Attachment C. Explanation of Changes to Data Collection Forms

Section A. New Forms and Associated Modules*

*Form revision details for existing forms mentioned below are included in Section B.

1. Patient Safety Component Device Associated Module −Central Line Insertion Practices Adherence Monitoring

This module will enable CDC and facilities to:

- Monitor central line insertion practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities. Facilities have the option of recording inserter-specific adherence data
- Link gaps in recommended practice with the clinical outcome (i.e., Central Line Associated Bloodstream Infections) both in individual facilities and for all participating facilities
- Facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing CLABSI rates.

To facilitate this additional collection of data, one new form is proposed:

- **Central Line Insertion Practices Adherence Monitoring Form (CDC 57.75JJ)**
  - Burden estimates – Total burden hours added are 12,500 at a cost of $433,125.00.

Modifications to the currently approved:

- **Patient Safety Monthly Reporting Plan (CDC Form 57.75A)** so that facilities may indicate their intention of monitoring Central Line Insertion Practices during the month.

2. Patient Safety Component – Multidrug-Resistant Organism (MDRO) Prevention Process Monitoring

This module will enable CDC and facilities to:

- Monitor processes and practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities
- Link gaps in recommended practice with the clinical outcome (i.e., MDRO infection) both in individual facilities and for all participating facilities
- Facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing MDRO infection rates.

In order to facilitate this additional collection of data, several new forms are proposed:

- **Multidrug-Resistant Organism Prevention Process and Outcome Measures Monthly Monitoring Form, (CDC 57.75LL)**

        - Burden estimates – Total burden hours added are 6,000 at a cost of $207,900.00
    - **MDRO Infection Event (CDC 57.75MM)**
        - Burden estimates – Total burden hours added are 54,000 at a cost of $1,871,100.00
    - **Laboratory-identified MDRO Event (CDC 57.75 NN)**
        - Burden estimates – Total burden hours added are 180,000 at a cost of $6,237,000
    - **Laboratory-identified MDRO Event – Summary Form (CDC 57.75TT).**
        - Burden estimates – Total burden hours added are 4,500 at a cost of $155,925.00.

Modifications to the currently approved:

- **Patient Safety Monthly Reporting Plan (CDC Form 57.75A)** so that facilities may indicate their intention of monitoring MDRO process and outcome measures during the month.

3. Patient Safety Component – High Risk Inpatient Influenza Vaccination

This module will enable CDC and facilities to:

- Monitor influenza vaccination practices for high risk patients and provide aggregate data in regard to the number of high risk patients receiving vaccination, those already vaccinated, and those who decline due to medical contraindications or other reasons
- Identify reasons that high risk patients are not receiving influenza vaccination.

In order to facilitate this additional collection of data, several new forms are proposed:

- **High Risk Inpatient Influenza Vaccination Monthly Monitoring Form – Method A (CDC57.75PP)**
    - Burden estimates – Total burden hours added are 120,000 at a cost of $4,158,000.00
- **High Risk Inpatient Influenza Vaccination Numerator Data Form - Method B (CDC 57.75QQ)**
    - Burden estimates – Total burden hours added are 20,833 at a cost of $721,863.45
- **High Risk Inpatient Influenza Vaccination Monthly Monitoring form - Method B (CDC 57.75RR)**
    - Burden estimates – Total burden hours added are 10,000 at a cost of $346,500.00
- **High Risk Inpatient Influenza Vaccination Denominator Data Form - Method B (CDC 57.75SS)**
    - Burden estimates – Total burden hours added are 10,417 at a cost of $360,949.05
- **High Risk Inpatient Influenza Vaccination Standing Orders Form – Optional (CDC 57.75VV).**

- Burden estimates – this is an optional form and is not reported to CDC.

4. The NHSN will be opening enrollment to any healthcare facility; therefore a registration form was needed. The **NHSN Registration Form (CDC Form 57.75OO)** was created to enable the NHSN to collect the necessary registration information.
    - Burden estimates – Total burden hours are 125 at a cost of $4,331.25.

