



March 31, 2020

Cara M. Christ, M.D., M.S.
Director
Arizona Department of Health Services
150 North 18th Avenue
Phoenix, Arizona 85007

Dear Dr. Christ:

The Arizona Hospital and Healthcare Association (AzHHA) submits this letter in accordance with the Governor's Executive Order No. 2020-16 regarding the need for waivers of state regulations governing hospitals. AzHHA sends this letter on behalf of member and nonmember hospitals and hospital systems. AzHHA has brought together hospitals from across the state in a virtual task force that has developed the requests for waivers set forth below. AzHHA and the hospitals of Arizona appreciate Governor Ducey's invitation in Executive Order No. 2020-16 to submit to ADHS any rules that require consideration of waiver in order to expand and provide services during this time of crisis.

AzHHA respectfully requests that ADHS waive the following regulations which, if they remain in effect, will impede the ability of hospitals to implement their emergency plans and provide needed services to patients under those emergency plans. We request that these waivers be retroactive to Governor Ducey's Declaration of Public Health Emergency on March 11, 2020 and that the waivers be implemented and remain in place until the Declaration of Public Health Emergency has ended.

Certain of these waiver requests are parallel to the federal regulatory waivers which the Centers for Medicare and Medicaid Services (CMS) granted on March 26, 2020 and March 30, 2020. In particular, in its March 30 waiver package, CMS prioritized the removal of burdensome documentation requirements during the emergency. A number of the requests below relate to documentation requirements.

First, to assist hospitals in accomplishing the emergency expansion plans required in the Governor's Executive Order, we request waiver of the requirements that the following services be provided in designated areas:

Surgical Services: R9-10-215(2)
Emergency Services: R9-10-217(A)(1)
Intensive Care Services: R9-10-221(1)
Perinatal Services: R9-10-223(A)(1)
Pediatric Services: R9-10-224(B)

In addition, on behalf of Arizona hospitals, we request waivers of the following regulations:

1. R9-10-113(1)(a)(i); R9-10-207(B); R9-10-230(5) (Tuberculosis Screening).

We request waiver of the requirement for tuberculosis screening and results within 12 months before the date individual begins providing services on behalf of a hospital. We also request waiver of the requirement that hospitals obtain evidence from medical staff members of freedom from infectious tuberculosis on or before their start date. Hospitals are actively looking for physicians, nurses, and other health care providers who presently are retired or working outside Arizona who will be willing to provide services, starting immediately, to hospital patients during the surge in the need for hospital services. It is anticipated that some of these physicians will not have current tuberculosis test results. Even when time allows for testing, hospitals anticipate longer than ordinary waits for results because resources are devoted to surge patients. Tuberculosis tests will be given and results obtained at the earliest possible time, but when practitioners are otherwise qualified and ready to provide services under a hospital's disaster plan, a tuberculosis test should not prevent them getting to work.

2. R9-10-204 (Quality Management).

We request waiver of the requirements in subsection B, and especially subsection (B)(1)(e) of this regulation on documentation of each occurrence of exceeding licensed capacity, for the duration of the emergency. We do not expect hospitals to be able to meet these requirements in the presence of very pressing other priorities during the emergency.

3. R9-10-206 (Personnel).

We request waiver of the following:

- (2) The requirement that personnel members' skills and knowledge are verified and documented before the personnel member provides services in the hospital. Hospitals anticipate periods during which personnel members will be assigned to services which they are capable of performing, but for which their skills and knowledge have not been formally verified and documented. During the emergency, we request that when such personnel are needed to provide services immediately, that verbal assurances of skills and knowledge will suffice and the formal verification and verification of skills may be delayed. The hospitals will follow their disaster plan provisions for assuring that personnel members are assigned within the scope of their skills and knowledge.
- (3) The requirement that sufficient personnel members are present on the hospital's premises with the qualifications, skills, and knowledge necessary to provide services, meet patient needs, and ensure the health and safety of patients. It may become impossible to ensure sufficient personnel to meet these standards when the number of patients surges or substantial numbers of hospital personnel become ill or need to be quarantined. Moreover, elevated need for hospital personnel to serve patients in

one area of the hospital may in times of surge make it difficult to meet the standards in other parts of the hospital.

