ADHERENCE CHECKLISTS AND MONITORING PROCEDURES

The following MM checklists are intended to be used both as an aid to the MM Clinician to follow in conducting the visits, and also as a means of tracking clinician adherence to MM treatment as it is outlined in the manual. Sessions will be audiotaped and rated for adherence by a trained rater. Note that the MM adherence checklists cover all phases of the MM intervention. Check off only those activities actually completed in the session. Where another staff member is responsible at your site for something on the checklist (i.e., BAC and vital signs), indicate NA on the form. Please feel free to add comments to the forms to document extraordinary circumstances or interactions that were not captured on the audiotape.

Detailed Adherence Checklists for Initial Session .............................................................. B-2

Detailed Adherence Checklists for Follow-up Session ...................................................... B-6

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Brief Checklist for Medical Attention Visit ................................................................. B-13

Monitoring Procedures ................................................................................................ B-14
MM INITIAL SESSION: ADVANCE PREPARATION

A. REVIEW OF CLINICIAN REPORT FORM INFORMATION

<table>
<thead>
<tr>
<th>1. Medical Information: Double check lab report, and record any other drinking-related medical symptoms as noted on physical examination or lab reports.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Alcohol Use: Record the number of drinking days per week, and average number of drinks per drinking day.</td>
</tr>
<tr>
<td>3. Consequences of Drinking: Record 1-3 negative consequences acknowledged by the patient. Select items with the highest score or impact to discuss as examples of drinking-related problems.</td>
</tr>
<tr>
<td>4. Diagnostic Information: Review Symptoms of Alcohol Dependence</td>
</tr>
</tbody>
</table>

B. PREPARE CHART MATERIAL

<table>
<thead>
<tr>
<th>1. Vital Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Concurrent Medication</td>
</tr>
<tr>
<td>3. SAFTEE</td>
</tr>
<tr>
<td>4. Menstrual Calendar</td>
</tr>
<tr>
<td>5. Patient Medication Information Sheets</td>
</tr>
<tr>
<td>6. Medication Compliance Plan</td>
</tr>
<tr>
<td>7. AA Materials</td>
</tr>
<tr>
<td>8. Emergency Contact Cards</td>
</tr>
<tr>
<td>9. Patient Instructions for Managing Side Effects</td>
</tr>
<tr>
<td>10. Find out if the participant is assigned to CBI</td>
</tr>
</tbody>
</table>
C. MM INITIAL SESSION: INTRODUCTION

1. Introduce yourself and your role.

2. Take vital signs, BAC. (If done by other staff, note NA)

3. Give structuring statement – an hour this session, then 8 more visits to see how you are doing.

4. Administer Concurrent Medication Form (wherever appropriate in the session). Ask specifically about NSAID use.

5. Administer the SAFTEE wherever appropriate in the session (this can be done early in the session or following the feedback). Get birth control information and complete the Menstrual Calendar if appropriate.

D. MM INITIAL SESSION: FEEDBACK

1. **Give structuring statement**: What I’d like to do next is tell you some of what we learned from your evaluation [Explain 4 areas you will cover: physical, amount of drinking, drinking-related problems, and symptoms of alcohol dependence].

2. **Explain briefly what the liver does, and how alcohol can affect it** (i.e., fat deposits, inflammation, scarring, and destruction of liver).

3. Review blood pressure reading, liver enzymes, any abnormal lab values, and other drinking-related medical symptoms. State your medical opinion of how alcohol is affecting the patient physically.

4. **Review drinking pattern date (from Form-90)**. On average, you have been drinking ___ days per week, and on days when you drink you have had an average of ___ drinks. State that this level of drinking has negative impact on patient. It is not necessary to discuss the quantity/frequency data at all. If it is discussed, the source of the data should be given (the Form 90) and the data should be presented as feedback and not opened for correction. The important thing is to avoid arguments about the amount.

5. Review consequences of drinking (by selecting three good examples of items marked on the DrInC). State your impression of the patient’s negative consequences.

6. Review the specific dependence criteria that the participant met. Repeat that together these symptoms confirm alcohol dependence, and that this diagnosis applies to the patient.