5. Amendments to several forms that comprise the Patient Safety Component portion of NHSN are proposed:
    - The *Form Number* in the upper left corner was removed from all NHSN forms
    - All forms are being re-versioned to facilitate identification of revisions. New forms are identified with *Effective date xx/xx/200x*. Revised forms will be identified as *Rev. #, Effective date xx/xx/200x.*

6. The Healthcare Personnel Safety Component − Influenza Module
   This module will enable CDC and facilities to:
    - Monitor influenza vaccination coverage among healthcare personnel at individual facilities and provide aggregate coverage estimates for all participating facilities
    - Monitor progress towards attaining the Healthy People 2010 goal of 60% vaccination coverage among healthcare personnel
    - Monitor influenza vaccination coverage by ward/unit of the facility and occupational group so that areas or groups with low vaccination can be targeted for interventions
    - Monitor adverse reactions related to receipt of the vaccine or receipt of antiviral medications
    - Assess the characteristics of influenza vaccination programs pre- and post-influenza season to identify practices associated with high immunization rates.

   New data collection forms for this module are:
    - **Healthcare Worker Influenza Vaccination (CDC 57.75FF)**
        - Burden estimates – Total burden hours are 12,500 at a cost of $433,125.00
    - **Healthcare Worker Influenza Antiviral Medication Administration (CDC 57.75 GG)**
        - Burden estimates – Total burden hours are 1,250 at a cost of $43,312.50
    - **Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel (CDC 57.75HH)**
        - Burden estimates – Total burden hours are 25 at a cost of $866.25
    - **Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel (CDC 57.75 II)**

- Burden estimates – Total burden hours are 25 at a cost of $866.25.

Modifications to the currently approved forms are being proposed to provide additional information relevant to influenza vaccination:

- **Healthcare Personnel Safety Reporting Plan (CDC Form 57.75B)**
- **Healthcare Worker Demographic Data (CDC Form 57.75X)**
- **Healthcare Personnel Safety Component Facility Survey (CDC Form 57.75Za).**

7. Healthcare Personnel Safety Component - New CDC Form **57.75KK: Laboratory Testing**

Previously, baseline and follow-up data collection for healthcare worker laboratory results had been recorded on a single CDC Form 57.75V (Exposure to Blood/Body Fluids). For ease of use in the collection of multiple laboratory results the Laboratory Testing form was created.

- Burden estimates – Total burden hours are 3, 750 at a cost of $64,687.50.

Section B: Edits and Revisions

CDC Form 57.75C Patient Data

1. Added: (Since NHSN is an on-line system, this will actually be a drop-down list for all forms that include patient data). They are not required fields.

Ethnicity: ____ *Hispanic or Latino*

____ *Not Hispanic or Not Latino*

Race: (check all that apply)

____ *American Indian or Alaska Native*

____ *Asian*

____ *Black or African American*

____ *Native Hawaiian or Other Pacific Islander*

____ *White*

Burden:

Response time for completion: Included in the associated patient event forms.

Total burden hours: Included in the associated patient event forms.

CDC Form 57.75R Facility Contact Information

(Back)

1. Added contact field for Microbiology Laboratory Director/Supervisor in order to better communicate with laboratory personnel.

Burden

Response time for completion: Unchanged.

Total burden hours: Increased due to a larger number of respondents.

CDC Form 57.75S Patient Safety Component Annual Facility Survey

(Front)

1. The title of the form has been changed to **"Patient Safety Component Annual Facility Survey"** due to the addition of these facility types in the respondent universe:

Long Term Acute Care Hospital (LTACH)

Ambulatory Surgery Center (ASC)

Long Term Care Facility (LTCF)

2. Added two additional options for Facility Ownership: *Physician owned* and *Managed Care Organization*

3. Added two fields to collect *number of patient days* and *number of admissions* for Acute Care Hospitals.

4. Survey information relevant to these facilities has been added:

Long Term Acute Care Hospital (LTACH)

Setting: _____Within a hospital ____Freestanding

Number of beds set up and staffed:

a. Ventilator beds ____

b. High-observation beds ____

c. All other beds____

Ambulatory Surgery Center (ASC)

Setting: _____Within a hospital ____Freestanding

Total number of procedures: __ Percent of procedures that are surgical ___%

What percentage of your ambulatory surgery patients were discharged or transferred to the following places:

____% Home/Customary Residence ___% Recovery Care Center ___%Acute Care Hospital

Long Term Care Facility (LTCF)

Number of resident days_____ Average length of stay _____

(Back)

5. *NCCLS* has been changed to *CLSI (formerly NCCLS)* to reflect name change of this organization.

