## Federal and State Regulatory Changes in Response to COVID-19

CMS		
Comprehensive List of Resources regarding CMS Waivers and Flexibilities		
ACTION	SOURCES & RESOURCES	
NC 1135 Waiver:	NC 1135 Waiver	
NC Medicaid requested these flexibilities from CMS on March 17, 2020. CMS		
responded on March 23, 2020, allowing additional waivers designed to address areas		
not covered by the blanket 1135 waivers discussed below. Flexibilities impact		
provider enrollment requirements, pre-admission screening, fair hearing requests		
and appeal timelines, and fee-for-service prior authorization requirements. All		
waivers will last throughout the duration of the public health emergency.		
Emergency Declaration Blanket 1135 Waivers:	Emergency Declaration Blanket Waivers	
CMS issued numerous 1135 waivers designed to make "sweeping regulatory	CMS Graphic Overview	
changes" to the health care system. These waivers are blanket waivers that apply	Provider Burden Relief FAQs	
nationwide without the need for providers to take further action. Waivers for	Physicians and Other Clinicians: CMS Flexibilities to	
various providers have been issued and are described by CMS in provider-specific	Fight COVID-19 Fact Sheet	
fact sheets.	Hospital Fact Sheet	
Blanket Waivers of Sanctions under the Physician Self-Referral Law:	Blanket Waivers of Section 1877(g)	
CMS issued blanket waivers of sanctions under the physician self-referral law to	Physician Self-Referral Spotlight	
assist in the COVID-19 response. Waiver available without notifying CMS. Individual		
waivers may also be granted upon request via email		
to <u>1877CallCenter@cms.hhs.gov</u> . The words "Request for 1877(g) Waiver" must be		
included in the subject line, and requests should include the following minimum		
information: 1) name and address of requesting entity; 2) name, phone number and		
email address of person designated to represent the entity; 3) CMS Certification		
Number or Taxpayer Identification Number of the requesting entity; and 4) nature of request.		



## Interim Final Rule: **CMS Interim Final Rule** CMS announced an Interim Final Rule (IFR), including the "Hospitals without Walls" Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 Factsheet initiative, designed to increase hospital inpatient surge capacity by utilizing outside Hospitals: CMS Flexibilities to Fight COVID-19 healthcare facilities and temporary expansion sites for non-COVID patients. The rule also includes provisions providing new regulatory flexibility, relaxed enrollment Factsheet requirements, expanded telehealth services, and revised physician supervision **Regulatory Changes Summary** policies designed to decrease administrative burden and increase access to care. **EMTALA Explanatory Memo EMTALA:** CMS is waiving the enforcement of section 1867(a) of the Act to allow hospitals, **Emergency Declaration Blanket Waivers** psychiatric hospitals, and critical access hospitals to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. The Director of the Quality Safety and Oversight Group also issued an explanatory memo regarding EMTALA requirements and implications related to COVID-19 which was subsequently revised to include additional guidance related to drive through testing sites and expectations regarding the triage process, medical screening examinations, and the use of telehealth. CMS Flexibilities to Fight Covid-19 Medicare: Medicare Enrollment Relief FAQs In an effort to provide enrollment relief, CMS will: 1) allow licensed physicians to provide services to Medicare beneficiaries outside their state of enrollment as long Notification of OCR Enforcement Discretion for as the physician is licensed in another state; 2) temporarily suspend certain **Telehealth** Medicare enrollment screening requirements, including criminal background checks and site visits; 3) postpone all revalidation actions; and, 4) expedite any pending or new enrollment applications. CMS has also lifted Medicare restrictions on the use of telehealth services during the COVID-19 response. Notable changes include: 1) payment for telehealth services at



the same rate as in-person visits for all diagnoses, not just services related to COVID-

19; 2) payment for audio-only telephone calls; 3) expanded the list of covered telehealth services; 4) permitting telehealth for both new and established patients; 5) allowing physicians to provide telehealth services from home without adding home to Medicare enrollment file; and 6) allowing flexibility for telehealth using popular video chat applications such as FaceTime or Skype without fear of

investigation by OCR even if the technologies are not fully compliant with the	
requirements of the HIPAA Rules.	
MIPS:	QPP COVID-19 Response Fact Sheet
CMS has extended the 2019 MIPS date submission deadline to April 30, 2020.	CMS Press Release Regarding Relief from Clinicians
Individual MIPS eligible clinicians who do not submit their MIPs date by the deadline	Participating in Quality Reporting Programs
will be eligible for the 2019 automatic extreme and uncontrollable circumstances	Extreme and Uncontrollable Circumstance Application
policy and will receive a neutral payment adjustment in 2021. The extreme and	QPP Participation Status Search Tool
uncontrollable circumstances application has also been reopened until April 30,	
2020, for those who began submitting data but are unable to complete submission	
due to COVID-19. CMS has also updated the QPP Participation Status Tool so eligible	
parties can determine whether the policy has been automatically applied.	