7. Pull together the physical, drinking, problem, and dependence feedback and draw your conclusions about problem severity.

8. Make your medical recommendation that the participant stop drinking.

9. If long-term abstention is resisted, recommend a trial period of abstinence. Note NA if already agreed to abstinence above.
### MM INITIAL SESSION: Medical Compliance

1. **Provide rationale for pharmacotherapy.** Explain that these medications have been found to work to help people to maintain abstinence, e.g., seems to reduce urges or desire to drink.

2. **Distinguish from other types of drugs** (disulfiram, addicting drugs, medications used in detoxification.). Address any misconceptions.

3. **Provide medication information sheets.**
<table>
<thead>
<tr>
<th>Step</th>
<th>Task Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Explain what is known about how the medication works. Explain possible side effects and their likelihood. Explain that these medications take some time to take effect – don’t expect immediate effects.</td>
</tr>
<tr>
<td>5.</td>
<td>Administer SAFTEE prior to giving the participant initial dose of medication.</td>
</tr>
<tr>
<td>6.</td>
<td>Observe participant take the morning dose (allow 20 minutes to watch for negative reaction)</td>
</tr>
</tbody>
</table>
| 7.   | Explain dosing: check separately.  
- a. Typically, 4 pills in morning, 2 pills at midday, 2 pills in evening.  
- b. Pills can be taken with food if desired  
- c. Explain what to do about missed doses, lost medication, etc.  
- d. Explain that there must be at least 2 hours between doses  
- e. Explain that pills cannot be crushed  
- e. Give patient handout on Patient Instructions for Managing Side Effects (Appendix C-8) |
| 8.   | Explain emergency procedures and provide emergency contact cards (1 for patient and 1 for significant other). |
| 9.   | Provide basic rationale for compliance & monitoring. Taking the full dosage as prescribed increases the effectiveness of medications. Advise the participant that the RA will be following up on medications taken at each MM session. |
- a. Discuss possible problems in taking medications properly, where applicable.  
- b. Decide level of need for plan for pill taking.  
- c. Decide on strategies to remember pills.  
- d. Record the personal medication compliance plan.  
- e. Tell participant that the plan will be revised, if needed. |
| 11.  | Advise participant to return blister packs at each visit, even if all pills are not taken. |
F. INITIAL SESSION WRAP-UP

<table>
<thead>
<tr>
<th>1. Summarize diagnosis briefly and recommendation of abstinence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Recommend support groups as an aid to change.</td>
</tr>
<tr>
<td>3. Provide literature on local support groups. Problem-solve attendance obstacles as necessary.</td>
</tr>
<tr>
<td>4. If participant is also assigned to CBI, complete MM Treatment Coordination Checklist and forward to PC</td>
</tr>
<tr>
<td>5. Communicate the number of pills prescribed to the RA</td>
</tr>
<tr>
<td>6. Schedule next session.</td>
</tr>
<tr>
<td>7. Advise participant that you will call in 3 days (when appropriate in session)</td>
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</table>
### G. MM SUBSEQUENT SESSIONS CHECKLIST PART I

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Take participant’s vital signs, BAC (if done by other staff, note NA).</td>
</tr>
</tbody>
</table>
| 2. | How have you been since our last visit? What was difficult? What went well?  
   If drinking has not been mentioned by the participant, specific questions should be asked:  
   How well were you able to keep from drinking? |
| 3. | **Medical Status**  
   -a. Record Concurrent Medication use (Ask specifically about NSAID use)  
   -b. Administer SAFTEE (from last visit)  
   -c. Complete Menstrual Calendar and get birth control information  
   -d. (as needed) complete Serious Adverse Event Report, if necessary  
   -e. (as needed) complete Inactive Status Form, if necessary  
   -f. (as needed) complete Active Status Form, if necessary  
   -g. (as needed) report lab results, when appropriate |
| 4. | Ask whether participant’s returned blistercard. Praise participant for medications taken.  
   Examine the blistercard and make sure that medications missing were actually taken. |
| 5. | Inquire about any skipped doses (even if pills appear taken). Query relation of skipped doses to any drinking. |
| 6. | Determine what treatment scenario is applicable, check which applies and complete appropriate Subsequent Visit Checklist Part II:  
   - Abstinent/medication compliant  
   - Abstinent/non-compliant  
   - Non-abstinent/medication compliant  
   - Non-abstinent/non-compliant |
| 7. | If participant is in CBI, complete the MM Treatment Coordination Checklist and forward to PC |
| 8. | Communicate the number of pills prescribed to the RA |
H. MM SUBSEQUENT SESSIONS CHECKLIST PART II

