

April 11, 2022

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop S106-9
Atlanta, GA 30341
Attn: Docket No. CDC-2022-0024

Re: Docket No. CDC-2022-0024: CDC Clinical Practice Guideline for Prescribing Opioids

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Centers for Disease Control and Prevention (CDC) for the opportunity to submit comments regarding the Proposed 2022 **CDC Clinical Practice Guideline for Prescribing Opioids**.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO appreciates the opportunity to comment on the CDC Clinical Practice Guidelines for Prescribing Opioids. BIO requests that CDC consider the following revisions to language referencing naloxone to be consistent with more general and product agnostic references. Specifically, BIO recommends that references to naloxone be more generic, using phrasing/language such as: "***FDA-approved opioid overdose reversal medication***."

This type of language is currently incorporated into the SAMHSA FY 2022 Harm Reduction Program Grant (<https://www.samhsa.gov/sites/default/files/grants/pdf/fy22-harm-reduction-nofo.pdf>). In addition, at least ten states have incorporated similar, reversal medication agnostic language in co-prescribing legislation. The requested change reflects efforts to develop new/innovative reversal agents in response to a request by NIH leadership to: "...work with private partners to develop stronger, longer-acting formulations of antagonists.....to counteract the very-high-potency synthetic opioids that are now claiming thousands of lives each year" (N. Volkow and F. Collins, N Engl J Med 377:1798, 2017).

BIO proposes the following changes:

- p.4, line 69: from "naloxone" to "an FDA-approved opioid overdose reversal medication"
- p.11, line 244: from "naloxone" to "an FDA-approved opioid overdose reversal medication"
- p.24, line 524: from "naloxone" to "an FDA-approved opioid overdose reversal medication"
- p.71, line 1654: from "naloxone" to "an FDA-approved opioid overdose reversal medication"
- p.75, line 1725: from "naloxone" to "an FDA-approved opioid overdose reversal medication"

- p.89, line 2086: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.100, line 2380: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.102, lines 2441, 2448: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.108, line 2593: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.114, line 2726: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.125, lines 3023, 3031-3034, 3037-3039: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.126, lines 3074 (twice), 3084: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.127, lines 3096, 3100, 3102, 3103: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.133, line 3251 (twice): from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.134, line 3275, 3278: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.135, lines 3288, 3293-96: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.136, lines 3328, 3338: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.137, line 3350: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.141, line 3474: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.145, line 3569: from “naloxone” to “an FDA-approved opioid overdose reversal medication”
- p.154, line 3821: from “naloxone” to “an FDA-approved opioid overdose reversal medication”

Sincerely,

/s/

Camelia Thompson, Ph.D.
Senior Director, Science and Regulatory Affairs
Biotechnology Innovation Organization

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
I.	RECOMMENDATIONS	
	In this section, there should be mention of payers providing coverage to an FDA-approved opioid overdose reversal medication.	BIO recommends that the CDC consider including that all payers provide coverage to an FDA-approved opioid overdose reversal medication.
II.	BOX 1: CDC RECOMMENDATION FOR PRESCRIBING OPIOIDS FOR OUTPATIENTS WITH PATIN OUTSIDE OF SICKLE CELL DISEASE-RELATED PAIN MANAGEMENT, CANCER PAIN TREATMENT, PALLIATIVE CARE, AND END-OF-LIFE CARE	
	In Box 1, sickle cell patients are excluded.	BIO recommends that the CDC consider including sickle cell disease-related disease as part of the recommendations.