- (4) The requirement to complete orientation of personnel members within the first 30 calendar days after the members begin providing hospital services. Depending on the length of the surge, it may become impossible to meet this requirement.
- (5) The requirement that medical and nursing services personnel are required to be CPR qualified within 30 days after their start date, and they must maintain current CPR qualification. This waiver would apply to current personnel and also to retired personnel who assist during the surge and may not have current CPR qualification. It also would apply to personnel who are providing services during the crisis whose CPR qualification lapses. Hospitals are concerned that giving up personnel while they obtain re-qualification would deprive patients of needed services during the surge period. Moreover, it is unclear whether CPR certification classes are available during this time.

4. R9-10-207 (Medical Staff).

In subsection (A)(7)(i), we request waiver of the requirement that hospitals establish and follow requirements for oral, telephone and electronic orders. We anticipate a rise in the need for verbal and telephonic orders, and delays in documentation of such orders compared to the time standards in hospital policies. This request parallels the March 26 CMS waiver related to verbal orders.

5. R9-10-208 (Admission).

- (1) We request waiver of the requirement that patients be admitted as inpatients only on the order of a medical staff member. We anticipate that many hospitals will use physicians with disaster privileges and physician extenders with who may not be medical staff members to make admission decisions during surge period. In some cases PAs and nurse practitioners or other advance practice RNs are not considered medical staff members, and RNs generally are not members of the medical staff, but personnel in any of these categories may have a sufficient skill set to admit infected patients during the surge; physicians would be responsible for such patients once in the hospital. Hospitals need flexibility in personnel assignments medical staff members may be used where they are needed most.
- (6) We request waiver of the requirement that a medical staff member perform a history and physical (H&P) within 48 hours after admission. Again, we anticipate that many hospitals will use physicians with temporary privileges and physician extenders who may not be medical staff members to perform H&Ps during the emergency. Physicians with temporary privileges and, at many hospitals, PAs and nurse practitioners or other advance practice RNs are not considered medical staff members, and RNs generally are not members of the medical staff, but personnel in any of these categories may have a sufficient skill set to perform a history and physical examination for infected

patients during the surge. This is consistent with the CMS waiver package of March 30.

6. R9-10 209 (Discharge Planning).

We request waiver of the following, parallel to the CMS waiver of federal discharge planning requirements on March 26:

- (A)(1) The requirement that a patient's specific needs after discharge be identified. It may not be possible to accomplish this for every patient during the surge.
- (A)(2) The requirement that the patient or representative participate in the discharge planning process. It is our understanding that most hospitals are not permitting visitors into the hospital during the emergency period to prevent the spread of the virus. Patients themselves, while certainly participating in the discharge itself, may not be able participate in the planning process, as it is likely to be very truncated, and options may be very limited.
- (A)(4), (A)(5) The requirement that the patient or patient representative receive written information identifying classes or subclasses of appropriate post-hospital institutions. As noted above, in all likelihood, this simply may not be possible during the surge period, at least for COVID-19 patients.
- (B)(1)-(3) The documentation requirements related to discharge, as they simply may not be possible to accomplish during the surge.
- (C) The requirement that discharges are accomplished according to the hospital's policies and procedures, for all the reasons set forth above.
- (D)(1) The requirement that a medical practitioner who provided services to the patient document a discharge order prior to discharge. During the surge hospitals anticipate that this requirement is likely to slow down throughput and the turnover of patients in the hospital, which as you know, will be critically important when hospital beds are scarce.

7. R9-10-210 (Transport).

We request that the transport requirements under this regulation be waived. Hospitals anticipate delays in obtaining appropriate licensed transport of COVID-19 patients during the surge, because of increases in the volume of need, the time necessary to clean vehicles between transports, and potential shortages of transport personnel. Hospitals need flexibility in the method used to safely move patients to ancillary facilities, including increased use of private vehicles. Hospitals expect that they simply will not be able to comply with their policies and procedures or this rule as the surge develops. This request parallels CMS' waiver of federal EMTALA regulations on March 26.

8. R9-10-211 (Transfer).

We request that the transfer requirements under this regulation be waived. In particular, we anticipate that hospitals will need flexibility in the process for coordination, patient assessment, the communication of risks and benefits, and medical record documentation under sections (1) and (3). We request that hospitals be permitted to transfer patients as needed to other facilities with their hospital medical records, but not necessarily in compliance with the other mandates in this rule. This request parallels CMS' waiver of federal EMTALA regulations on March 26.

9. R9-10-212 (Patient Rights).

(A)(1) We request waiver of the requirement to post patient rights language to the extent that tents or similar temporary or repurposed structures are used to house patients during the emergency.