If abstinent and medication compliant (A/C):

| 1. Reinforce ability to stick to the plan. Praise progress. Ask how patient did it. |
| 2. Remind the participant it is necessary to continue to take all medications and attend sessions until the end of treatment. |
| 3. Review benefits of abstinence. |
| 4. Complete Medication (Non) Compliance Checklist |
| 5. Provide support. |
| 6. Reinforce or inquire about AA or other support group attendance. Note as not willing to consider (NWTC) if the patient is adamantly opposed. |
| 7. Conclude visit on a positive note, with general encouragement and praise. |
I. MM SUBSEQUENT SESSIONS CHECKLIST PART II

Non-abstinent and medication compliant (NA/C):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Reinforce participant for taking medication.</td>
</tr>
<tr>
<td>2.</td>
<td>Review the CRF to remind the patient of why s/he sought treatment.</td>
</tr>
<tr>
<td>3.</td>
<td>Praise small steps of progress.</td>
</tr>
<tr>
<td>4.</td>
<td>Review benefits of abstinence (in general terms).</td>
</tr>
<tr>
<td>5.</td>
<td>Complete the Medication (Non) Compliance Checklist</td>
</tr>
<tr>
<td>6.</td>
<td>Remind participant medications work gradually over time.</td>
</tr>
<tr>
<td>7.</td>
<td>Review the benefits of other aspects of treatment (CBI/support group)</td>
</tr>
<tr>
<td>8.</td>
<td>Reinforce or inquire about AA or other support group attendance. Note here as not willing to consider (NWTC) if patient is adamantly opposed.</td>
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<tr>
<td>9.</td>
<td>Conclude visit on a positive note, with general encouragement and praise.</td>
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</table>
J. MM SUBSEQUENT VISITS CHECKLIST PART II

If abstinent and medication non-compliant (A/NC):

<p>| | |</p>
<table>
<thead>
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<tbody>
<tr>
<td>1.</td>
<td>Reinforce participant for remaining abstinent.</td>
</tr>
<tr>
<td>2.</td>
<td>Review general benefits of abstinence, and how medications help abstinence.</td>
</tr>
<tr>
<td>3.</td>
<td>Probe why medications are not taken regularly – problem-solve.</td>
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<tr>
<td>4.</td>
<td>Emphasize that taking medications faithfully can improve chances of staying abstinent.</td>
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<tr>
<td>5.</td>
<td>Complete Medication (Non) Compliance Checklist</td>
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<tr>
<td></td>
<td>-a. review common reasons for non-compliance</td>
</tr>
<tr>
<td></td>
<td>-b. reconstruct Medication Compliance Plan (as needed)</td>
</tr>
<tr>
<td>6.</td>
<td>Reinforce or inquire about AA or other support group attendance. Note here as not willing to consider (NWTC) if patient is adamantly opposed.</td>
</tr>
<tr>
<td>7.</td>
<td>Conclude visit on a positive note, with general encouragement and praise.</td>
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</table>
### K. MM SUBSEQUENT SESSIONS CHECKLIST PART II

Non-abstinent and medication non-compliant (NA/NC):

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>1.</strong> Reinforce participant for any progress you see (including coming in for session).</td>
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<tr>
<td><strong>2.</strong> Review the benefits of abstinence, and review reasons for stopping (from initial session CRF).</td>
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<tr>
<td><strong>3.</strong> Encourage “Give treatment a chance”.</td>
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<tr>
<td><strong>4.</strong> Emphasize that taking medication faithfully can improve chances of staying abstinent.</td>
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<tr>
<td><strong>5. Complete Medication (Non) Compliance Checklist. If primarily due to problems taking medications then:</strong></td>
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<td><strong>6. If participant no longer motivated to stop or reduce drinking, then:</strong></td>
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<tr>
<td><strong>7. Reinforce or inquire about AA or other support group attendance. Note here as not willing to consider (NWTC) if patient is adamantly opposed.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>8. Conclude visit on a positive note, with general encouragement and praise.</strong></td>
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</tbody>
</table>
L. Brief Checklist for Initial Session