6. Two additional options for testing codes added in *Q3*: *2.1=Vitek 2, 3.1=BD Phoenix*

7. Based on results of the first data cut, *Q4* has been divided into 2 questions, *Q4* and *Q5*, to capture more clearly whether the method used to confirm vancomycin resistant staphylococci is the same or different from that used initially. Questions that follow have been renumbered to reflect this addition.
8. *Q6* (old Q5), *NCCLS* has been changed to *CLSI*

Burden

Response time for completion: Unchanged. While fields have been added to encompass more facility types, the amount of information entered for a particular facility remains about the same.

Total burden hours: Increased due to additional numbers of respondents.

CDC Form 57.75A Patient Safety Monthly Reporting Plan

(Front)

1. An additional category, *central line insertion practices (CLIP)* under the **Device-associated Module** has been added.

2. Under **Procedure-associated Module** the first field has been changed from *Procedures* to *Locations* to clarify the location of the procedure monitoring area.

(Back)

3. Two new modules have been added to the plan: **Multidrug-resistant Organism Module (MDRO)** and **Patient Influenza Vaccination Module.**

4. The **Multidrug-resistant Organism Module** includes two sections:

Active Surveillance Culturing (ASC) Option – collects ASC process and outcome measure fields including: *location, organism, ASC-timing, ASC-eligible, Incidence and Prevalence*

Process and Laboratory-Identified MDRO Event (LIME) Monitoring Option – collects process and laboratory identified event fields including: *location, organism, LIME, HH (hand hygiene), and GG (gown and gloves).*

5. The proposed **High Risk Patient Influenza Module** will allow facilities to monitor vaccination of high risk patients for influenza using either Method A or Method B.

Burden

Response time for completion: Increased 10 minutes per response due to the two additional modules.

Total burden hours: Increased due to additional numbers of respondents and additional response time for completion.

CDC Form 57.75D Primary Bloodstream Infection (BSI)

(Front)

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.
2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.
3. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module.
4. Under ***Risk Factors*** added *Location of Device Insertion* and *Date of Device Insertion* to capture the location of the patient at the time the device was inserted and therefore, the possible location of where the infectious agent may have been introduced.

Burden

Response time for completion: Increased 5 minutes per response due to additional collection of patient race/ethnicity, both NHSN and ICD-9-CM codes, and whether due to an MDRO.

Total burden hours: Significantly increased due to additional numbers of respondents with corresponding increases in numbers of events, and additional response time for completion of each form.

CDC Form 57.75G Pneumonia (PNEU)

(Front)

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.

2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.

3. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module to capture pneumonia due to MDRO.

4. Under ***Risk Factors*** Added *Location of Device Insertion* and *Date of Device Insertion* to capture the location of the patient at the time the device was inserted and therefore, the possible location of where the infectious agent may have been introduced.

5. In the ***Event Details*** Section, added *Specify criterion used:____* after:

_____Clinically defined pneumonia (PNU1)

_____Pneumonia with specific laboratory findings (PNU2)

_____Pneumonia in immunocompromised patients (PNU3)

Criterion refers to diagnostic algorithms: 57.75Ga "Any Patient – Pneumonia flow Diagram" and 57.75Gb "Infant and Children – Pneumonia Flow Diagram." These algorithms define the type of pneumonia event based on results of clinical, diagnostic and laboratory tests and ensure consistent definitions within and across multiple facilities and facilitates later data analysis.

Burden

Response time for completion: Increased 5 minutes per response due to additional collection of patient race/ethnicity, both NHSN and ICD-9-CM codes, and whether due to an MDRO. Diagnostic algorithms to define pneumonia event type had been used previously, but were not in flow diagram format. Therefore, these are not expected to impact the burden estimates.

Total burden hours: Significantly increased due to additional numbers of respondents with corresponding increases in numbers of events, and additional response time for completion of each form.

CDC Form 57.75H Urinary Tract Infection (UTI)

(Front)

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.

2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.

3. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module to identify Urinary Tract Infections (UTIs) due to MDRO.

4. Under ***Risk Factors*** Added *Location of Device Insertion* and *Date of Device Insertion* to capture the location of the patient at the time the device was inserted and therefore, the possible location of where the infectious agent may have been introduced.

