MEDICAL REVIEW OFFICER (MRO) GUIDANCE MANUAL: STATUS FOR URMG AND OFMG MANDATORY GUIDELINE UPDATES

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DRUG TESTING MANDATORY GUIDELINES UPDATES

The Department of Health and Human Services (HHS) published the following Federal Register notices October 12, 2023:

Urine Mandatory Guidelines (UrMG)

- *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) with revised standards and technical requirements with an effective date of February 1, 2024*

Oral Fluid Mandatory Guidelines (OFMG)

- *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) with revised standards and technical requirements with an effective date of October 10, 2023*

MAJOR CHANGES - URINE MANDATORY GUIDELINES *FEBRUARY 1, 2024*

- *Raised morphine confirmatory cutoff to 4,000 ng/mL*
- *Publish a separate FRN annually with drug testing panel, biomarker testing panel, and required nomenclature*
- *Report Substituted (not Invalid) based on biomarker testing*
- *Require MRO semiannual summary reports to SAMHSA*
- *Requirements for a federal agency regarding use of an MRO*
- *MRO verification of positive codeine/morphine specimens (removed 15,000 ng/mL threshold to report positive)*
- *Apply same "refusal to test" criteria for all donors*
- *Medical Review Officer Review/Verification– additional edits*

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MAJOR CHANGES - URINE MANDATORY GUIDELINES
FEBRUARY 1, 2024

Additional section 13.5 MRO Review/Verification edits:

- *Added in item (c)(2) that, for specimens with multiple results, the MRO takes action for an invalid result when the specimen's other results (positive, adulterated, or substituted) are verified negative based on a legitimate medical explanation.*
- *Added new item (d)(1) stating that the MRO reports a positive result when the donor admits unauthorized use of the drug(s) that caused the positive test result. Added that the MRO must document the donor's admission of unauthorized use in the MRO records and the report to the federal agency.*
- *Revised items (d)(2)(i) and (ii) to apply to any positive urine drug test results, not only positive marijuana results: item i re passive exposure, item ii re ingestion of food products containing a drug.*
- *Added item (d)(2)(iii) stating that a physician's authorization or medical recommendation for a Schedule I controlled substance is not an acceptable medical explanation for a positive drug test.*
- *Revised (f)(2(ii) re when a recollection after invalid is still invalid, MRO cancels test and recommends recollection of different specimen type. Added: if agency does not authorize another specimen type, MRO consults with agency to arrange clinical evaluation to determine if there is a valid medical reason for the invalid result.*

MAJOR CHANGES - ORAL FLUID MANDATORY GUIDELINES *OCTOBER 10, 2023*

- *Publish a separate FRN annually with drug testing panel, biomarker testing panel, and required nomenclature*
- *Report Substituted (not Invalid) based on biomarker testing*
- *Require MRO semiannual summary reports to SAMHSA*
- *Requirements for a federal agency regarding use of an MRO*
- *MRO verification of positive codeine/morphine specimens (negative <150 ng/mL threshold)*
- *Apply same "refusal to test" criteria for all donors*
- ***Collection Devices***
- *Medical Review Officer Review/Verification– additional edits*

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MAJOR CHANGES - ORAL FLUID MANDATORY GUIDELINES *OCTOBER 10, 2023*

Additional section 13.5 MRO Review/Verification edits:

- *Added in item (c)(2) that, for specimens with multiple results, the MRO takes action for an invalid result when the specimen's other results (positive, adulterated, or substituted) are verified negative based on a legitimate medical explanation.*
- *Added new item (d)(1) stating that the MRO reports a positive result when the donor admits unauthorized use of the drug(s) that caused the positive test result. Added that the MRO must document the donor's admission of unauthorized use in the MRO records and the report to the federal agency.*
- *Revised item (c)(2)(i) re ingestion of food products containing a drug to apply to any positive drug test results, not only positive marijuana results; added wording to include the exceptions for positive codeine and morphine.*
- *Added item (c)(2)(iii) stating that a physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate explanation for a positive drug test result.*
- *Revised (e)(2)(ii) re when a recollection after invalid is still invalid, MRO cancels test and recommends recollection of different specimen type. Added: if agency does not authorize another specimen type, MRO consults with agency to arrange clinical evaluation to determine if there is a valid medical reason for the invalid result.*

DOCUMENT SUITE (URINE AND ORAL FLUID)

DOCUMENTS REQUIRING UPDATES *PRIOR* TO EDIT-UPDATES TO MEDICAL REVIEW OFFICER GUIDANCE MANUAL (MRO MANUAL)

