## Exhibit 424

# Guidance for Certifying Deaths Due to Coronavirus Disease 2019

U.S. Department of Health and Human Services • Centers for Disease Control and Prevention • National Center for Health Statistics • National Vital Statistics System <a href="https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf">https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf</a>

## N Senator and Dr. Reveals HHS Document Coached Him on How to Overcount COVID-19 Cases

https://www.thegatewaypundit.com/2020/04/huge-mn-senator-dr-reveals-hhs-document-coaching-overcount-covid-19-cases-copy-document-video/

## Vital Statistics Reporting Guidance My

Report No. 3 - Released April 2020 – Expanded February 2023



# **Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19)**

## Expanded in February 2023 to Include Guidance for Certifying Deaths Due to Post-acute Sequelae of COVID-19

#### Introduction

In December 2019, an outbreak of a respiratory disease associated with a novel coronavirus was reported in the city of Wuhan in the Hubei province of the People's Republic of China (1). The virus has spread worldwide and on March 11, 2020, the World Health Organization declared Coronavirus Disease 2019 (COVID-19) a pandemic (2). The first case of COVID-19 in the United States was reported in January 2020 (3) and the first death in February 2020 (4), both in Washington State. Since then, the number of reported cases in the United States has increased and is expected to continue to rise (5).

In public health emergencies, mortality surveillance provides crucial information about population-level disease progression, as well as guides the development of public health interventions and assessment of their impact. Monitoring and analysis of mortality data allow dissemination of critical information to the public and key stakeholders. One of the most important methods of mortality surveillance is through monitoring causes of death as reported on death certificates. Death certificates are registered for every death occurring in the United States, offering a complete picture of mortality nationwide. The death certificate provides essential information about the deceased and the cause(s) and circumstances of death. Appropriate completion of death certificates yields accurate and reliable data for use in epidemiologic analyses and public health reporting. A notable example of the utility of death certificates for public health surveillance is the ongoing monitoring of pneumonia and influenza deaths. Accurate and timely death certificate data are integral to detecting elevated levels of influenza activity in real time (https://www.cdc.gov/flu/weekly/index.htm).

Monitoring the emergence of COVID-19 in the United States and guiding public health response will also require accurate and timely death reporting. The purpose of this report is to provide guidance to death certifiers on proper cause-of-death certification for cases where confirmed or suspected COVID-19 infection resulted in death. As clinical guidance on COVID-19 evolves, this guidance may be updated, if necessary. When COVID-19 is determined to be a cause of death, it is important that it be reported on the death certificate to assess accurately the

effects of this pandemic and appropriately direct public health response.

#### **Cause-of-Death Reporting**

When reporting cause of death on a death certificate, use any information available, such as medical history, medical records, laboratory tests, an autopsy report, or other sources of relevant information. Similar to many other diagnoses, a cause-of-death statement is an informed medical opinion that should be based on sound medical judgment drawn from clinical training and experience, as well as knowledge of current disease states and local trends (6).

#### Part I

This section on the death certificate is for reporting the sequence of conditions that led directly to death. The immediate cause of death, which is the disease or condition that directly preceded death and is not necessarily the underlying cause of death (UCOD), should be reported on line a. The conditions that led to the immediate cause of death should be reported in a logical sequence in terms of time and etiology below it.

The UCOD, which is "(a) the disease or injury which initiated the train of morbid events leading directly to death or (b) the circumstances of the accident or violence which produced the fatal injury" (7), should be reported on the lowest line used in Part I.

#### **Approximate interval: Onset to death**

For each condition reported in Part I, the time interval between the presumed onset of the condition, not the diagnosis, and death should be reported. It is acceptable to approximate the intervals or use general terms, such as hours, days, weeks, or years.

#### **Part II**

Other significant conditions that contributed to the death, but are not a part of the sequence in Part I, should be reported in Part II. Not all conditions present at the time of death have to be reported—only those conditions that actually contributed to death.