_____ Introduce yourself and your role, check vitals, give overview and timeline of intervention

_____ Conduct baseline SAFTEE (reference last 90 days)

_____ Complete Concurrent Medication Form (reference last 90 days). Ask specifically about NSAIDs.

_____ Complete Menstrual Calendar (indicate NA if not appropriate)

_____ Provide Feedback from CRF (Vital Signs, lab results, drinking related symptoms, drinking pattern and consequences, dependence criteria)

_____ Provide Information (importance of the liver and how it works, effects of alcohol, diagnostic information, reasons for abstinence)

_____ Give professional opinion about severity of the problem

_____ Recommend abstinence

_____ Ask participant for commitment to abstinence (if participant is unwilling to commit to long-term abstinence, restate the rationale for and seek agreement to abstinence for duration of study)

_____ Explain purpose and function of medications, and provide Medication Information Sheets

_____ Discuss likelihood of side effects and give Patient Instructions for Managing Side Effects

_____ Explain proper medication use (extra doses, 2 hrs between doses, don’t crush, can take with food, morning dose always first) and give first dose (allow 20 mins for observation)

_____ Give Medical Emergency Cards and explain emergency procedures

_____ Provide rationale for and complete Medication Compliance Plan

_____ Briefly review diagnosis, recommendation, and plan

_____ Encourage AA/support group attendance, give list of local meetings

_____ Schedule next visit and discuss 3-day phone call (prepare Day 3 Phone Contact Form)

_____ Complete MM Treatment Coordination Checklist (if appropriate) and Session Record Form
M. Brief Checklist for Follow Up Session

_____ Review Vital Signs and BAC with participant

_____ Conduct brief assessment of drinking, medication compliance, and general function

_____ Complete Concurrent Medication Form. Ask specifically about NSAIDs.

_____ Conduct SAFTEE (reference time since last visit) (complete Serious Adverse Event Report, Inactive Status Form, or Active Status Form as needed)

_____ Complete Menstrual Calendar (indicate NA if not appropriate)

_____ Review new lab results if appropriate; compare with earlier results

_____ Check blistercard for missed doses or trouble with medication compliance (complete Medication (Non) Compliance Checklist if indicated)

_____ Reinforce and praise progress

Session Type:

___1. Abstinent/medication compliant  ___ 2. Non-abstinent/medication compliant

___3. Abstinent/non medication compliant  ___4. Non-abstinent/non-medication compliant

Options for review and problem solving; Opportunities for praise and reinforcement

_____ Benefits of abstinence

_____ Participant’s reasons for seeking treatment (from original CRF)

_____ How the medications work

_____ Importance of medication compliance

_____ Suggestions of strategies for abstaining from alcohol

_____ Suggestions for improving medication compliance

Wrap-up

_____ Inquire about and encourage AA/support group attendance

_____ Provide support; complete MM Treatment Coordination Checklist, Session Record Form, and MM Follow-up Coordination Checklist (session 12 only)
N. Brief Checklist for Medical Attention Visit

_____ Review Vital Signs and BAC with participant

_____ Conduct brief assessment of drinking and general function

_____ Complete Concurrent Medication Form. Ask specifically about NSAIDs.

_____ Conduct SAFTEE (reference time since last visit) (complete Serious Adverse Event Report, Inactive Status Form, or Active Status Form as needed)

_____ Complete Menstrual Calendar (indicate NA if not appropriate)

_____ Review new lab results if appropriate; compare with earlier results

Options for review and problem solving; Opportunities for praise and reinforcement

