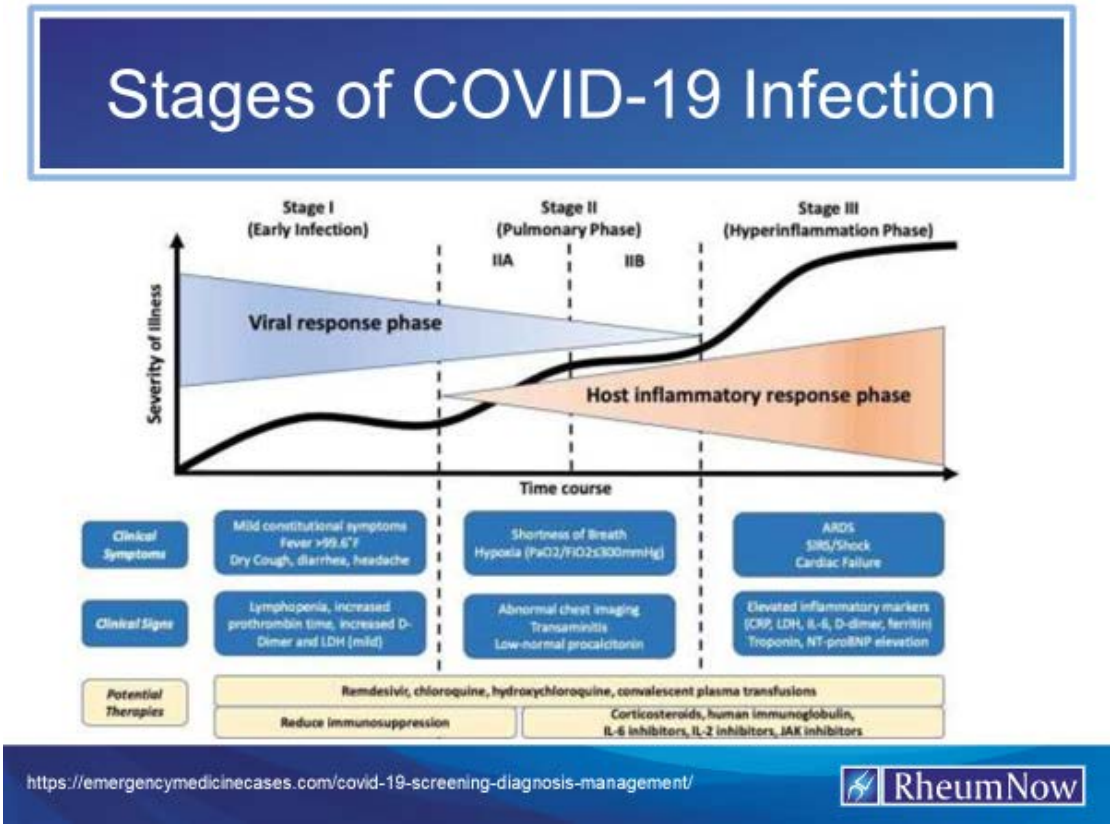
RESOLUTION

Resolution: 103A.20

SUBJECT:	AMA Statements Must Be In Line with Existing Policy
SUBMITTED BY:	Medical Association of Atlanta
REFERRED TO:	Reference Committee A

Whereas, SARS-CoV-2 is the novel coronavirus that causes COVID-19; and

Whereas, three distinct stages of COVID-19 infection have been observed in some people who test positive for the disease and have variable degrees of symptoms as noted (1); and



Whereas, During the early infection phase (Stage 1), the virus multiplies inside the body and is likely to cause mild symptoms that may be confused with a common cold or flu; and

Whereas, the second phase is the pulmonary phase (Stage 2), when the Immune System becomes strongly affected by infection and leads to primarily respiratory symptoms such as persistent cough, shortness of breath and low oxygen levels. Problems with blood clotting—especially with the formation of blood clots —may be predominant in Stage 2; and

Whereas, the third hyperinflammatory phase (Stage 3), occurs when a hyperactivated immune system may cause injury to the heart, kidneys, and other organs. A "cytokine storm"—where the body attacks its own tissues—may occur in this phase; and