#### **Certifying deaths due to COVID-19**

If COVID-19 played a role in the death, this condition should be specified on the death certificate. In many cases, it is likely that it will be the UCOD, as it can lead to various life-threatening conditions, such as pneumonia and acute respiratory distress syndrome (ARDS). In these cases, COVID-19 should be reported on the lowest line used in Part I with the other conditions to which it gave rise listed on the lines above it.

Generally, it is best to avoid abbreviations and acronyms, but COVID-19 is unambiguous, so it is acceptable to report on the death certificate.

In some cases, survival from COVID-19 can be complicated by pre-existing chronic conditions, especially those that result in diminished lung capacity, such as chronic obstructive pulmonary disease (COPD) or asthma. These medical conditions do not cause COVID-19, but can increase the risk of contracting a respiratory infection and death, so these conditions should be reported in Part II and not in Part I.

When determining whether COVID-19 played a role in the cause of death, follow the CDC clinical criteria for evaluating a person under investigation for COVID-19 and, where possible, conduct appropriate laboratory testing using guidance provided by CDC or local health authorities. More information on CDC recommendations for reporting, testing, and specimen collection, including postmortem testing, is available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html and https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html. It is important to remember that death certificate reporting may not meet mandatory reporting requirements for reportable diseases; contact the local health department regarding regulations specific to the jurisdiction.

In cases where a definite diagnosis of COVID-19 cannot be made, but it is suspected or likely (e.g., the circumstances are compelling within a reasonable degree of certainty), it is acceptable to report COVID-19 on a death certificate as "probable" or "presumed." In these instances, certifiers should use their best clinical judgement in determining if a COVID-19 infection was likely. However, please note that testing for COVID-19 should be conducted whenever possible.

#### **Common problems**

Common problems in cause-of-death certification include:

- 1. reporting intermediate causes as the UCOD (i.e., on the lowest line used in Part I),
- 2. lack of specificity, and
- illogical sequences.

Intermediate causes are those conditions that typically have multiple possible underlying etiologies and thus, a UCOD must be specified on a line below in Part I. For example, pneumonia is an intermediate cause of death since it can be caused by a variety of infectious agents or by inhaling a liquid or chemical. Pneumonia is important to report in a cause-of-death statement but, generally, it is not the UCOD. The cause of pneumonia, such as COVID-19, needs to be stated on the lowest line used in Part I.

Additionally, the reported UCOD should be specific enough to be useful for public health and research purposes. For example, a "viral infection" can be a UCOD, but it is not specific. A more specific UCOD in this instance could be "COVID-19."

All causal sequences reported in Part I should be logical in terms of time and pathology. For example, reporting "COVID-19" due to "chronic obstructive pulmonary disease" in Part I would be an illogical sequence as COPD cannot cause an infection, although it may increase susceptibility to or exacerbate an infection. In this instance, COVID-19 would be reported in Part I as the UCOD and the COPD in Part II. While there can be reasonable differences in medical opinion concerning a sequence that led to a particular death, the causes should always be provided in a logical sequence from the immediate cause on line a. back to the UCOD on the lowest line used in Part I.

## Certifying deaths due to post-acute sequelae of COVID-19

In the acute phase, clinical manifestations and complications of COVID-19 of varying degrees have been documented, including death. However, patients who recover from the acute phase of the infection can still suffer long-term effects (8). Post-acute sequelae of COVID-19 (PASC), commonly referred to as "long COVID," refers to the long-term symptoms, signs, and complications experienced by some patients who have recovered from the acute phase of COVID-19 (8-10). Emerging evidence suggests that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, can have lasting effects on nearly every organ and organ system of the body weeks, months, and potentially years after infection (11,12). Documented serious post-COVID-19 conditions include cardiovascular, pulmonary, neurological, renal, endocrine, hematological, and gastrointestinal complications (8), as well as death (13).