_____ Benefits of abstinence

_____ Participant’s reasons for seeking treatment (from original CRF)

_____ Suggestions of strategies for abstaining from alcohol

_____ Reinforce need to continue coming to MA/MM appointments

_____ Reinforce and praise progress

_____ Plans for resuming the medication (if appropriate)

Wrap-up

_____ Inquire about and encourage AA/support group attendance

_____ Provide support; complete MM Treatment Coordination Checklist, Session Record Form, and MM Follow-up Coordination Checklist (session 12 only)
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   Coding Procedures
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      Subscale Standards
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         Direction
         Authoritativeness
         Warmth
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         (Avoiding) Non-protocol
      Overall
   Adherence Checklists
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      Feedback
      Red-Line Warning
      Red-Line
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B.1. Medical Management (MM)

B.1.1 Monitoring

Purpose
Ongoing performance monitoring of the COMBINE interventions (both CBI and MM) serves two purposes. First, the process is designed to identify and correct any drift from trial standards determined for each intervention. The process also provides documentation of the fidelity of the interventions such that adherence and discriminability of protocols can be demonstrated in scientific peer review.

Session Record Form data
There is an ongoing review and rating of selected sessions for each certified practitioner after certification. All sessions are audio-taped, and details of the sessions are recorded on the Session Record Form (SRF). SRFs are entered at each site. The data from the SRFs are retrieved regularly by the Coordinating Center+, and the compiled data from all sites is sent to the Monitoring Center monthly. The data from SRFs are used by the Monitoring Center to identify sessions to be requested for monitoring. The completion and entry of the SRFs must be kept up-to-date by the sites for current and timely feedback.

Selection of Sessions
Overall, the Monitoring Center will request one tape for every two MM cases. Tapes will be selected so that all types of clinical presentations (abstinent/ compliant, non-abstinent/ compliant, abstinent/ non-compliant, non-abstinent/ non-compliant) at all times of treatment (initial session, follow-up weeks) will be monitored. There may be additional sessions requested from a practitioner’s first cases following certification or if there is some concern or question about performance. The Monitoring Center will chose all sessions to be monitored and will also chose replacements for any sessions not available.

Coding Procedures
All ratings are based on a 7-point Likert scale. Ratings are based primarily on the practitioner's own behavior during the session. A single grade is assigned to every subscale, and every subscale is graded. Ratings are given in whole numbers. The coder should record notes on the performance of the practitioner during the session. At the end of the session, these notes are compiled to help the coder determine a global rating for the subscale. The practitioner begins the session with a rating of 6 on each item. This rating will change in accordance to the notes made regarding each item. The notes regarding the practitioner’s performance may be in half points or in whole points, however, the global rating must be in whole numbers. In the notes, if only a half point has been added or subtracted, round to the whole number one. However, if 1.5, 2.5, 3.5, etc. have been added or subtracted round to the lowest whole number. For example, a 1.5 rounds to 1, 2.5 rounds to 2. So, only the first half rounds up, any following halves round down. For any digression made by the practitioner, only detract from one area. For example, if in the initial session the SAFTEE is done after the first dose of medication is delivered, the coder should detract from direction only and not from protocol too.

Likert Scale of Coding Scores

1 = Absence of this characteristic
2 = Some ability to convey this characteristic
3 = Inconsistent evidence of this characteristic but evidence that therapist is attempting to achieve
4 = Some need for improvement on this characteristic
5 = Acceptable level of this characteristic; therapists may have one or two scores at this level, indicating differences in personality and emphasis in therapeutic approach.
6 = Moderate to high levels of this characteristic
7 = High levels of this characteristic: top 10% of therapists

Subscale Standards

Informative

Score 6 (Pass): Practitioner communicates information to the participant appropriately and effectively. The information is provided in a way so that it is clear, concise and understandable to the participant. This includes information about the participant’s clinical feedback; the study; action, dosing, and side effects of the medication; self-help organizations.

Score 4 (Marginal Fail): Practitioner fails to provide clear and appropriate information on parts of the treatment elements, or the practitioner provides inaccurate or misleading or irrelevant information.

Score 2 (Fail): Practitioner fails to provide clear and appropriate information for the whole treatment session, or the practitioner provides a great deal of inaccurate, misleading or irrelevant information.

