CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

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Subject: UnitedHealthcare's Sepsis Policy

Dear Dr. Chang:

Thank you for meeting with the California Hospital Association (CHA) and our members on March 6 to discuss UnitedHealthcare's (UHC) revised policy pertaining to sepsis treatment and payment, as announced in the UHC October 2018 Network Bulletin. UHC has indicated that, effective January 1, 2019, it will use only the Sepsis-3 definition — which has not yet been universally adopted — for post-payment reviews of payments made to providers that currently contract with UHC using the Medicare Severity Diagnosis Related Groups (MS-DRG) fee schedule. Further, UHC indicates that if, upon review of the medical record, it determines that the patient has not met the Sepsis-3 definition, it will downgrade the MS-DRG to reflect, "sepsis was not present and sepsis treatment services should not have been included as part of the member's claim."

While we appreciate the dialogue on March 6, CHA and our member hospitals and health systems remain vigorously opposed to this change in policy. UHC's position is seriously misguided, fails to recognize the importance and value of early intervention to avoid poor outcomes, second guesses the medical decisions of infection disease specialists, misinterprets the Sepsis-3 definition, is inconsistent with Centers for Medicare & Medicaid Services' (CMS) requirements, and may violate California law. CHA urges UHC to rescind this policy immediately.

We offer the following observations and data for additional consideration and future dialogue on the importance of immediately halting the implementation of this policy.

I. Policy Fails to Recognize Importance, Value of Early Intervention

A definitive diagnosis of sepsis is a clinically complex decision. Critical care, emergency medicine, and infectious disease specialists agree that early intervention supported by clinical evidence-based protocols is essential in preventing the escalation of the disease and mortality. Hospitals and physicians have worked for years to appropriately identify, treat, and document sepsis based on the Sepsis-2 definition, which is consistent with CMS requirements. Sepsis-2 bases the initial recognition of sepsis on the presence of Systemic Inflammatory Response Syndrome (SIRS) in conjunction with signs of infection,

and, therefore, allows clinicians to consider a sepsis diagnosis much earlier in the disease's progress. A clinically appropriate screening process for identifying patients with suspected sepsis must be highly sensitive; once identified, clinicians initiate rigorous monitoring and treatment protocols to avoid escalation into organ dysfunction, further morbidity, and mortality. The Sepsis-3 definition is less sensitive than the Sepsis-2 definition and **fails to identify patients who are at significant risk for mortality.**

Clinicians decide which treatment best serves their patients **based on the information available at the time of the decision**. CMS recognizes the Sepsis-2 criteria as the foundation for clinically relevant and evidence-based protocols that have been proven to decrease the mortality rate for patients with sepsis and are followed by clinicians across the country; the protocol is later coded to reflect its resource intensity. This is not the case for the Sepsis-3 definition, which:

- Has not been rigorously studied
- Is more cumbersome for clinicians to use
- Has been rejected as a basis for sepsis screening by a number of physician professional organizations, as well as CMS
- Has been shown, in published studies, to be inferior to the Sepsis-2 definition in early identification of patients with sepsis

The original paper for the Sepsis-3 definition stated:

> Neither qSOFA nor SOFA is intended to be a stand-alone definition of sepsis. It is crucial, however, that failure to meet 2 or more qSOFA or SOFA criteria should not lead to a deferral of investigation or treatment of infection or to a delay in any other aspect of care deemed necessary by the practitioners. qSOFA can be rapidly scored at the bedside without the need for blood tests, and it is hoped that it will facilitate prompt identification of an infection that poses a greater threat to life. If appropriate laboratory tests have not already been undertaken, this may prompt testing to identify biochemical organ dysfunction. These data will primarily aid patient management but will also enable subsequent SOFA scoring. The task force wishes to stress that SIRS criteria may still remain useful for the identification of infection.

California hospitals have worked diligently over the past nine years to reengineer clinical workflow to ensure early recognition and aggressive treatment of the initial signs and symptoms of sepsis. Evidence has shown that resources expended on early and focused intervention contribute to reduced morbidity and mortality, much like for stroke and heart attack. From 2010 to 2017, California hospitals decreased sepsis cases that resulted in death by 38.9 percent (from 24.4 to 14.9 percent). California's 14.9 percent sepsis mortality rate in 2017 was 40.4 percent lower than the national rate of 25 percent. These resource-intensive protocols are, therefore, appropriately reflected in the higher weight of the MS-DRG.