Consequently, when completing the death certificate, certifiers should carefully review and consider the decedent's medical history and records, laboratory test results, and autopsy report, if one is available. For decedents who had a previous SARS-CoV-2 infection and were diagnosed with a post-COVID-19 condition, the certifier may consider the possibility that the death was due to long-term complications of COVID-19, even if the original infection occurred months or years before death. If it is determined that PASC was the UCOD, it should be reported on the lowest line used in Part I with the condition(s) it led to on the line(s) above in a logical sequence in terms of time and etiology. If it is determined that PASC was not the UCOD but was still a significant condition that contributed to death, then it should be reported in Part II. Certifiers should use standard terminology, that is, "Post-acute sequelae of COVID-19." See Scenario IV in the Appendix for an example certification. In accordance with all death certification guidance, if the certifier determines that PASC did not cause or contribute to death, then they should not report it anywhere on the death certificate.

#### **Manner of death**

The manner of death, sometimes referred to as circumstances of death, is also reported on death certificates. Natural deaths are due solely or almost entirely to disease or the aging process (14). In the case of death due to a COVID-19 infection, the manner of death will almost always be natural.

## When to Refer to a Medical Examiner or Coroner

Some jurisdictions have requirements for referring deaths involving threats to public health to the medical examiner or coroner, so certifiers should follow the regulations in the jurisdiction in which the death occurred. As always, if a death involved an injury, poisoning, or complications thereof, then the case should be referred. The local medical examiner or coroner should be consulted with questions on referral requirements.

#### **Conclusion**

An accurate count of the number of deaths due to COVID-19 infection, which depends in part on proper death certification, is critical to ongoing public health surveillance and response. When a death is due to COVID-19, it is likely the UCOD and thus, it should be reported on the lowest line used in Part I of the death certificate. Ideally, testing for COVID-19 should be conducted, but it is acceptable to report COVID-19 on a death certificate without this confirmation if the circumstances are compelling within a reasonable degree of certainty.

For more guidance and training on cause-of-death reporting in general, see the Cause of Death mobile app available from: https://www.cdc.gov/nchs/nvss/mobile-app.htm and the Improving Cause-of-Death Reporting online training module available from: https://www.cdc.gov/nchs/nvss/improving-cause-of-death-reporting.htm (free Continuing Medical Education credits and Continuing Nursing Education credits available). For current information on the COVID-19 outbreak, see the CDC website at: https://www.cdc.gov/coronavirus/2019-nCoV/index.html.

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#### Appendix. Scenarios and Example Certifications for Deaths Due to COVID-19

## Scenario I: A 77-year-old male with a history of hypertension and chronic obstructive pulmonary disease

A 77-year-old male with a 10-year history of hypertension and chronic obstructive pulmonary disease (COPD) presented to a local emergency department complaining of 4 days of fever, cough, and increasing shortness of breath. He reported recent exposure to a neighbor with flu-like symptoms. He stated that his wheezing was not improving with his usual bronchodilator therapy. Upon examination, he was febrile, hypoxic, and in

moderate respiratory distress. His chest x-ray demonstrated hyperinflation and his arterial blood gas was consistent with severe respiratory acidosis. Testing of respiratory specimens indicated COVID-19. He was admitted to the ICU and despite aggressive treatment, he developed worsening respiratory acidosis and sustained a cardiac arrest on day 3 of admission.

**Comment:** In this case, the acute respiratory acidosis was the immediate cause of death, so it was reported on line a. Acute respiratory acidosis was precipitated by the COVID-19 infection, which was reported below it on line b. in Part I. The COPD and hypertension were contributing causes but were not a part of the causal sequence in Part I, so those conditions were reported in Part II.

