph (c) are without any authority in state or federal law. Among the authorities Is not "within the authority delegated to the when and whether providers can bill so-cited in the History Note is 42 C.F.R. § 447.15. But this federal regulation does not provide the authority needed by DMA, as it only says the State Plan must limit participation to providers "who accept, as payment in full, the amounts paid by the [Medicaid] agency" (emphasis added). If a patient is enrolled in a restrictive Medicaid eligibility category like FP that clearly does not cover the provider's services, nothing will be "paid by" the agency, 42 C.F.R. § 447.52(e) does not authorize the offending restrictions, either, as it merely governs cost-sharing maximums and [2] The rule does not make clear what it related details. The same is true for 42 C.F.R. § 433.139, which only addresses the state's payment of Medicaid claims in the context of third-party liability. In addition, N.C.G.S. § 108A-54.1, upon which DMA 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 DMA can determine "the terms and conditions of eligibility for applicants and recipients." (Emphasis added). In short, there is no state or federal authority for requiring a provider to "forewarn" a patient that their coverage categorically will not and cannot pay for the services in question. Moreover, the provider should be able to bill the patient regardless of when it discovers there is no actual Medicaid coverage for the services rendered. for a civil penalty." N.C.G.S. § 150B-19(3). Under the rule as drafted, the provider violates state regulations with only a single instance in which they treat a "FPonly" patient, erroneously bill Medicaid for the non-covered services, and then bill the uninsured patient directly. There is no authority for penalizing a provider that bills the patient in that situation. This rule thus violates N.C.G.S. § \$150B-21.9(a)(2). 150B-21.9(a)(1) as well as N.C.G.S. § 150B-19(3) ("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"). No statutory or public policy objective is furthered by this subparagraph.

> [2] The language of paragraph (c) is unclear and/or ambiguous because the act of "billing" is not defined. This is problematic because, depending on how DMA 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 N.C.A.C. 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 the rule in question does not distinguish between the Bill of Rights scenario and others in which the hospital bill is provided to the patient. In addition, 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. In addition, 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 DMA from unlawfully penalizing a provider for issuing a bill or statement of charges to patients in these sorts of situations. It is thus impermissibly vaque.

agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not "expressly authorized by federal or State law." N.C.G.S. § 150B-19.1(a)(1).

The rule "filmposes criminal liability or a civil penalty for an act or omission. including the violation of a rule, [without] a law specifically authoriz[ing] the agency to do so or a law declarfing that violation of the rule is a criminal offense or is grounds

Is not "clear and unambiguous." N.C.G.S.

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22J.0106(c)(4)	This subparagraph provides an exception to the general "do not bill a Medicaid recipient" rule, but the language is either impermissibly restrictive or vague (or both).	[See description of concerns for 10A N.C.A.C. 22J.0106(c)(2).] Regardless of whether any of paragraph (c) is retained, subparagraph (c)(4) must be revised to reflect the reality of timing considerations. The concept of "no longer eligible for Medicaid" is unworkably burdensome from a provider perspective for persons who are technically eligible for "Medicaid" but who are not eligible for coverage of the services being provided—as is the case for persons who are found only to have Family Planning coverage despite presenting a "Medicaid" card. And in any case, the conditions imposed by this subparagraph are not based on any federal or state law.	Is not "within the authority delegated to the agency by the General Assembly," N.C.G.S. § 150B-21.9(a)(1), and is not "expressly authorized by federal or State law." N.C.G.S. § 150B-19.1(a)(1). The rule "[i]mposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, [without] a law specifically authoriz[ing] the agency to do so or a law declar[ing] that violation of the rule is a criminal offense or is grounds for a civil penalty." N.C.G.S. § 150B-19(3). Is not "clear and unambiguous." N.C.G.S. § 150B-21.9(a)(2).