HHS Office for Civil Rights & HIPAA	
ACTION	SOURCES & RESOURCES
Limited Waiver of HIPAA Sanctions:	COVID-19 & HIPAA Bulletin Limited Waiver of HIPAA
Secretary Azar has waived certain sanctions and penalties against a covered hospital	Sanctions and Penalties During a Nationwide Public
that does not comply with the following provisions of the HIPAA Privacy Rule: 1) the	Health Emergency
requirements to obtain a patient's agreement to speak with family members or	
friends involved in the patient's care; 2) the requirement to honor a request to opt	
out of the facility directory; 3) the requirement to distribute a notice of privacy	
practices; 4) the patient's right to request privacy restrictions; and, 5) the patient's	
right to request confidential communications.	
Telehealth:	Enforcement Discretion Related to HIPAA and
OCR issued guidance explaining that covered health care providers will not be	<u>Telehealth</u>
subject to penalties for violations of the HIPAA Privacy, Security, and Breach	
Notification Rules that occur in the good faith provision of telehealth during the	
COVID-19 nationwide public health emergency.	
Guidance:	Guidance from OCR Regarding HIPAA, Civil Rights, and
OCR shared guidance designed to remind entities covered by civil rights authorities	COVID-19
of their obligations under laws and regulations that prohibit discrimination on the	
basis of race, color, national origin, disability, age, sex, and exercise of conscience	



and religion in HHS-funded programs and to refrain from unlawful discrimination	
against people with disabilities when making treatment-related decisions during the	
COVID-19 response.	

Governor Cooper's Executive Orders  Complete List of all Executive Orders related to COVID-19	
EO 135:	<u>EO 135</u>
Extends Stay At Home Order to May 8, 2020.	
EO 131:	<u>EO 131</u>
This Order imposes new restrictions on retailers and long-term care facilities and	EO 131 FAQs
streamlines unemployment benefits process. This Order provides mandatory	
requirements for nursing homes and long-term care facilities including requiring all	
staff to wear medical masks, prohibiting communal activities, required daily	
temperature screenings for staff, and close monitoring of residents for coronavirus	
health indicators.	
EO 130:	EO 130
This Order temporarily waives some legal or regulatory constraints in an attempt to	EO 130 FAQs
increase the state's health care resources during the public health emergency. The	
Order is designed to increase hospital capacity and expand pool of health care	
workers, lifts regulations to increase the quantity of available hospital beds and	
medical equipment, permits out-of-state and retired providers to provide care,	
expands telehealth services, and allows ambulatory surgical facilities to operate as	
temporary hospitals.	
EO 121:	EO 121
This Order issues a statewide Stay at Home Order until April 29, 2020, and instructs	EO 121 FAQs
individuals to stay at home except to visit essential businesses, exercise outdoors, or	Additional Guidance
to help a family member. Order specifically bans gatherings of more than 10 people	
and instructs people to physically stay at least 6 feet away from others.	
EO 116:	EO 116
This Order declares a state of emergency.	



North Carolina Medical Board		
ACTION	SOURCES & RESOURCES	
Licensure:	Order Waiving Certain Requirements for a Limited	
The NCMB has authorized several emergency measures to increase the supply of	Emergency License to Physicians in a Fellowship	
available medical professionals in the state by easing barriers to medical licensure.	Order Postponing Step-Level 2 Requirements for RTL	
These measures include: 1) allowing fully qualified physicians who are completing	Order Postponing Background Checks	
advanced fellowship training with a North Carolina training institution to apply for a	Order Extending Emergency License Expiration	
limited emergency license, which provides a temporary full and unrestricted medical	Order Waiving Certification Exams for New PA Grads	
license during the declared state of emergency; 2) postponing certain medical	Order Waiving Certification Exams for New NP Grads	
license examinations (USMLE and COMLEX–USA Step/Level 2) for fourth year		
medical students who have matched with a North Carolina training institution; 3)		
temporarily suspending criminal background checks for license applications due to		
lack of availability of fingerprinting services; and, 4) extending the timeline for		
emergency licenses issued to 30 days after the current state of emergency is lifted.		
The NCMB also authorized measures to temporarily allow new physician assistant		
and nurse practitioner graduates who have not been able to complete national		
certifying examinations due to testing facility closures to receive a temporary license		
valid for up to 6 months.		
Supervision of APPs:	Emergency Reassignments of PAs Order	
The NCMB authorized a temporary waiver of paperwork requirements for PAs and	Emergency Reassignments of NPs Order	
NPs who are temporarily reassigned to a new practice area within a hospital, health		
system or multi-specialty group during the COVID-19 pandemic. The supervising		
physician and facility administration must ensure the PA/NP: 1) is reassigned to		
perform only those medical tasks for which he or she is competent and qualified to		
do; 2) has reasonable and immediate access to a physician, either in person or		
electronically, should medical issues arise; and 3) complies with all applicable rules		
including the requirement to confer at least monthly with a physician to ensure		
meaningful supervision and quality assurance within the new practice setting.		
Prescribing:	COVID-19 Drug Preservation Rule	
	Guidance Regarding Preemptive Prescribing"	



