## Dragon, Karen E. (CDC/NIOSH/EID)

**From:** Alan Tice [alantice@idlinks.com]
**Sent:** Tuesday, September 13, 2011 3:40 AM
**To:** NIOSH Docket Office (CDC)
**Cc:** Monica Quen
**Subject:** Ryan White extension

( Docket#219 Public Comments
NIOSH Docket Officer
"Infectious Diseases"
"42 U.S.C.300jj-131")

Dear Ryan White Act People

I wrote you a letter about concerns I have and suggestions I had as a public comment on the extension of the Ryan Whte Act on February 6, 2011.

I have not heard back from you regarding the response that I believe is required.

Let me know what more I can do to help you understand the system and to develop a safe and inexpensive response to a variety of infections our Emergency Response Employees are exposed to in their valiant efforts to protect us all.

Please let me know where things stand with the law and the infections that will be covered are.

Have there been any attempts to enforce the regulations that were signed off by President Obama in 2009? Will there be penalties?

Thanks

cell 808-341-2020

Alan Tice, MD, FACP
**Infections Limited Hawaii**
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## Dragon, Karen E. (CDC/NIOSH/EID)

**From:** Spahr, James S. (CDC/NIOSH/OD)
**Sent:** Tuesday, September 13, 2011 10:51 AM
**To:** NIOSH Docket Office (CDC); alantice@idlinks.com
**Cc:** Dragon, Karen E. (CDC/NIOSH/EID)
**Subject:** RE: Ryan White extension

Dr. Tice
Thank you for your email concerning our progress in finalizing the reportable disease component within the Reauthorization of the Ryan White Act (RWA).
I know it seems like these things take a really long time to get accomplished.
The first time this was done it took four years, this time we will have it done in less than half that time.

The process involves five steps:
First, the delegation to do this work from HHS to the CDC - and then to NIOSH;
Second, the drafting of the proposed disease list and its posting into the NIOSH Docket for Public Comment;
Third, the review of the public comments and an adjudication process to review each comment and to include relevant comments into a final proposed disease listing;
Fourth, a departmental level review of the final draft listing by the CDC, HHS, the Office of the General Counsel, the Office for Civil Rights, and other White House offices; and
Fifth, the completion of any final revisions as a result of the departmental review, and the creation of the final disease listing which will be re-posted into the NIOSH Docket.
This posting will include the final list, a report on each public comment, as well as the two sets of related guidance documents which the Secretary of HHS delegated to CDC/NIOSH to develop to help clarify the changes in the disease listing and a description of the reporting options.

I am happy to report that we are at the fifth step.
I can also report:

1. That we received 83 public comments as a result of the Federal Register invitation to comment. Approximately half of these dealt with disease specific issues and the other half dealt with administrative issues.
2. The current final listing and guidance materials (23 pages) are tightly focus to achieve an updating of only that narrow scope of the delegation of duties tasked to the CDC.
3. The updated disease list includes all of the original diseases listed plus more than 10 new reportable conditions.
4. Diseases added to the list include: cutaneous anthrax, avian influenza, and other influenza strains with a pandemic severity index of 3 or greater, HCV, measles, mumps, pertussis, rubella, SARS-CoV, vaccinia, varicella, and select biowarfare agents (including smallpox).
5. In August, I provided a series of Ryan White Reportable Disease Update workshops to the attendees at the Redmond-Barbera Symposium in New York City.

I reviewed the comments that your organization provided to the Docket.
As you can see we did include select biowarfare agents but did not include MDROs after consultation with subject matter experts within the CDC.
Two of your other issues were administrative in nature, and were outside the limited scope of the delegation given to us by HHS.

Where comments were outside the scope of the new delegation, then the original RWA regulation language still holds. That is true for enforcement action.
An injunction could still be brought against any reporting facility which might willfully neglect this reporting requirement. Such an injunction would deny the facility the ability to receive further federal funds, and it actually quite a "big stick".
When the original RWA was implemented, the CDC never did actually have to resort to such actions.
We are hopeful that will again be the case this time around.

The final clearances and department approvals may take through the end of September or a tad longer, but once completed, and it is signed by the Office of the CDC Director, the list and guidance materials will be immediately posted in the FR (NIOSH Docket). Thirty days after that it become the final regulation.

NIOSH will have an informational topic webpage on the subject and the HHS/CDC will provide appropriate press announcements.

This all should happen "relatively" soon.

I hope this reply addresses your questions.

***JIM***

James S. Spahr, RS, DAAS, MPH
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**From:** Dragon, Karen E. (CDC/NIOSH/EID) **On Behalf Of** NIOSH Docket Office (CDC)
**Sent:** Tuesday, September 13, 2011 7:09 AM
**To:** Spahr, James S. (CDC/NIOSH/OD)
**Cc:** Dragon, Karen E. (CDC/NIOSH/EID)
**Subject:** FW: Ryan White extension

**Good morning ! Can you answer this e-mail or forward it to the correct person? Also, please let me know when it has been answered. Thanks, Karen**

Karen E. Dragon | Docket Office Specialist | NIOSH Docket Office | 4676 Columbia Parkway, C-34 | Cincinnati, OH 45226 | v:(513) 533-8303 | f: (513) 533-8285

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