SAMHSA – Center for Substance Abuse Prevention (CSAP)

- *Mandatory Guidelines (MG): UrMG, OFMG*
- *Federal Custody Control Forms, Paper and Electronic (CCF, ECCF)*
- *Collection Handbooks, Collection Site Manuals, Collection Site Checklist*

National Laboratory Certification Program (NLCP)

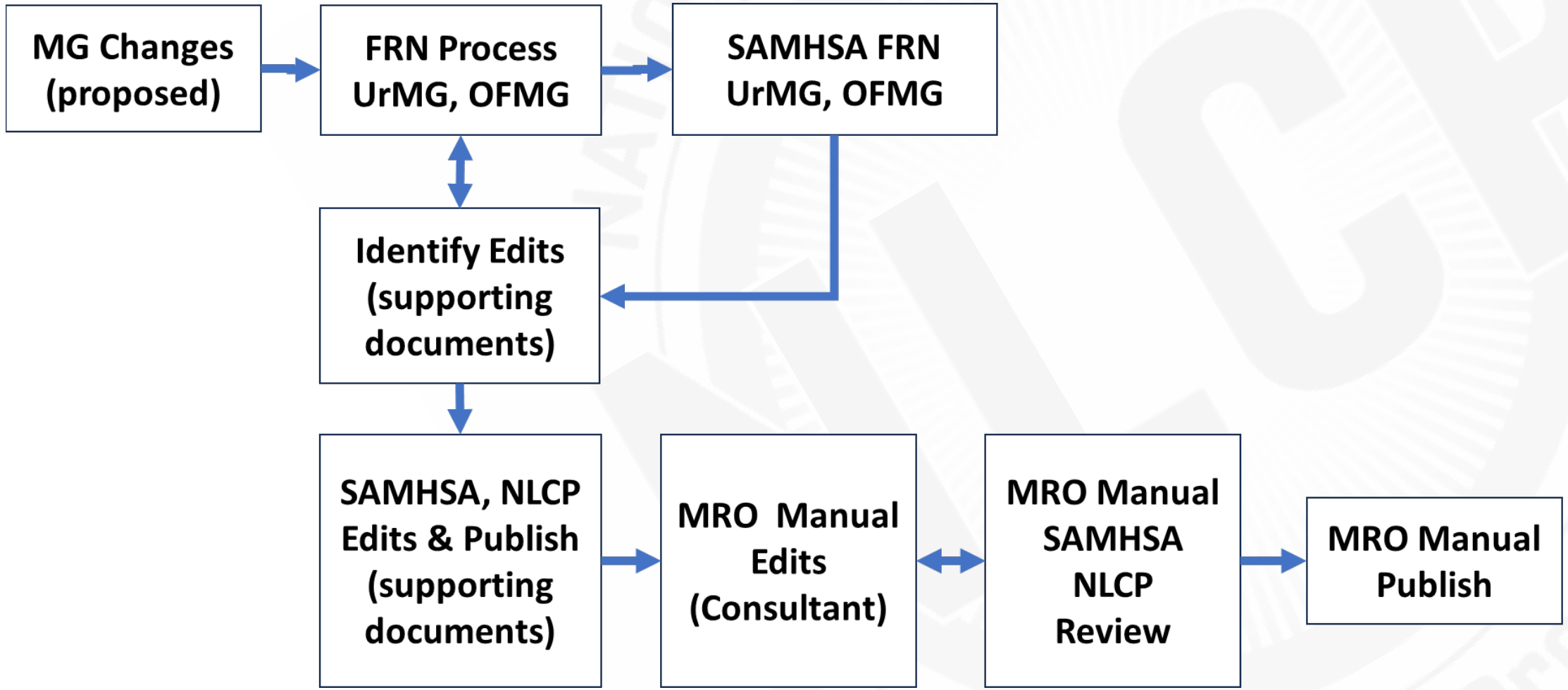
- *Instrumented Initial Test Facility (IITF): Urine Manual, Urine IITF Checklists*
- *Laboratory: Urine Manual, Urine Laboratory Checklists*
- *Laboratory: Oral Fluid Manual, Oral Fluid Laboratory Checklists*