Direction

Score 6 (Pass): Practitioner maintains appropriate control of the session and follows the recommended sequencing. The practitioner provides appropriate structure, moves smoothly through treatment procedures and brings the participant back on task when conversation drifts away to tangential subjects. The direction of the session moves in a cohesive flow that is logical and builds a case for the treatment.

Score 4 (Marginal Fail): Practitioner does not maintain a consistent structure throughout the session that is in accordance with the adherence checklist. The direction of the session may be disjointed, illogical and hard for the participant to follow. In other instances, the participant may determine the topics of discussion and the practitioner experiences difficulty in returning to the appropriate topic.

Score 2 (Fail): The segments of the intervention are provided in a scattered fashion and the session is severely lacking in cohesion. The participant determines the topics of discussion, and the practitioner follows along wherever the participant goes instead of bringing the participant back to structured agenda.

Authoritativeness

Score 6 (Pass): Practitioner high on authoritativeness give the participant the impression that they have expert advice and suggestions for recovery. They convey confidence in their competence to effectively provide treatment to the participant. The practitioner acts in a professional manner and appears as an expert in the field.

Score 4 (Marginal Fail): Practitioner is lacking in confidence in delivering the treatment elements. The practitioner is only weakly affirmative in his/her suggestions and the treatment, therefore, lacks in impact on the participant.

Score 2 (Fail): Practitioner is unable to convey to the participant confidence in effectively offering treatment. They fail to communicate to the participant "I have expertise in this area and can help you”. The practitioner is not affirmative in his/her suggestions to the participant, and the practitioner is, therefore, ineffectual in offering the treatment to the participant.

Warmth

Score 6 (Pass): Practitioner is perceived as warm, friendly, engaged, compassionate, helpful, and concerned.

Score 4 (Marginal Fail): Practitioner presents an impression of being cool, aloof, detached, or unfriendly, showing little overt evidence of helpful concern and compassion during sections of the session or to a moderate degree during the entire session.

Score 2 (Fail): Practitioner presents an impression of being cold, distant, detached, or unfriendly, showing little overt evidence of helpful concern and compassion through the majority of the session or to a severe degree during sections. The practitioner may also appear condescending or judgmental toward the participant.
**Protocol**
This is the extent to which the practitioner is delivering treatment procedures as prescribed in the MM manual. (The extent to which things other than the protocol are also being delivered is covered next). Be particularly careful not to detract from protocol and from some other area for the same digression made by the practitioner. For example, if the practitioner forgets to do a section of the adherence checklist, this detracts from protocol only and not from direction.

In assigning a grade to the protocol performance, the coder is to rely on the completion of all steps outlined in the MM manual. The content of the session should correspond to the procedures in the manual for the initial session and the presenting profile at follow up sessions. These elements include appropriate sequencing of material, clear adherence to the treatment procedures described for this portion of MM, and appropriate use of procedures, forms, and materials. As the practitioner deviates from these elements, the score will be lowered from the starting score of a six. For the majority of cases, the practitioner will be graded based on his/her completion of elements listed in the adherence checklist. However, the score will also reflect sessions that run excessively long or short in time.

**(Avoiding) Non-protocol**
This is the extent to which the practitioner is delivering appropriate treatment procedures other than those prescribed in the MM manual.

**Score 6 (Pass):** Practitioner delivers only procedures prescribed in the MM manual. **Score 4 (Marginal Fail):** Practitioner delivers treatment procedures not included in the MM manual during sections of the session. Non-protocol procedures may or may not be inconsistent with the overall approach of MM. For example, working of a particular AA "step" in the session, while consistent with MM advice to use self-help, is not part of the MM protocol. The non-protocol score may be lowered as a result of excessive interruption of the session (phone calls, knocks on the door, etc.) or counseling the participant. **Score 2 (Fail):** Practitioner delivers treatment procedures not included in the MM manual for large sections of the session.

**Overall**
The Overall rating summarizes the practitioner’s overall skillfulness in this session. It will ordinarily be close to the arithmetic average of the 6 practitioner scales. Participant ratings are not considered in this overall scale score.