(A)(2) We request waiver of the requirement that a patient or patient representative receive written patient rights statements upon admission. We expect that efforts will be made to provide the information, but it will take up valuable time and resources to sterilize electronic signature pads; and it may not be possible to provide paper documents to COVID-19 patients sick enough to be admitted to the hospital.

(B)(2)(a), (b) Many hospitals are developing policies and procedures, guidelines, or other tools to evaluate COVID-19 patients and their medical conditions with respect to their chances of survival in the hope of saving the most patients. We request assurances that, in situations in which scarce equipment, beds or personnel must be allocated among COVID-19 patients and hard choices must be made to save patients, that such choices will not provide grounds to allege that a patient has been subject to abuse or neglect.

(B)(2)(h) We request that quarantine placement of patients who require hospital care not be considered "seclusion." Alternatively, we request that the rule prohibiting seclusion of patients (except in emergencies or in behavioral health settings with limitations) be waived for COVID-19 patients. COVID-19 patients necessarily must be kept in quarantine, in settings that might be interpreted as seclusion, to avoid spread of the infection. Patients must not be permitted to refuse consent to being placed in quarantine rooms or areas in the hospital or in ancillary locations that provide hospital care for so long as they remain in under hospital care. We further request that if quarantine orders are considered seclusion, that such orders may be given verbally with documentation at a later time. This parallels CMS' waiver of federal seclusion regulations.

(B)(3)(c) We request waiver of the requirements in this subsection regarding providing information to patients about (ii) hospital rates, (iii) patient complaint policies (iii); (iv) research protocols. Hospitals may not be able to comply with all these information provisions consistently during surge admission periods.

- (B)(3)(d) We request waiver of the requirement to provide information to patients about health care directives. This is parallel to the CMS waiver on March 26 of requirements under the Patient Self Determination Act.
- (C) We request waiver of the following with respect to COVID-19 patients during surge periods:
- (C)(1) We request assurances that, if circumstances require the use of tools to prioritize the allocation of scarce equipment, personnel and beds among COVID-19 patients, that ADHS will not consider such prioritization to constitute discrimination.
- (C)(3) The privacy requirement. In surge periods and locations, it is likely to be extremely difficult to maintain patient privacy to the extent that it is maintained in normal times.
- (C)(4) The requirement that patients have access to telephones in ancillary locations, where this simply may not be possible. Moreover, sharing cell phones with COVID-19 patients may not possible to do safely, even with cleaning procedures; and cleaning procedures for telephones would take staff away from more important patient care duties.
- (C)(6) The requirement that referrals to other health care institutions be provided in certain circumstances. This simply may not be possible during surge periods.
- (C)(7) The requirement to allow COVID-19 patients or their representatives to participate in the development of or decisions concerning treatment, as this may be impossible to accommodate during surge periods.
- (C)(9) The requirement to allow assistance from a representative in understanding the patient's rights, to the extent that such assistance requires the personal presence of such individuals on hospital/ancillary premises. Visitors are not being permitted on premises during the emergency, in order to prevent the spread of infection.

Further, as a general matter, we request that documentation of patient verbal authorizations is permitted to proceed on HEA Assistor or similar consent forms in a manner other than a recorded authorization or signature.

10. R9-10-213 (Medical Records).

We request waiver of the following:

- (A)(3)(c) The verbal order requirement, as set forth above.

- (A)(5), (6) The requirements regarding availability of the medical record. To the extent that patients are located in temporary or repurposed spaces, it may become impossible to meet medical record accessibility and timing requirements where computers may not be as available as they would be otherwise.
- (A)(7) The requirement that the record be protected against loss, damage or unauthorized use. While hospitals will take due precautions, there are scenarios, particularly in temporary or repurposed space, in which it may not be possible to comply with this requirement.
- (C) Documentation requirements with respect to medical records. During surge periods, other priorities and the need to sanitize computers after use may make it impossible to meet all of these requirements at all times.

11. R9-10-214 (Nursing Services).

We request waiver of the following:

- (C)(2)(b) The acuity plan requirement during surge periods, when staff may become a scarce resource and hospitals may not be able to meet their own acuity staffing expectations.
- (C)(3) The requirement that all RNs are knowledgeable about and implement the acuity plan. To the extent that retired, traveling, or volunteer RNs provide services in the hospital, there may not be time during surge periods to assure that they have such knowledge or implement the acuity plan.
- (C)(4) The requirement that when licensed capacity is exceeded or patients are kept in areas without licensed beds, nursing personnel are assigned according to the specific rules for an organized service. We understand that the Governor's Executive Order 2020-16 requires compliance with this rule. However, during the emergency, this may not be possible.