#### Scenario I

	CAUSE OF DEATH (See instructions and examples) <u>vents</u> diseases, injuries, or complicationsthat directly caused the death. DO NOT entricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter o		Approximate interval: Onset to death
IMMEDIATE CAUSE (Final disease or condition>	Acute respiratory acidosis		3 days
resulting in death)	Due to (or as a consequence of):		1 week
if any, leading to the cause listed on line a. Enter the	Due to (or as a consequence of):		
UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST	Due to (or as a consequence of):		
PART II. Enter other significant cor	ditions contributing to death but not resulting in the underlying cause given in PAR	T I 33. WAS AN AUTOPSY PERFO	PRMED?
Chronic obstructiv	re pulmonary disease, hypertension	34. WERE AUTOPSY FINDING COMPLETE THE CAUSE OF DI	
35. DID TOBACCO USE CONTRI TO DEATH?	BUTE 36. IF FEMALE:  □ Not pregnant within past year	37. MANNER OF DEATH  ■ Natural □ Homicide	
□ Yes □ Probably	□ Pregnant at time of death	□ Accident □ Pending Investigation	
■ No □ Unknown	□ Not pregnant, but pregnant within 42 days of death	□ Suicide □ Could not be determined	
	□ Not pregnant, but pregnant 43 days to 1 year before death		
	☐ Unknown if pregnant within the past year		

## Scenario II: A 34-year-old female with no significant past medical history

A 34-year-old female with no significant past medical history presented to her primary care physician complaining of 6 days of fever, cough, and myalgias. She was found to be febrile, hypotensive, and hypoxic. She was admitted to the hospital and underwent a CT scan of the chest, which revealed diffuse ground-glass opacification indicative of viral pneumonia. Respiratory specimens were sent for testing and rRT-PCR confirmed COVID-19. Her condition deteriorated over the next

2 days and she developed acute respiratory distress syndrome (ARDS). She was transferred to the ICU and started on positive pressure ventilation. Despite aggressive resuscitation, the patient expired on hospital day 4.

**Comment:** In this case, the immediate cause of death was ARDS, so it was reported on line a. as a consequence of pneumonia, which was reported on line b. The underlying cause of death (UCOD) was COVID-19 so it was reported on line c., the lowest line used in Part I.

#### Scenario II

CAUSE OF DEATH (See instructions and examples)  32. PART I. Enter the <a href="mailto:chain of events">chain of events</a> —diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.				Approximate interval: Onset to death		
IMMEDIATE CAUSE (Final disease or condition>	A.	Acute respiratory distress syndrome			2 days	
resulting in death)		Due to (or as a consequence of):				
Sequentially list conditions,	b. Pn	neumonia				10 days
if any, leading to the cause		Due to (or as a consequence of):				10.1
listed on line a. Enter the UNDERLYING CAUSE	c. CC	OVID-19				10 days
(disease or injury that		Due to (or as a consequence of):				
initiated the events resulting in death) LAST	d					
in death) LAGI	u					-
PART II. Enter other <u>significant conditions contributing to death</u> but not resulting in the underlying cause given in PART I 33. WAS AN AUTOPSY PERFOI					FORMED?	
				ļ.	☐ Yes ■ No	100 41/41/40/5 TO
					34. WERE AUTOPSY FINDIN COMPLETE THE CAUSE OF	
35. DID TOBACCO USE CONTE	RIBLITE	36. IF FEMALE:	37. MANNER			DEATH?   Yes   No
TO DEATH?	(IDOTE	■ Not pregnant within past year	Or. WARREIN	01 00		
			■ Natural	□ Hon	nicide	
□ Yes □ Probably		□ Pregnant at time of death				
			□ Accident	□ Pen	iding Investigation	
■ No □ Unknown		□ Not pregnant, but pregnant within 42 days of death	□ Suicide		ald not be determined	
		□ Not pregnant, but pregnant 43 days to 1 year before death	Suicide	_ C00	iiu noi pe deteimmed	
		That program, but program 40 days to 1 year belore death				
		☐ Unknown if pregnant within the past year				