**MM Coder Adherence Checklists**
The Adherence Checklists are used by the practitioner in conducting the sessions and by the Monitoring Center in grading the sessions. The coder adherence checklists attached give the grade weighting connected to each element of the checklist. The weight described is the maximum that would be added or subtracted from that element. However, the total weight may not be given by the coder on any single element. The overall grade given for a subscale will be determined in part by the weightings of each item and by the judgment of the coder.

**Tape Issues**
Any problems observed with the tape are to be listed in the feedback form under ‘tape issues’. These issues may include mislabeling of the tape, poor quality of the tape, or other issues.

**Feedback**
The audiotapes of the sessions chosen for monitoring will be listened to and coded by trained coders at the Monitoring Center. The sessions are coded according to standardized procedures (see section B.2.2.3). The coding sheets are then reviewed by the MM Monitoring Coordinator for consistency. If
there is any question about the ratings by the Coordinator or if the coder requests, the session is coded by a second coder. The Coordinator sends the coding results to the PC or the site’s designee at each site.

If the rating for any dimension falls below criterion (5 on the 7-point Likert Scale), the Monitoring Center will provide written feedback about the session. Additionally, the Coordinator may chose to send written feedback about performance when several sessions have been reviewed in a short period of time. It is the Monitoring Center’s policy to review tapes in the order received unless there is a specific reason that other tapes take priority. It is also the policy to monitor more recent sessions first in order that the feedback may be more relevant.

**Red-Line Warning**
A red-line warning will be issued by the Monitoring Center as a preliminary step prior to red-lining. This warning triggers an intensification of monitoring both recent and new sessions. Priority is given to monitoring these sessions so a determination can be made expeditiously as to whether to proceed to red-lining. The Monitoring Center will request specific tapes to review, and role-play sessions may also be required. In the interim, the MM practitioner may continue to see COMBINE participants, including new participants.

**Red-Line**
If adherence to protocol drops below the criterion level (average of 5 on a 7-point Likert Scale), a MM practitioner may be red-lined (decertified) by the MM Monitoring Coordinator. The PI and all staff designated to receive feedback at the site will be immediately notified, and a remedial plan will be created and implemented. The MM practitioner is prohibited from beginning new cases until adherence returns to an acceptable level. Session monitoring will increase during this period. Improved adherence may be demonstrated with cases that were already in treatment at the time of the decertification, or with additional practice cases that will not be included in the main trial data. The MM Monitoring Coordinator must recertify the MM practitioner as consistently adhering to the MM protocol (ratings of 5 or higher) before he or she may see new research participants.
Coder’s Checklist for Initial Visit

Weights of Items on Coder’s Adherence Checklist for Initial Visit

Participant ID _____________ Follow up week _____________
Practitioner ID _____________ Date _______________________

Initial MM Visit

*When grading, only detract or add to one subscale score for any one event. For example, if an item on the checklist is omitted, subtract from protocol only and not from direction too.*

___ Introduce yourself and your role, check vitals, give overview and timeline of intervention
1 point maximum.

___ Conduct baseline SAFTEE (reference last 90 days)
1 point maximum.

___ Complete Concurrent Medication Form (reference last 30 days)
1 point maximum.

___ Complete Menstrual Calendar (indicate NA if not appropriate)
1 point maximum.

___ Provide Feedback from CRF (Vital Signs, lab results, drinking related symptoms, drinking pattern and consequences, dependence criteria)
2 points maximum.

___ Provide Information (importance of the liver and how it works, effects of alcohol, diagnostic information, reasons for abstinence)
2 points maximum.

___ Give professional opinion about severity of the problem
½ point maximum.

___ Recommend abstinence
1 point maximum.

___ Ask participant for commitment to abstinence (if participant is unwilling to commit to long-term abstinence, restate the rationale for and seek agreement to abstinence for duration of study)
1 point maximum.

___ Explain purpose and function of medications, and provide Medication Information Sheets
1 point maximum.

___ Discuss likelihood of side effects and give Patient Instructions for Managing Side Effects
1 point maximum.

___ Explain proper medication use (extra doses, 2 hrs between doses, don’t crush, can take with food, morning dose always first) and give first dose (allow 20 minutes for observation)
2 points maximum.