12. R9-10-215 (Surgical Services).

- (2) To the extent surgical areas are used for nonsurgical patients under hospital surge expansion plans, we request waiver of the provisions of this rule.

13. R9-10-217 (Emergency Services).

We request waiver of the following requirements, related to CMS' waiver of EMTALA regulations on March 26 and the CMS waiver package on March 30:

- (A)(1) As set for above, that emergency services be provided in a designated area of the hospital. Emergency services will be provided in the emergency department and elsewhere as hospitals set up temporary and repurposed patient care areas.

- (A)(4) That emergency services are provided to all individuals requesting them. We expect that hospitals will only have the capacity to provide emergency services to patients who require hospital care, and even that capacity will be tested. Hospitals need the flexibility to send appropriate patients to lower levels of care (*e.g.*, urgent care) to assure that resources are available to patients with emergent conditions.
- (A)(5) That if emergency services cannot be provided at the hospital, measures and procedures are implemented to minimize the risk until the patient is transported or transferred to another hospitals. It is doubtful that, during a surge period, other hospitals will be available to accept patients. Please consider this request in conjunction with our requests under R9-10-210 (transport) and -211 (transfer). We anticipate that during surge periods, unorthodox methods of transport and transfer may be necessary, including the use of private vehicles. Hospitals will implement risk minimization strategies to the extent feasible while engaging in rigorous throughput practices to assure that sufficient space and resources remain available for the sickest patients.
- (A)(7), (8) Chronological log requirements. It is likely be difficult to consistently maintain the ED log in times of greatest surge.
- (D) The ED seclusion room requirements, the extent that seclusion rooms are repurposed for quarantine use.

14. R9-10-221 (Intensive Care Services).

- (1) As set forth above, we request a waiver of the requirement that intensive care services be provided only in a designated rea. During the surge, it is anticipated that intensive care services will be provided outside the ICU, including in operating suites.
- (3) We request a waiver from the requirement that admission and discharge criteria for intensive care services are established. While these criteria have been established in every hospital, we anticipate it will be difficult or impossible to comply with such criteria consistently during surge periods.
- (5) We request waiver of the staffing requirements for intensive care services, in the anticipation that staff will become a scarce resource to be deployed based on areas of greatest need.

15. R9-10-222 (Respiratory Care Services).

We request waiver of the following requirements:

- (1) That all respiratory care services are performed under the direction of a medical staff member. When physicians are unavailable, to avoid delays it may be necessary to have midlevel providers direct respiratory care services.

- (3) Documentation requirements. During surge periods it may become difficult or impossible to comply with these provisions.
- (4) The requirement that regardless the location, the hospital complies with laboratory requirements. This is likely to be impossible in temporary or repurposed structures.

16. R9-10-223 (Perinatal Services).

We request waiver of the following:

- (A)(1) The requirement that perinatal services be provided in designated areas of the hospital. This may not be possible during surge periods.
- (A)(2), (4) The requirements that only patients in need of perinatal services are allowed in the perinatal services area, as this may be impossible as hospitals expand capacity in anticipation of a surge of COVID-19 patients. Similarly, the requirement that only medical and surgical services approved by the medical staff may be performed on the perinatal unit should be waived, as it may not be possible to accomplish that during surge preparations.
- (A)(5) The requirement that patients receiving gynecological services are not placed with patients receiving perinatal services. As hospitals prepare their expansion plans, perinatal and gynecologic patients may need to be placed together, and if the surge worsens, they may need to be placed with other patients.
- (A)(6) The chronological log requirement, for the reasons set forth with respect to ED logs under R9-10-217 (A)(7) and (8).
- (A)(17) The requirement of neonate-only nurseries are set aside for the mother's convenience, as it may not be possible to maintain such nurseries under hospital surge expansion plans.

17. R9-10-224 (Pediatric Services).

We request the following waivers:

- (A)(4) As noted above, the requirements for pediatric intensive care services, consistent with the request for intensive care services above.
- (B), (C) The requirements that pediatric services are provided in a designated area, that pediatric and adult patients may not share a room, and that pediatric and adult medicines must be stored separately. Because Executive Order 2020-16(7) requires that pediatric units accept admissions of patients up to 21 years of age (who are adults under Arizona law), it is possible that children and adults may share a room. Every effort will be made to assure that age ranges are matched, but hospitals need flexibility in addressing scarce bed problems as they expand capacity and beds become scarce.

- (E) The required procedures for using pediatric beds for adults, for the reasons set forth above.