Furthermore, quality improvement initiatives, measurement and tracking, and implementation of written protocols for early identification using the SIRS criteria (and the Sepsis-2 definition) have made a measurable difference in outcomes of care — particularly in sepsis mortality. While Sepsis-3 criteria support clinicians in identifying patients with the highest likelihood of poor outcomes, they do not address how to identify patients in the early stages of sepsis. Thus, their use for clinical interventions could delay the diagnosis of sepsis until a patient's condition worsens.

Studies have reported Sepsis-3 specificity to range from 70-85 percent, which carries an inherent 15-30 percent false positive rate (1-Specificity). UHC post-payment review rejects cases that it deems to have been falsely positive — when a patient is treated for sepsis but does not have sepsis. UHC essentially is assuming that hospitals can eliminate the false positive rates to zero when this is statistically impossible since the false positive is inherent to the Sepsis-3 test. Until there is a 100 percent specific test, UHC cannot penalize hospitals for treating patients who later turn out to be falsely positive because it is beyond the statistics of the test UHC is electing to use.

UHC's post-payment review process disregards the use of Sepsis-2 and uses a different tool to validate that the protocol's coding is appropriate to the MS-DRG. More troubling is that in this process, UHC selects only limited claims, reviews the entire medical record, and bases its assessment on all the information known after the fact, rather than on what is known to the clinician at that critical time when early intervention is so key to preventing adverse outcomes. This violates California Health and Safety Code §1371.5 (c), which prohibits health plans from second guessing an emergency physician's diagnostic impression after the fact.

In this review process, UHC benefits from a position of hindsight that enables it to ignore the evidence-based protocols that led to the clinical decision and instead cite other — often inappropriate — clinical guidelines. Such a policy will confuse clinicians and likely slow the progress to date on decreasing sepsis mortality.

II. Policy Is Inconsistent with Federal and State Requirements

From a quality measurement standpoint, CMS requires hospitals to submit data on hospital adherence to an evidence-based sepsis treatment bundle. The case inclusion criteria for these measures are also based on Sepsis-2 criteria and a different definition for organ dysfunction than the one included in Sepsis-3. Therefore, the denominator of sepsis patients under the current CMS reporting program is different and larger than the more narrowly defined Sepsis-3. Changing national definitions, which have a robust body of evidence supporting their use, could impede ongoing quality improvement efforts. Furthermore, following Sepsis-3 guidelines may result in underreporting of conditions to both state and federal databases, which may result in under surveillance by infection control entities.

Using only the Sepsis-3 definition is a radical departure from the current use of Sepsis-2. Sepsis-3 is inconsistent with the ICD 10 coding guidelines, which still define sepsis as SIRS due to an infection. Application of this policy on a post-payment review is completely inappropriate and would impose unnecessary burden. It will be nearly impossible for coders to correctly align codes for sepsis and severe sepsis when physicians use the Sepsis-3- definition. An appropriate post-payment review should apply the same clinical guidelines required for coding the claim.

In 2016, CMS proposed — but did not adopt — a definition that Sepsis-3 was designed as a research definition to help classify sepsis patients for academic study; it was never intended to be criteria on which to base payments. CMS rejected Sepsis-3 in its July 26, 2016, letter to the editor of the JAMA. CHA does not believe the Sepsis-3 definition was ever intended to diminish the importance and value of clinical protocols developed to support early identification and treatment of sepsis. Hospitals and doctors must initiate treatment when sepsis is suspected based on the Sepsis-2 definition. UHC's

proposal to recognize only the most severe cases of sepsis pursuant to the Sepsis-3 definition will undermine efforts to improve sepsis treatment and outcomes, and will result in providers not being compensated for sepsis treatment services provided to patients before they become critically ill.