MRO MANUAL - CHANGES

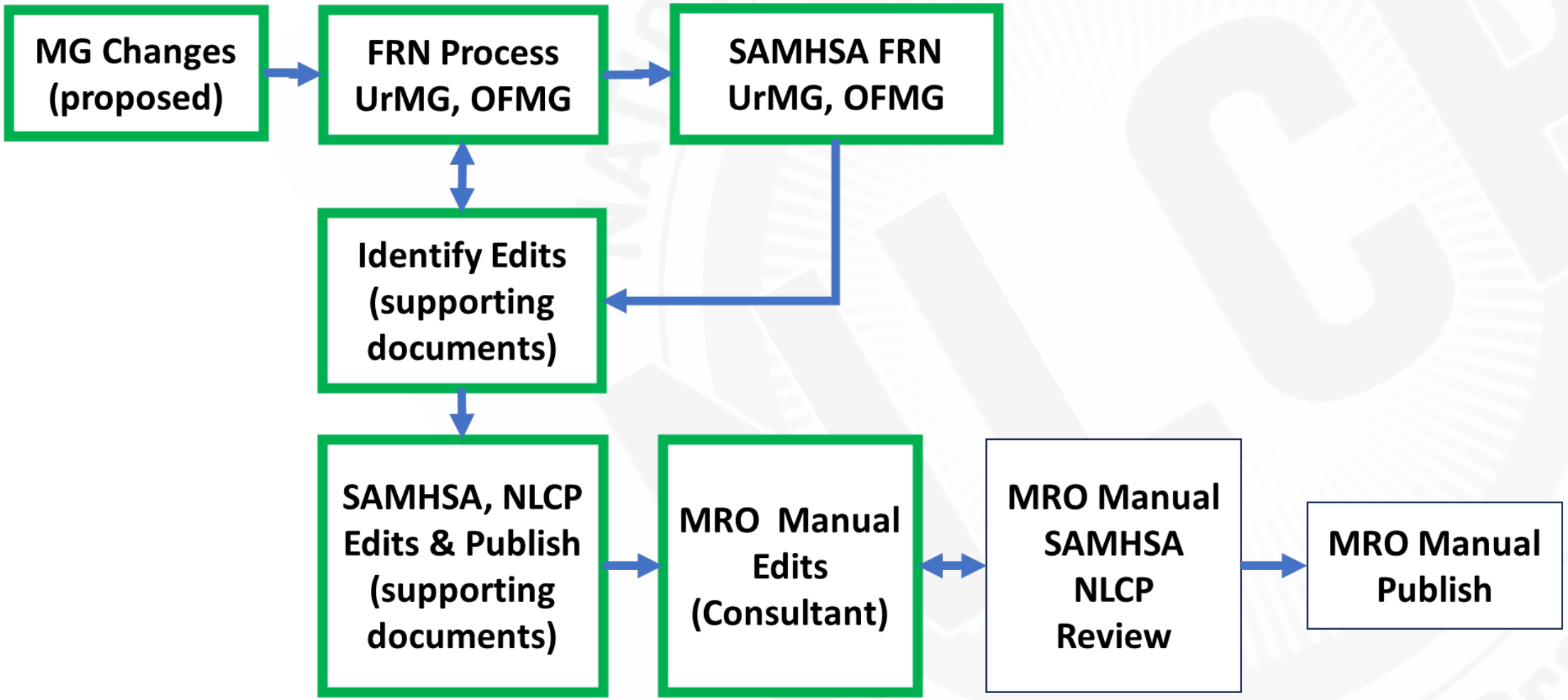
MAJOR CHANGES (PREVIOUS SLIDES) AND ADDITIONAL CHANGES:

- *Align language to match UrMG, OFMG*
- *Update Tables for MRO actions (Bottle A, Split Bottle B, re-tests, refusal,…)*
- *Update Ur and OF Case studies to support major changes*
- *Update CCF illustration*
- *Add additional information to alert MROs of additional agency-specific reporting and collection-based non-MRO determinations (e.g., refusal to test not reviewed by MRO)*
- *Expired CCFs and actions taken*
- *Update CBD information*
- *Delete confirmatory amphetamine qualifier for reporting methamphetamine*

MRO MANUAL – CHANGE PROCESS



MRO MANUAL – CHANGE PROCESS



MRO MANUAL – CHANGE TIMELINE

NOVEMBER 2022 → **REVISION DATE TARGET: DECEMBER 2023**

TAKE-HOME MESSAGES

MRO Guidance Manual

- *Supporting document based upon **but does not replace** current versions of SAMHSA and NLCP guidelines and manuals.*
- *Support resource integrating DTAB SME inputs for drug metabolism and results interpretation*
- *Depends upon completion of SAMHSA and NLCP publications = MRO Manual is last in line for publication*

Thank you