## Scenario III: An 86-year-old female with an unconfirmed case of COVID-19

An 86-year-old female passed away at home. Her husband reported that she was nonambulatory after suffering an ischemic stroke 3 years ago. He stated that 5 days prior, she developed a high fever and severe cough after being exposed to an ill family member who subsequently was diagnosed with COVID-19. Despite his urging, she refused to go to the hospital, even when her breathing became more labored and temperature escalated. She was unresponsive that morning and her husband phoned emergency medical services (EMS). Upon EMS arrival, the

patient was pulseless and apneic. Her husband stated that he and his wife had advanced directives and that she was not to be resuscitated. After consulting with medical command, she was pronounced dead and the coroner was notified.

Comment: Although no testing was done, the coroner determined that the likely UCOD was COVID-19 given the patient's symptoms and exposure to an infected individual. Therefore, COVID-19 was reported on the lowest line used in Part I. Her ischemic stroke was considered a factor that contributed to her death but was not a part of the direct causal sequence in Part I, so it was reported in Part II.

#### Scenario III

	CAUSE OF DEATH (See instructions and examples)  ts-diseases, injuries, or complications-that directly caused the death. DO NOT ricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter of the complex of the comple		Approximate interval: Onset to death
IMMEDIATE CAUSE (Final disease or condition> a.	Acute respiratory illness		1 day
resulting in death)	Due to (or as a consequence of):		
Composition list conditions b	Probable COVID-19		5 days
Sequentially list conditions, b if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE C.	Due to (or as a consequence of):		_
(disease or injury that	Due to (or as a consequence of):		_
initiated the events resulting	, ,		
in death) LAST d			_
PART II. Enter other significant condit	ions contributing to death but not resulting in the underlying cause given in PAR	T I 33. WAS AN AUTOPSY PE	RFORMED?
		□ Yes ■ No	
Ischemic stroke		34. WERE AUTOPSY FIND	INGS AVAILABLE TO
		COMPLETE THE CAUSE C	F DEATH? ☐ Yes ☐ No
35. DID TOBACCO USE CONTRIBU		37. MANNER OF DEATH	
TO DEATH?	■ Not pregnant within past year	■ Natural □ Homicide	
□ Yes □ Probably	□ Pregnant at time of death	■ Natural □ Homicide	
Tes   Probably	☐ Fregriant at time of death	□ Accident □ Pending Investigation	
■ No □ Unknown	□ Not pregnant, but pregnant within 42 days of death	27 tooldone 27 chaing investigation	
■ NO □ UNKNOWN	110t program, but program within 42 days or doubt	□ Suicide □ Could not be determined	
	□ Not pregnant, but pregnant 43 days to 1 year before death		
	☐ Unknown if pregnant within the past year		

## Scenario IV: A 48-year-old male with post-acute sequelae of COVID-19

A healthy 48-year-old male had severe respiratory symptoms, severe fatigue, and brain fog in the course of an acute SARS-CoV-2 infection. He did not require hospitalization and gradually improved over several weeks. Fatigue and exercise intolerance persisted. Clinical examination and imaging revealed severe cardiac dilatation with ongoing myocardial injury; heart biopsies indicated lymphocytic myocarditis. The patient was stable for several months but gradually developed severe congestive heart

failure. He died in hospital. Autopsy revealed marked fourchamber dilatation of the heart with diffuse myocardial fibrosis of the ventricles.

**Comment:** In this instance, the immediate cause of death was congestive heart failure, so it was reported on line a., which was due to the dilated cardiomyopathy reported on line b., which was a consequence of the lymphocytic myocarditis reported on line c. The UCOD was post-acute sequelae of COVID-19, so it was reported on line d., the lowest line used in Part I.