Whereas, there is no current Federal Drug Administration (FDA) indication for the treatment of Early Coronavirus infection, but early emergency use authorization (EUA) originally approved the use of hydroxychloroquine and then rescinded it (2); and

Whereas, the FDA limited use of convalescence plasma but now has rescinded that limitation (3); and
Whereas, Hydroxychloroquine and Chloroquine are FDA approved medications for over 50 years, and these medications are safely prescribed long-term for other indications (2); and

Whereas, the AMA President, Patrice A. Harris, MD, issued the following statement: “The AMA is calling for a stop to any inappropriate prescribing and ordering of medications, including chloroquine or hydroxychloroquine, and appealing to physicians and all health care professionals to follow the highest standards of professionalism and ethics,” (4); and

Whereas, the AMA, American Pharmacists Association, and American Society of Health System Pharmacists issued a joint statement on March 25, 2020 on inappropriate ordering, prescribing, or dispensing of medications to treat COVID-19 (4); and

Whereas, some states, pharmacy boards and institutions have forbidden the use of these medications for COVID -19 infection (4, 5); and

Whereas, a proposed regimen to treat COVID 19 for Stage 1, includes 10 days of hydroxychloroquine, Azithromycin, zinc, and on occasion Vitamin D (6); and

Whereas, this regimen is not being advocated for Stage 2 and Stage 3 COVID therapy; and

Whereas, the original studies published in The Lancet and The New England Journal of Medicine (NEJM) initially citing harm due to hydroxychloroquine and chloroquine use were retracted by said journals due to dubious research methodology and incorrect conclusions (7, 8, 9); and

Whereas, AMA policy: Patient Access to Treatments Prescribed by Their Physicians (H-120.988) supports a physician’s autonomy to prescribe medications the physician believes to be in the patient’s best interest, where the benefits outweigh risk and the patient consents; and

Whereas, physicians have used off label medications for years and this use is supported by existing policy; and

Whereas, data regarding harm have been limited due to poorly designed studies or studies usually in Stage 2 or later, or stopped without harm but no effect in phase 2 and hypothesis (7, 8, 9, 10, 11, 12); and

Whereas, there are many studies that indicate that the use of Hydroxychloroquine, Azithromycin is effective and front-line physicians are using the therapy where permissible, (13, 14, 15); and

Whereas, the COVID-19 pandemic is a serious medical issue, people are dying, and physicians must be able to perform as sagacious prescribers; now therefore be it

RESOLVED, that the MAG delegation to the American Medical Association (AMA) present a resolution asking for the AMA to rescind its statement calling for physicians to stop prescribing Hydroxychloroquine and chloroquine until sufficient evidence becomes available to conclusively illustrate that the harm associated with use outweighs benefit early in the disease course; and be it further

RESOLVED, that MAG requests that the AMA rescind its joint statement with the American Pharmacists Association and American Society of Health System Pharmacists; and be it further

RESOLVED, that MAG requests that the AMA send a letter asking the FDA to rescind its ruling preventing outpatient use of Hydroxychloroquine; and be it further

RESOLVED, that MAG requests that the AMA officers refrain from statements that contradict existing AMA policy.

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AMA Policy

Patient Access to Treatments Prescribed by Their Physicians, H-120.988

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited, or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.

6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

Long-Term Care Prescribing of Atypical Antipsychotic Medications, H-25.989
Our AMA: (1) will collaborate with appropriate national medical specialty societies to create educational tools and programs to promote the broad and appropriate implementation of non-pharmacological techniques to manage behavioral and psychological symptoms of dementia in nursing home residents and the cautious use of medications; (2) supports efforts to provide additional research on other medications and non-drug alternatives to address behavioral problems and other issues with patients with dementia; and (3) opposes the proposed requirement that physicians who prescribe medications with "black box warnings on an off-label basis certify in writing that the drug meets the minimum criteria for coverage and reimbursement by virtue of being listed in at least one of the authorized drug compendia used by Medicare."

Food and Drug Administration H-100.980
(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate.