In addition to being inconsistent with CMS requirements for quality reporting and national coding guidelines, UHC's policy may violate California law, which specifically requires plans to "demonstrate to the department [Department of Managed Health Care] that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management (California Health and Safety Code §1367(g))." Based on UHC's attached presentation to CHA and our March 6 discussion, it appears that UHC's sepsis policy is being driven primarily by the desire to reduce costs because, as UHC recognizes, "[s]epsis is the most expensive condition treated in [the] U.S." It is true that sepsis is a costly, difficult diagnosis with a high mortality rate — but early identification and treatment of sepsis has substantially increased the survival rates. The expertise and technology needed to save those lives is reflected in the higher-weighted MS-DRG, as intended, and must be adequately reimbursed.

State law (California Business and Professions Code §2400) also prevents unlicensed persons from interfering with or influencing a physician's professional judgment. This policy is intended to leave the ultimate overall care of the patient, including available treatment options, to clinicians. As noted above, UHC's application of a post-payment review of these clinical decisions using tools and guidelines that are inconsistent with the current national guidelines for appropriate coding and billing procedures for patient care services is inappropriate. We remain concerned that this policy's application is undermining the evidence-based protocols clinicians currently use to treat this disease.

III. Policy Solely Aimed at Reducing Payment to Providers

The early intervention of sepsis, supported by clinical evidence-based protocols to prevent the escalation of the disease and mortality, is resource intensive. This is reflected in the weight of MS-DRGs 871-872, as outlined in Table 1 below, which thereby reimburses hospitals for those clinically appropriate interventions. Such resource-intensive treatment protocols must be accurately coded and paid for as stipulated in nationally recognized coding and billing guidelines. UHC's stated policy of a post-payment review of the medical record with the application of the Sepsis-3 definition using a different tool aims to do nothing more than reduce payment to providers.

When asked directly about the application of this post-payment review policy to the Medicare Advantage (MA) line of business, UHC was unclear as to its applicability and was only able to state that this policy applies to MS-DRG contracts. As MS-DRGs were designed for Medicare patients, CHA can only reasonably assume (as UHC was not able to confirm) that this policy includes the MA line of business as well as any contracts that currently pay providers on the MS-DRG fee schedule.

CHA believes that, if applied to the MA line of business, not only would this policy violate CMS requirements, but also that UHC would inappropriately reduce payments to providers while simultaneously experiencing no change in their plan payments from Medicare. This would create a windfall of dollars for the health plan — dollars that would not be passed on to MA members or reflected in lower premium and out-of-pocket costs. CHA also has equity concerns related to MA and fee-for-service (FFS) members, as UHC's proposal would result in providers receiving different payments for treating Medicare members.

The table below illustrates this point further by showing the change in two relevant sepsis MS-DRGs if Medicare were to apply this policy in the FFS setting, using these alternative guidelines, and begin to audit selected claims on a post-payment review. This would likely result in a significant change to the length of stay (LOS); for example, selecting cases from MS-DRG 871 and 872 and removing those cases would cause inappropriate distortions in the weights and geometric mean LOS that will not reflect this population's clinical complexity. Currently, the weights have typically increased. Under UHC's policy, this trend will flip, and we will likely see an increase in LOS that will only add unnecessary costs and risks to patient outcomes. Pulling these cases from the MS-DRG weights, absent a coding change, would have significant payment implications for hospitals. **This payment policy is flawed in its application, and its unintended consequences for patient care cannot be underestimated.**

Table 1

MS-DRG/Title	Year	Weights	Geometric Mean LOS	Arithmetic Mean LOS
871 SEPTICEMIA OR SEVERE SEPSIS W/O MV >96 HOURS W MCC	2014	1.8527	5.1	6.7
	2019	1.8564	4.8	6.3
		⇧ 0.20%	⇩ 5.88%	⇩ 5.97%
872 SEPTICEMIA OR SEVERE SEPSIS W/O MV >96 HOURS W/O MCC	2014	1.0687	4.1	4.9
	2019	1.0529	3.7	4.4
		⇩ 1.48%	⇩ 9.76%	⇩ 10.20%

CHA strongly urges UHC to withdraw this misguided policy. As our members shared during our March 6 discussion, California hospitals will not alter the high-quality care they provide sepsis patients to conform with UHC's policy. We look forward to revisiting this policy with your team on April 30. In the meantime, if you have any questions, please contact me at (916) 552-7543.