5. In the ***Event Details*** Section, added:

Specify criterion used: ____Criterion 1____ Criterion 2 to *Asymptomatic bacteriuria (ASB).*

Specify criterion used: ___Criterion 1___ Criterion 2____(specify)___ Criterion 3 ____ Criterion 4____(specify) to *Symptomatic UTI (SUTI).*

Specify criterion used:____ Criterion 1____ Criterion 2____ Criterion 3__(specify) ____Criterion 4__(specify) to *Other UTI (OUTI).*

The criterion used for defining the event is contained in the Patient Safety Component Protocol and is based on clinical signs and symptoms and laboratory test results. This ensures consistent definitions within and across multiple facilities and facilitates later data analysis.

Burden

Response time for completion: Increased 5 minutes per response due to additional collection of patient race/ethnicity, both NHSN and ICD-9-CM codes, and whether due to an MDRO. Diagnostic criteria to define urinary tract infection event type had been used previously, but were not collected on the form. Therefore, these are not expected to impact the burden estimates.

Total burden hours: Significantly increased due to additional numbers of respondents with corresponding increases in numbers of events, and additional response time for completion of each form.

CDC Form 57.75N Surgical Site Infection

(Front)

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.

2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.

3. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module to identify Surgical Site Infections (SSIs) due to MDRO.

4. Added *Specify criterion used: _____* to each of the SSI Event Types:

Superficial Incisional Primary (SIP)

Superficial Incisional Secondary (SIS)

Deep Incisional Primary (DIP)

Deep Incisional Secondary (DIS)

Organ / Space: _____.

The criterion used for defining the event is contained in the Patient Safety Component Protocol and is based on clinical signs and symptoms and laboratory test results. This ensures consistent definitions within and across multiple facilities and facilitates later data analysis.

Burden

Response time for completion: Increased 5 minutes per response due to additional collection of patient race/ethnicity, both NHSN and ICD-9-CM codes, and whether due to an MDRO. Diagnostic criteria to define surgical site infection event type had been used previously, but were not collected on the form. Therefore, these are not expected to impact the burden estimates.

Total burden hours: Significantly increased due to additional numbers of respondents with corresponding increases in numbers of events, and additional response time for completion of each form.

CDC Form 57.75E Dialysis Event

(Front)

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.

2. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module to identify dialysis events due to MDRO.

3. Under the ***Risk Factors*** section, added *Date of Access* and *Don't Know* fields for each type of vascular access.

4. Changed *Blood culture* label to *Patient with a positive blood culture* and moved to the ***Event Details*** Section. Fields for *positive, negative, unknown, not done* under blood culture have been removed. Therefore, information is collected only on positive blood cultures.

5. Moved previous question: *If positive, suspected source of positive blood culture (check one): ___ Vascular access ___ A source other than the vascular access ___ Contamination ___ Uncertain* and *Pathogens Identified: ____ Y ____ N. If Yes, specify on reverse→,* and placed under *Patient with a positive blood culture*

6. In ***Event Details*** under *Problem(s)* section, expanded *Vascular access problem <u>without</u> infection* to specify whether it was: *Clotting __Bleeding ___Other.*.

7. In ***Event Details*** the following problems were removed from the list:

> *__ *Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)*
>
> * __ *Respiratory infection not meeting above criteria for pneumonia (e.g., bronchitis)*
> *__ *Urine culture with >100,000 organisms/ml with not more than 2 species isolated*
> *__ *Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc.)*
> **Blood culture (check one): ___ Positive ___ Negative ___ Unknown ___ Not done*

Burden

Response time for completion: Increased 3 minutes per response due to additional collection of patient race/ethnicity, addition of dates of vascular access insertion and expansion of question 6 to include a description of other access problem. The deletion of

some question 7 event details offsets some of the time of the capture of the additional items.

Total burden hours: Increased due to revised estimates of annual numbers of events per facility and slight increase in time for completion.

CDC Form 57.75I Custom Event

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.
2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.
3. Added event type: *MDRO Infection: ___Y ___N* prompted by the addition of the MDRO Module to capture events due to MDRO.
4. Added the following to ***Event Details***:

    Specific Event Type: _____

    Secondary Bloodstream Infection: ____ Y ____ N

    Died: ____ Y ____ N

    Event Contributed to Death: ____ Y ____ N

    Discharge Date: ____ / ____ / _____

Burden

No burden estimates since these events are not reported to CDC and forms are used at the discretion of the facility.