FDA H-100.992
1. Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials, RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
2. The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
3. It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

FDA Intrusion into the Practice of Medicine H-270.977

The AMA strongly opposes the FDA's intrusion into the practice of medicine by making decisions for individual care and mandated informed consent documents written without the input of specialists in the related field of medicine.

AMA Code of Medical Ethics: 7.3.10 Expanded Access to Investigational Therapies
Physicians who care for patients with serious, life-threatening illness for whom standard therapies have failed, are unlikely to be effective, or do not exist should determine whether questions about access to investigational therapy through the U.S. Food and Drug Administration's "expanded access" program are likely to arise in their clinical practice. If so, physicians should familiarize themselves with the program to be better able to engage in shared decision making with patients.

When a patient requests expanded access to an investigational therapy, physicians should:

(a) Assess the patient's individual clinical situation to determine whether an investigational therapy would be appropriate, including:

(i) whether there is a satisfactory alternative therapy available to diagnose, monitor, or treat the patient's disease or condition;

(ii) the nature of potential risks of the investigational therapy and whether those risks are not unreasonable in the context of the patient's disease or condition;

(iii) whether the potential benefit to the patient justifies the risks of the investigational therapy;

(iv) whether the patient meets inclusion criteria for an existing clinical trial of the investigational therapy.

(b) As part of the informed consent process, advise the patient (or parent/guardian if the patient is a minor) that the investigational therapy has not yet been demonstrated to be effective in treating the patient's condition and may pose as yet unknown risks. Physicians should explain the importance of clinical trials, encourage patients who meet inclusion criteria to participate in an existing trial rather than seek access to investigational therapy through the FDA expanded access program, and direct patients who wish to participate in research to appropriate resources.

(c) Decline to support an application for expanded access to an investigational therapy when:

(i) the physician judges the treatment with the investigational therapy not to be in the patient's best interest, and explain why; or

(ii) the physician does not have appropriate resources and ability to safely supervise the patient's care under expanded access.

In such cases, physicians should refer the patient to another physician with whom to discuss possible application for expanded access.

(d) Discuss the implications of expanded access for the patient and family and help them form realistic expectations about what it will mean to be treated with the investigational therapy outside a clinical trial. Physicians should alert patients:

(i) to the possibility of financial or other responsibilities associated with receiving an investigational therapy through expanded access;

(ii) to the lack of infrastructure to systematically monitor and evaluate the effects of the investigational therapy outside a clinical trial;

(iii) that they need information about how to contact the manufacturer for guidance if they seek emergency care from a health care professional who is not affiliated with a clinical trial of the investigational therapy;

(iv) that the physician has a responsibility to collect and share clinical information about the patient's course of treatment with the investigational therapy, as well as to report any adverse events that may occur over the course of treatment;

(v) to the conditions under which the physician would recommend stopping treatment with the investigational therapy.

AMA Principles of Medical Ethics: V,VI

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

MAG Policy

120.985 Physician Prescribing
HD 10/16/2010
MAG supports the physician's right to prescribe individual drugs which are appropriate for the medical condition in question, Committee 4.10: Appendix III (Reaffirmed 10/17/2015)

120.986 Dispensing Legally Valid Prescriptions
EC 2/26/2006
MAG supports legislation that requires pharmacists to fill legally valid prescriptions; however in the case of a pharmacist who has issued a written objection to dispensing abortion drugs, such pharmacist shall provide immediate referral to an appropriate alternative dispensing pharmacy, and immediately return the prescription to the prescription holder, without interference. (Reaffirmed 10/16/2011; 10/15/2016)

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4. "The A.M.A. is calling for a stop to any inappropriate prescribing and ordering of medications, including chloroquine or hydroxychloroquine, and appealing to physicians and all health care professionals to follow the highest standards of professionalism and ethics," said AMA President Patrice A. Harris, MD.

The American Medical Association, American Pharmacists Association, and American Society of Health System Pharmacists issued a j oint statement on March 25, 2020 on inappropriate ordering, prescribing or dispensing of medications to treat COVID-19.

https://www.ama-assn.org/system/files/2020-04/board-of-pharmacy-covid-19-prescribing.pdf

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