Sincerely,

Amber Kemp
Vice President, Health Care Coverage

cc: Steven Slack, MD, MBA, Medical Director, Payment Integrity, UnitedHealthcare
Gregory Siebert, California Market Vice President, Network Management, UnitedHealthcare
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Sepsis Management and Coding

Identifying and Treating a Life-Threatening Illness

UnitedHealthcare

Agenda

- Sepsis Overview
- Sepsis-3 and Surviving Sepsis Campaign International Guidelines
- Sepsis Definitions
- Surviving Sepsis Campaign History
- Do the Sepsis 6
- UnitedHealthcare Clinical Guidelines
- Sepsis (SEP-1) Care Bundle Results
- Sequential Organ Failure Assessment (SOFA) Score
- SOFA Criteria

Sepsis Management Guidelines

Sepsis Overview

- Sepsis is the most expensive condition treated in U.S. for all payers.[1]
  - $24 billion dollars annually
  - 6.2 percent of all U.S. hospital costs
- Sepsis **kills 258,000 people per year** in the U.S or 1 person every 2 minutes.[1]
- Sepsis diagnoses have increased due to inaccurate diagnosis, coding or documentation.[1]
- **Inaccurate Sepsis coding is the most common miscoding area in the hospital environment.**[1]

[1] Healthcare Cost and Utilization Project (HCUP) and the Agency for Healthcare Research and Quality (2016)

Sepsis-3 and Surviving Sepsis Campaign International Guidelines

UnitedHealthcare

- Starting Jan. 1, 2019, UnitedHealthcare will adopt the Sepsis-3 definition in our post-payment claim reviews.
- We will also use the **Surviving Sepsis Campaign International Guidelines for Management of Sepsis and Septic Shock (2016)** to assess member care.
- The guidelines were developed in 2016 by a consensus committee of 55 international experts representing 25 international organizations.
- We believe adherence to these management guidelines can result in better care and better coding.

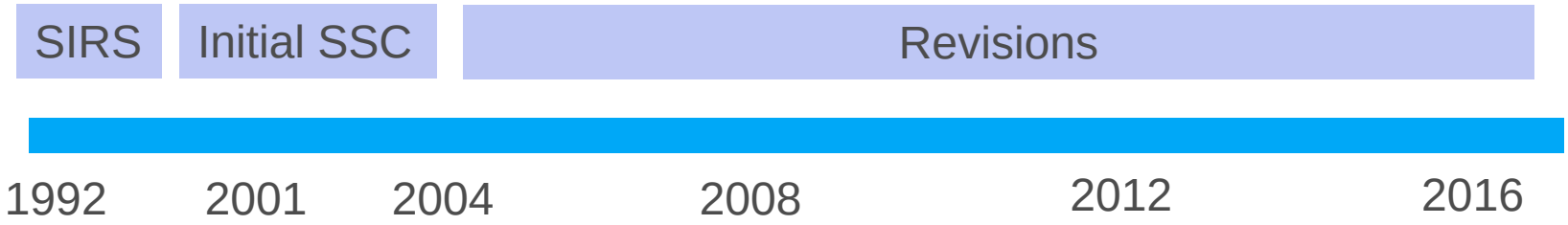
Sepsis Definitions

	Sepsis-1 (1991) Broad definition to create awareness	Sepsis-2 (2004) Broad definition with expansion of SIRS criteria thought to correlate to infection more than Sepsis-1	Sepsis-3 (2016) Defined as “life-threatening organ dysfunction caused by host immunologic response to infection. Organ dysfunction is reflected in a Sequential Organ Failure Assessment (SOFA) score of > 2 points above baseline.” *
Sepsis	Systemic Inflammatory Response Syndrome (SIRS)	Known/suspected infection and > 2 SIRS criteria	Use 2 or more SOFA points above baseline to identify sepsis
Severe Sepsis		Sepsis and end organ dysfunction	Not a category
Septic Shock		Sepsis and refractory hypotension	Vasopressors and lactate >2 mmol/L

[1] Healthcare Cost and Utilization Project (HCUP) and the Agency for Healthcare Research and Quality (2016)

Surviving Sepsis Campaign History

- The campaign began in 2002.
- The goal was to reduce sepsis deaths by 25 percent in five years.
- Guidelines for diagnosing and managing severe sepsis and septic shock have evolved over time:



- Earlier treatment was a protocol-driven, quantitative resuscitation strategy.
- Current treatment is a patient-centered resuscitation approach. Hemodynamic assessment includes dynamic variables for fluid response and ongoing reevaluation of the response to treatment.