CDC Form 57.75P Antimicrobial Use and Resistance (AUR) - Microbiology Laboratory Data

1. Added an additional antimicrobial, *imipenem*, due to its increased usage in treating Gram negative organisms.

Burden

Response time for completion: Unchanged.

Total burden hours: Significantly increased due to increased numbers of respondents.

CDC Form 57.75Q Antimicrobial Use and Resistance (AUR) - Pharmacy Data

1. Newly available antibiotics *moxifloxacin* and *tigecycline,* added to list of *Parenteral Antibiotics.*

Burden

Response time for completion: Unchanged.

Total burden hours: Significantly increased due to increased numbers of respondents.

CDC Form 57.75O Denominator for Procedure

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.
2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.
3. Added option under ***Procedure Details*** to indicate that the procedure was for an implant and an option to specify implant type.
4. Two additional options added for *Spinal level*
5. Modification of original choices for *HPRO* (Hip Prosthesis): *Total* now reads *Total Primary*, *Partial* now reads *Partial Primary*, and *Revision* has been changed to specify *Total Revision* or *Partial Revision*.
6. Modification of original choices for *KPRO* (Knee Prosthesis): *Total* now reads *Primary (Total)* and *Revision* now reads *Revision (Total or Partial).*

Burden

Response time for completion: Increased 3 minutes per response due to additional collection of patient race/ethnicity and both NHSN and ICD-9-CM codes.

Total burden hours: Significantly increased due to increased numbers of respondents.

CDC Form 57.75EE Denominator for Custom Procedure

1. Added *Ethnicity* and *Race* fields for identification and analysis of trends within certain patient populations and sub-groups.
2. Changed *NHSN/ICD-9-CM Procedure Code* to separate fields: *NHSN Procedure Code* and *ICD-9CM-Procedure Code* to allow collection of each data element.
3. Added field under ***Procedure Details*** to indicate procedure was for *Implant* with a field to *specify* the implant type.

Burden

No burden estimates since these events are not reported to CDC and forms are used at the discretion of the facility.

CDC Form 57.75BB Dialysis Survey

CDC and CMS (Centers for Medicare and Medicaid) currently have OMB approved Dialysis Surveys. (CMS OMB No. 0920-0033) (CDC OMB No. 0920-0666) It is proposed that these two surveys be combined and administered through the NHSN.

The dialysis survey which would replace the current dialysis practices survey in the NHSN Patient-Safety Module, Device-Associated component would enable participating facilities and HHS (CDC and CMS) to:

a. Describe and compare frequent infection control staffing and resources available, and practices routinely used to prevent infections in dialysis patients.

b. Assess the potential for electronic capture of data to simplify surveillance activities for dialysis events in the future.

c. Monitor influenza and hepatitis testing practices and vaccination coverage among staff and patients in dialysis facilities.

Burden

Response time for completion: Unchanged.

Total burden hours: Unchanged.

Healthcare Personnel Safety Component Revisions

Amendments to several forms that comprise the Healthcare Personnel Safety Component portion of NHSN are proposed:

- The *Form Number* in the upper left corner was removed from all NHSN forms.
- All forms are being re-versioned to aid in identification of revisions. New forms are identified with "Effective date xx/xx/200x." Revised forms will be identified as "Rev. #, Effective date xx/xx/200x."

Burden

No change in burden associated with these revisions.

CDC Form 57.75B Healthcare Personnel Safety Reporting Plan

1. Changed *mm/yy – mm/yy* to *Month/Year*.

2. Deleted:

Healthcare Worker Exposure to Communicable Disease option

Disease Investigation Modules:

Tuberculosis (TB) Exposure Investigation

Communicable Disease Exposure Investigation (not TB)

Surveys:

Healthcare Worker Survey"

Healthcare Worker Survey Plan section

Added:

Healthcare Worker Vaccination Module:

Influenza

Burden

Response time for completion: No change.

Total burden hours: Increased due to increased numbers of respondents.

CDC Form 57.75V Exposure to Blood/Body Fluids

(Front)

1. Form name: Ending *s* removed from *Exposures*

2. Form has been revised to include section and question numbers so as to provide clarification for skip patterns.

3. ***Section I: General Exposure Information*** (formerly: General Exposure Information).