#### Scenario IV

	events-	CAUSE OF DEATH (See instructions and examples) diseases, injuries, or complications—that directly caused the death. DO NOT lar fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter of			Approximate interval: Onset to death
IMMEDIATE CAUSE (Final disease or condition>	a.	Congestive heart failure			weeks
resulting in death)		Due to (or as a consequence of):			
Sequentially list conditions,	b	Dilated cardiomyopathy			months
if any, leading to the cause		Due to (or as a consequence of):			
listed on line a. Enter the UNDERLYING CAUSE	c	Lymphocytic myocarditis			months
(disease or injury that		Due to (or as a consequence of):			
initiated the events resulting in death) <b>LAST</b>	d.	Post-acute sequelae of COVID-19			months
,					
PART II. Enter other significant of	ondition	s contributing to death but not resulting in the underlying cause given in PAR1	ГΙ	33. WAS AN AUTOPSY PERF	FORMED?
				■ Yes □ No  34. WERE AUTOPSY FINDIN	00 4)/411 401 5 70
				COMPLETE THE CAUSE OF	
35. DID TOBACCO USE CONT	RIBLITE	36. IF FEMALE:	37. MANNER		DEATH! Tes   NO
TO DEATH?		□ Not pregnant within past year		o. 52	
		2 Not program mamin past your	■ Natural	□ Homicide	
□ Yes □ Probably		□ Pregnant at time of death			
			□ Accident	□ Pending Investigation	
■ No □ Unknown		□ Not pregnant, but pregnant within 42 days of death	- 0	□ Could not be determined	
		□ Net were next, but we sweet 42 days to 4 years before death	□ Suicide	☐ Could not be determined	
		□ Not pregnant, but pregnant 43 days to 1 year before death			
		□ Unknown if pregnant within the past year			
•		•	•		

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#### **Vital Statistics Reporting Guidance**

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# HUGE! MN Senator and Dr. Reveals HHS Document Coached Him on How to Overcount COVID-19 Cases — WITH COPY OF DOCUMENT (VIDEO)

By Cristina Laila Apr. 8, 2020 3:50 pm 736 Comments

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**Dr. Scott Jensen**, a Minnesota physician and Republican state senator said he received a 7-page document coaching him to fill out death certificates with a COVID-19 diagnosis without a lab test to confirm the patient actually had the virus.

"Last Friday I received a 7-page document that told me if I had an 86-year-old patient that had pneumonia but was never tested for COVID-19 but some time after she came down with pneumonia we learned that she had been exposed to her son who had no symptoms but later on was identified with COVID-19, then it would be appropriate to diagnose on the death certificate COVID-19," Dr. Scott Jensen said.

Dr. Jensen explained that this is not a normal procedure.

Dr.. Jensen said for example if the same patient had pneumonia during flu season and he didn't have a test confirming the patient also had influenza, he would never diagnose the patient with influenza on the death certificate.

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#### WATCH:





SHOCKING: MN Sen & Dr. <u>@drscottjensen</u> said that he received a 7 pg doc from <u>@mnhealth</u> to fill out death certificates with a diagnosis of #COVID-19 whether the person actually died from COVID-19 or not.