Rule established restricting the prescription of chloroquine, azithromycin and other medications to ensure that these drugs are available to patients who need them and to reduce the occurrence of reported stockpiling or inappropriate prescribing of these medications.

\*\*The NC Board of Pharmacy issued an identical rule that can be found <a href="here">here</a>.\*\*

North Carolina Midwifery Joint Committee		
ACTION	SOURCES & RESOURCES	
Licensure:	Nurse Midwife Emergency Temporary Graduate	
The Joint Committee authorized measures to temporarily allow new graduates who have not been able to complete national certifying examinations due to testing facility closures to receive a temporary license valid for up to 6 months and will permit a nurse midwife to practice under the supervision of an on-site physician or certified nurse midwife who has been practicing for a minimum of 2 years. The Committee also authorized the temporary waiver of certain application requirements to permit reinstatement if the nurse midwife is reinstating to practice	Nurse Midwife Emergency Temporary Reinstatement	
in an established practice and provides the practice location to the Board of Nursing.		
Supervision:	Emergency Temporary Extension of Approval to	
The Joint Committee authorized a temporary waiver of required physician supervision to allow an approval to practice to be extended in cases of emergency such as the injury or sudden illness of a supervising physician during the declared state of emergency without submitting documentation establishing a new supervising physician. A CNM seeking an extension must first notify Board of Nursing staff, who may grant an extension for up to 45 days.	<u>Practice</u>	
Prescribing:	COVID-19 Drug Preservation Rule	
Proposed temporary rule restricting the prescription of chloroquine, azithromycin and other medications to ensure that these drugs are available to patients who need them and to reduce the occurrence of reported stockpiling or inappropriate prescribing of these medications.		



North Carolina Department of Insurance		
ACTION	SOURCES & RESOURCES	
Advisory issued by DOI to insurance companies regarding policyholders affected by the COVID-19 virus recommended the state's insurance industry consider the following actions: 1) relax due dates for premiums payments; 2) extend grace periods; 3) waive late fees and penalties; 4) allow payment plans for premiums payments to otherwise avoid a lapse in coverage; and, 5) consider cancellation of non-renewal of policies only after exhausting other efforts to work with policyholders to continue coverage.	Advisory to Insurance Companies Regarding Policyholders Affected by the COVID19 Virus	
DOI directed all licensed health benefit plans to allow for extra prescriptions during the declared state of emergency. Covered persons may obtain one refill on a prescription if there are authorized refills and not contrary to the dispensing authority of the pharmacy.	Bulletin 20-B-04	
Commissioner's Order activating G.S. § 58-2-46 requires insurance companies to give their customers affected by the COVID-19 health emergency the option to defer premium and debt payments	Order 20-B-06 Order & Bulletin 20-B-06 FAQs	
Although not binding regulation, the Commissioner has issued a press release encouraging insurance companies to facilitate diagnostic testing and treatment needed for COVID-19. Recommendations included asking insurers to waive prior authorization for COVID-19 diagnostic tests and covered services, increase access to certain drugs and to make expedited formulary exceptions if needed or if there is a shortage of a certain medication, expand telehealth services, implement consistency in coding including that of out-of-the box services such as curb-side help, extend their preapproval time limits, review internal processes and operations to ensure readiness to address COVID-19 cases, promptly notify providers, helpline staff and customer service personnel on policies regarding COVID-19, and verify that provider networks are adequate to handle the increases as more COVID-19 cases are diagnosed.	Press Release Requesting Speedy Access	



North Carolina Industrial Commission		
ACTION	SOURCES & RESOURCES	
The Industrial Commission issued guidance for health care providers regarding telehealth visits for workers' compensation cases. Per the IC, neither the Workers' Compensation Act nor any Industrial Commission Rules disallow telehealth. Evaluation & Management visits conducted via telehealth can be billed using the same Evaluation & Management codes that are used for an in-person office visit, except that "02" should be used as the "Place of Service" code.	COVID-19 FAQs	