Q1 added: *Did the exposure occur in this facility? If no, specify name of facility in which the exposure occurred.*

Q7c: *Skin: Was skin intact?* moved from Section II – Mucous Membrane and/or Skin Exposure on the old form. Skip pattern included if the answer is *No.*

Q8: *Type of fluid/tissue involved in exposure: (check one). If body fluid, indicate one body fluid type:* Added a field for *Other.*

(Page 2 and 3)

Section II: Percutaneous Injury (formerly Section I: Percutaneous Injuries)

1. Former question: *What device or item caused the injury?* has been changed to Q*3. What needle or sharp object caused the injury?* Response choice categories have been reduced from 6 to 3.

Old categories:

Hollow-bore needles, Suture needles, Other Sharp objects, Glass, Other device or item, Additional device codes for dental/surgical injuries

New categories:

Hollow-bore needles, Solid sharp/Object, Other sharp object/device

One new option under *Hollow-bore needles*: *hemodialysis needle*

Hypodermic needle attached to a disposable syringe and *hypodermic needle attached to non-disposable syringe,* have been combined to a single option *hypodermic needle attached to a syringe.*

Hypodermic needle attached to I.V. tubing has been deleted.

*Suture needle, rod, extraction forceps (*now just *forceps)* and *elevator* have been moved to *Solid sharp/Object*.

Bone chip/chipped tooth and *Sharp object type unknown* have been moved to *Other sharp object/device.*

Capillary tube, medication ampule/vial/I.V. bottle, Pipette (glass), Slide, and *Specimen/test/vacuum tube* have been moved to *Other sharp object/device.*

2. *Brand name of device* has been changed to: *Q4. Manufacturer and Model*

3. *Was the needle or other sharp object involved in the injury intended to be a safety device?* has been changed to *Q5. Did the needle or other sharp object involved in the injury have a safety feature?*

Q5a. Response option for *Mylar wrapping/plastic* added.

4. Question: *Was training in proper use of the device provided to the injured person prior to the injury?* has been deleted.

5. Question: *How did the injury occur?* has been changed to a series of questions and the responses extensively revised to answer the new questions (see detail table below of old and new questions and responses):

Q7. For what purpose or activity was the sharp device being used?

Q8. What was the activity at the time of injury?

Q9. Who was holding the device at the time the injury occurred?

Q10. What happened when the injury occurred?

Old Form Version	**New Form Version**
How did the injury occur (circle up to 2) While manipulating patient or needle/sharp 01. Patient moved and jarred device 02. While inserting needle in patient 03. While inserting needle in line 04. While manipulating needle in patient 05. While manipulating needle in line 06. While withdrawing needle from patient 07. While withdrawing needle from line 08. Passing or transferring equipment While in operative field or during suturing procedures or autopsy: 09. Suturing	7. For what purpose or activity was the sharp device being used? (check one) *Obtaining a blood specimen percutaneously* ____ Performing phlebotomy ____ Performing arterial puncture ____ Performing a fingerstick/heelstick ____ Other blood-sampling procedure (specify) _____ *Giving a percutaneous injection* ____ Giving an IM injection ____ Giving a SC injection ____ Placing a skin test (e.g., tuberculin, allergy, etc.) *Performing a line-related procedure* ____ Inserting or withdrawing a catheter