The Sepsis 6

The following “Sepsis 6 guidelines” mirror Medicare SEP-1 bundle.

Give 3
1. Oxygen
2. Fluids
3. Antibiotics

Take 3
1. Cultures
2. Blood
3. Urine Output

- These guidelines can reduce the relative risk of death by 46.6 percent.
- One additional life is saved for every five care episodes.
- Mortality is reduced from 44 percent to 20 percent.

UnitedHealthcare Clinical Guidelines

- These guidelines detail the third international consensus definition for:
  - Sepsis and sepsis shock
  - The early management and resuscitation of patients with sepsis or septic shock
- Clinical guidelines are **not used** to decide UnitedHealthcare benefit coverage. Coverage decisions are based upon language in the benefit document.
- To review the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), visit **ncbi.nlm.nih.gov/pmc/articles/PMC4968574.**
- To review the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2016, visit **journals.lww.com/ccmjournal > Most Popular > Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2016.**

Sepsis Coding and Documentation

Sepsis Care Bundle Results

- Care providers will report their performance to Centers for Medicare & Medicaid Services on the CMS Sepsis Care bundle.
- The CMS Sepsis Care bundle is a measurement of the care provider's ability to achieve early recognition and treatment of members who present with signs and symptoms that may evolve into sepsis.

Here's how to prepare a provider-specific slide for SEP-1 care bundle results:

1. Go to **medicare.gov/hospitalcompare/search.html.**
2. Enter the hospital's identifiers, including ZIP code, state and hospital name.
3. Select Timely and Effective Care > Sepsis Care > Graph.
4. Copy graph and insert into the slide.
5. Submit your slide.

Sequential Organ Failure Assessment (SOFA) Score

UnitedHealthcare

Please use the following chart to define patients with sepsis.

SOFA Score	1	2	3	4
PaO2/FIO2 (mm Hg) ratio	<400	<300	<220	<100
SaO2/FIO2	221-301	142-220	67-141	<67
Platelets ×103/mm3	<150	<100	<50	<20
Bilirubin (mg/dL)	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
Hypotension	MAP <70	Dopamine ≤5 or dobutamine (any)	Dopamine >5 or norepinephrine ≤0.1	Dopamine >15 or norepinephrine >0.1
Glasgow Coma Score	13-14	10-12	6-9	<6
Creatinine (mg/dL) or urine output (mL/d	1.2-1.9	2.0-3.4	3.5-4.9 or <500	>5.0 or <200

SOFA Criteria

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SOFA Criteria	0	1	2	3	4
Respiratory					
PaO2/FIO2, mm Hg [kPa]	☐ >400 (53.0)	☐ <400 (53.3)	☐ <300 (40)	☐ <200 (26.7)	☐ <100 (13.3) with respiratory support
Coagulation					
Platelets, ×103/µL	☐ >150	☐ <150	☐ <100	☐ <50	☐ <20
Liver					
Bilirubin, mg/dL (umol/L)	☐ <1.2 (20)	☐ 1.2–1.9	☐ 2.0–5.9	☐ 6.0–11.9	☐ >12.0 (204)
Cardiovascular					
Blood pressure	☐ MAP ≥70	☐ MAP <70	☐ Dopamine <5 or dobutamine (any dose)	☐ Dopamine 5.1-15 or epinephrine <0.1 or norepinephrine <0.1	☐ Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1
Central nervous system					
Glasgow Coma Scale	☑ 15	☐ 13-14	☐ 10-12	☐ 6-9	☐ <6
Renal					
Creatinine, mg/dL (umol/L)	☐ <1.2 (110)	☐ 1.2–1.9	☐ 2.0–3.4	☐ 3.5–4.9	☐ >5.0 (440)
Urine output, mL/d				☐ <500	☐ <200

Thank you.

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