Why is **#MN** inflating COVID-19 death numbers? **pic.twitter.com/llvHDoIMGH** 

- Chris Berg (@chrisbergPOVNOW) April 8, 2020

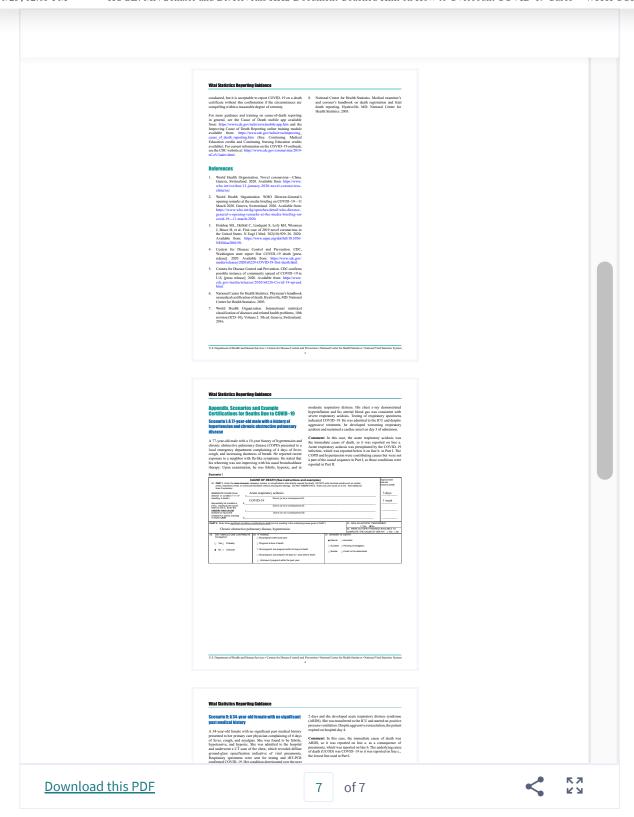
The Gateway Pundit has a copy of the HHS letter sent out to doctors across the country on counting COVID-19 victims.

The document is here.

US HHS Document to Doctors ... by Jim Hoft on Scribd







As TGP reported over the weekend, the amount of Americans who are reported to have died from the Coronavirus is based on a CDC coding system that will "result in COVID-19 being the underlying cause more often than not."





A new ICD code was established to keep track of Coronavirus deaths.

The U07.1 code will be used for death by Coronavirus infection.

However, there's another secondary code, U07.2, "for clinical or epidemiological diagnosis of COVID-19 where a laboratory confirmation is inconclusive or not available," the CDC guidelines read.

"The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not," the guidelines read.

Dr. Birx on Tuesday told a reporter during a Coronavirus task force briefing, "We've taken a very liberal approach to mortality."

"Can you talk about your concerns about deaths being misreported by Coronavirus because of either testing or standards for how they are characterized?" the reporter asked Birx.

"If someone dies with COVID-19, we are counting that as a COVID-19 death," Birx said.

There is a big difference between dying with the virus and from the virus.



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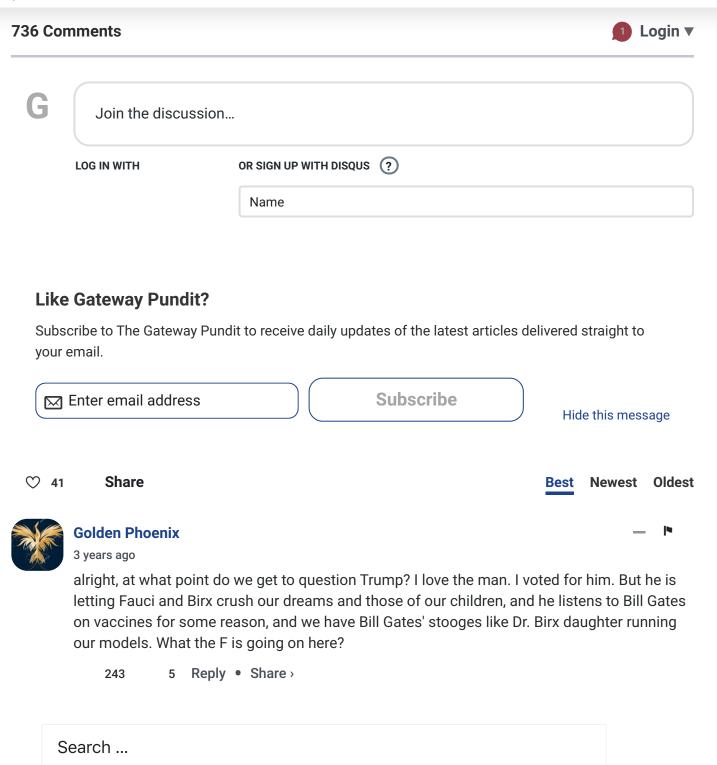
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