10. Tying sutures 11. Manipulating suture needle in holder 12. Incising 13. Palpating/Exploring 14. Passing or receiving equipment Handling equipment or specimens 15. Handling equipment on a tray or stand 16. Transferring blood/body fluids into specimen container 17. Processing specimens 18. Passing or transferring equipment 19. Recapping (missed or pierced cap) 20. Cap fell off after recapping 21. Activating safety device 22. Disassembling device or equipment 23. Decontamination/processing of used equipment 24. During clean-up 25. In transit to disposal 26. Opening/breaking glass containers Collision/contact with sharp object 27. Collided with co-worker or other person 29.[sic] Sharp object dropped 30. Struck by detached I.V. line needle Disposal related: 31. While placing sharp in container, injured by sharp being disposed 32. While placing sharp in container, injured by sharp already in container 33. While manipulating container 34. Over-filled sharps container 35. Punctured sharps container 36. Protruding from opened container Sharps in unusual locations: 37. In trash 38. In linen/laundry 39. Left on table/tray 40. Left in bed/mattress 41. On floor 42. In pocket/clothing 43. Other unusual location Other circumstances: 44. Other 45. Unknown	____ Obtaining a blood sample from a central or peripheral I.V. line or port ____ Injecting into a line or port ____ Connecting I.V. Line *Performing surgery/autopsy/other invasive procedure* ____ Suturing Specify procedure:_____ ____ Incising ____ Palpating/exploring 8. What was the activity at the time of injury? *Handling device/equipment or specimen* ___Handling equipment ___Recapping ___Transferring/passing/receiving device ___Disassembling device/equipment ___Decontamination/processing used equipment ___Opening/breaking glass container (ampule) ___Performing procedure *Disposing device* ___Placing sharp in container *Housekeeping/patient-care activities, not described above* ___Cleaning room ___Collecting/transporting waste *Other (specify)* 9. Who was holding the device at the time the injury occurred? ___Exposed person ___Co-worker/other person ___No one – the sharp was an uncontrolled sharp in the environment 10. What happened when the injury occurred? ___Patient moved and jarred device ___Device slipped ___Device rebounded ___Sharp was being recapped ___Collided with co-worker or other person ___Overfilled/punctured sharps container ___Improperly disposed sharp ___Other ___Unknown

(Page 4)

Section III: Mucous Membrane and/or Skin Exposure (formerly: Section II)

If skin exposure, was skin intact? has been moved to **Section 1 – General Exposure Information**, Question 7c.

Q2. Options remain the same but have been ordered alphabetically

Q3. Options remain the same but have been ordered alphabetically

Section IV: Bite (formerly: Section III):

Q2. Options remain the same but have been re-ordered.

(Page 5)

Section V: Source information (formerly: Source Information):

This section has been moved from page 2 to page 5.

Q3. *NT=not tested* option added

Section VI: For HIV Infected Source (formerly: For HIV Infected Source):

Q4. Viral load: option for *Undetectable* has been added.

(Page 6)

Old section: Follow-up Care Given to Healthcare Worker has been divided into two sections: **Section VII: Initial Care Given to Healthcare Worker** and **Section VIII: Follow-up**

Question: *Indicate if the HCW has missed time from work due to the exposure* has been deleted.

Question: *Is it recommended that the HCW return to employee health for follow-up of this exposure?* has been changed to: *Is it recommended that the HCW return for follow-up of this exposure? 1.a. If yes, will follow-up be performed at this facility?* This question has been moved to section VIII.

Lab Results – this section has been deleted. Baseline and follow-up laboratory testing results are now collected on CDC Form 57.75KK: "Laboratory Testing."

Section X: Narrative (formerly Section V): Moved before Prevention section

Section XI: Prevention (formerly Section IV): Moved after Narrative section.

CDC Form 57.75W Healthcare Worker Postexposure Prophylaxis

(Front)

1. *PEP ID#* field renamed to *MedAdminID*

2. Field added to collect the name of the *Infectious Agent* involved in the exposure event

3. Text field *Indication: Prophylaxis* added to clarify that the drugs entered in these fields are intended for prophylaxis only.

4. (*2) Regimen Change* sections re-named *PEP Change 1* and *PEP Change 2*

5. *Adverse Signs and Symptoms* section re-named *Adverse Reactions*

6. Instruction box at bottom of form deleted

Burden

Response time for completion: No change.

Total burden hours: Increased due to increased numbers of respondents.

CDC Form 57.75Za Healthcare Personnel Safety Component Facility Survey

(Front)

Added fields:

Total number of part-time personnel

Total number of full-time personnel

Burden

Response time for completion: Increased 2.5 hours due to revised estimates of the time it takes to collect the information.

Total burden hours: Increased due to increased numbers of respondents and added time for response.

CDC Form 57.75Z Implementation of Engineering (safety devices) Controls for Sharps Injury Prevention

Device Types have been revised to reflect those currently in use

Fields: *Your Code*, *Safety Feature*, and *Manufacturer and Model* replace old fields: *Safety Device Name* and *Safety Device Code*

Device Implementation and *Device Discontinuation* fields have additional column added for *Yr* designation

Burden

Response time for completion: Unchanged.

Total burden hours: Increased due to increased numbers of respondents.