18. R9-10-225 (Psychiatric Services).

(A)(2) We request waiver of the requirement that inpatient admitted to an organized psychiatric unit have a behavioral health diagnosis. Some hospital surge expansion plans may include the use of beds in psychiatric units for other purposes.

(5)(f-j)(7), (9-20) Again, we request that the seclusion requirements not apply to COVID-19 patients.

19. R9-10-228 (Multi-Organized Service Unit).

(B)(2) We request waiver of the requirement that a multi-organized service unit be in compliance with the rules that would apply if each service were offered as a single organized service unit. Specifically, the waivers requested above, if granted, should apply equally to multi-organized service units.

(B)(3) We request waiver of the requirement that a multi-organized service unit and the beds in it all comply with physical plant requirements in R9-1-412. To the extent that hospitals are building temporary structures or repurposing structures for temporary surge usage, it likely will be impossible to comply with the ADHS physical plant requirements. This is related to the March 26 CMS waiver of physical environment regulations.

20. R9-10-229 (Social Services).

We request waiver of the requirements in subsection (5), as in ancillary bed areas in particular it may not be possible to provide for privacy in communicating with patients about social services needs.

21. R9-10-230 (Infection Control).

We request waiver of the requirements in subsection (4) regarding the implementation of written policies and procedures to prevent, minimize, identify, report and investigate infections and communicable diseases. Hospitals' focus will need to be implementing procedures to protect staff and other patients from infection from COVID-19, but strict compliance with existing policies may not be possible.

22. R9-10-231 (Dietary Services).

We request a waiver from the requirement in subsection (8) that that nutrition assessments be performed according to policies and procedures during the surge period, as time and staff resources may not permit such assessments.

23. R9-10-233 (Environmental Standards).

- (2) We request a waiver from the requirements of this subsection. Of course, hospitals and their personnel will make all possible efforts under the circumstances to keep prevent, minimize and control infection; but strict compliance with policies may not be possible. In addition, hospitals may not be able to guarantee that premises and equipment are free from a condition or situation that may cause a patient or others to suffer injury.

- (7)(c) We request a waiver from the requirement that equipment used to provide services is only used according to the manufacturer's recommendations. For example, if ventilators become a scarce resource in Arizona hospitals, personnel may wish to use adapted anesthesia ventilation equipment, provide ventilation to two patients using one ventilator, or other methods of ventilation. These emergency lifesaving measures should not be the source of regulatory violations.

24. R9-10-234 (Physician Plant Standards).

We request waiver of the provisions of this rule to the extent that temporary or repurposed patient care areas are in use. This is consistent with the CMS waiver package of March 3) regarding "hospitals without walls."

In addition to the specific regulatory waivers set forth above, we request that Governor Ducey and ADHS declare that all beds/locations utilized during the emergency are licensed. This is necessary to avoid payor denials of payment in the absence of facility licensure. As you know, hospitals will incur dramatic losses during this period. We would like to avoid unnecessary disputes to the extent possible.

Finally, Arizona's Health Information Organization (HIO) law requires health care providers (including hospitals) who participate in a health information exchange (HIE) to distribute (and document distribution) of the HIO notice in the same way they distribute/document a HIPAA notice of privacy practices (NPP). ARS 36-3608(E). The HIO notice is a document that explains to patients how their health information may be used and disclosed through a HIE and their right to opt out. Consistent with recent HHS waivers of the NPP requirement, health care providers in Arizona would benefit from an express state waiver of the HIO notice distribution and documentation requirement during the COVID-19 crisis.

Again, our thanks to you, to ADHS, and to Governor Ducey for allowing AzHHA to submit this comprehensive set of regulatory COVID-19 waivers. We have seen the impact of the patient surge on hospitals in other areas of the country. A great deal of planning has been underway for several weeks so that hospitals can be as ready as possible to meet the wave of expected patients and provide them optimal care while keeping front line hospital personnel as safe as possible. The waivers requested in this letter are intended as emergency measures to get through the expected challenges and permit hospitals and their personnel to laser focused on providing that care.

We welcome your questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann-Marie Alameddin". The signature is fluid and cursive, with the first name "Ann-Marie" and the last name "Alameddin" clearly distinguishable.

Ann-Marie Alameddin
President and Chief Executive Officer
Arizona Hospital and Healthcare Association

cc: Christina Corieri, Senior Policy Advisor to Governor Doug Ducey
Jami Snyder, Director, Arizona Health Care Cost Containment System