___ Give Medical Emergency Cards and explain emergency procedures
1 point maximum.

___ Provide rationale for and complete Medication Compliance Plan
1 point maximum.

___ Briefly review diagnosis, recommendation, and plan

½ point maximum.

___ Encourage AA/support group attendance, give list of local meetings

1 point maximum.

___ Schedule next visit and discuss 3-day phone call (prepare Day 3 Phone Contact Form)

1 point maximum.

___ Complete MM Treatment Coordination Checklist (if appropriate) and Session Record Form
Coder’s Checklist for Follow Up Visit

Weights of Items on Coder’s Adherence Checklist for Follow Up Visits

Participant ID ____________ Follow up week ____________

Practitioner ID ____________ Date ______________________

Follow Up MM Visit

When grading, only detract or add to one subscale score for any one event. For example, if an item on the checklist is omitted, subtract from protocol only and not from direction too.

___ Review Vital Signs and BAC with participant
   ½ point maximum.

___ Conduct brief assessment of drinking, medication compliance, and general function
   1 point maximum.

___ Complete Concurrent Medication Form
   1 point maximum.

___ Conduct SAFTEE (reference time since last visit) (complete Serious Adverse Event Report, Inactive Status Form, or Active Status Form as needed)
   1 point maximum.

___ Complete Menstrual Calendar (indicate NA if not appropriate)
   1 point maximum.

___ Review new lab results if appropriate; compare with earlier results
   1 point maximum.

___ Check blistercard for missed doses or trouble with medication compliance (complete Medication (Non) Compliance Checklist if indicated)
   1 point maximum.

___ Reinforce and praise progress
   1 point maximum.

Session Type: 1 point maximum.

___ 1. Abstinent/medication compliant
___ 2. Non-abstinent/medication compliant
___ 3. Abstinent/non medication compliant
___ 4. Non-abstinent/non-medication compliant

Options for review and problem solving; Opportunities for praise and reinforcement

2 points maximum.

_____ Benefits of abstinence

_____ Participant’s reasons for seeking treatment (from original CRF)

_____ How the medications work

_____ Importance of medication compliance

_____ Suggestions of strategies for abstaining from alcohol

_____ Suggestions for improving medication compliance
Wrap-up

___ Inquire about and encourage AA/support group attendance

   *1 point maximum.*

___ Provide support; complete MM Treatment Coordination Checklist, Session Record Form, and MM Follow-up Coordination Checklist (session 12 only)

   *1 point maximum.*
B.1.2 Tape Management

Purpose
The purpose of providing tape management instructions is to help ensure the Sites are able to effectively record sessions, label tapes, and ship tapes. Effective tape management helps maintain quality in tape monitoring.

Recording of Sessions
Medical Management sessions should be recorded. Prior to actually recording, the Site should test the placement of the recorder within the room of the session to make sure the voices of the MM practitioner and the participant can be heard. The Site should try and limit the amount of background noise heard on the tape (e.g., do not place the recorder next to a heating vent where the fan noises will be recorded as well and might interfere with the audibility of the voices). Other noises that can occasionally make parts of the session inaudible are telephones, cellular phones, pagers and computer noises. Each session recording should start with the practitioner clearly stating his/her MM practitioner ID number, the participant’s ID number (in case of role player session, the first name of the pseudo participant. i.e., Gina or Martin), the date, and the week number. Practitioners are also advised to check the quality of recording before the session starts (see below- Quality Check of Recording). The practitioner should avoid pausing the tape during the session. If the tape has to be paused, the reason for the interruption should be stated on the recording.

Quality check of recordings requested by Monitoring Center
The Monitoring Center will send each Site a request for tapes of specific sessions to be monitored. Before tapes are copied and sent to the Monitoring Center, the Site is to check the tapes to ensure that they are of sufficient quality to be coded. Coders must be able to hear and understand both the practitioner and the participant. The Site may record multiple sessions on a tape but only the session requested by the Monitoring Center is to be copied and sent. In case of poor recording, the tape is not to be sent to the Monitoring Center. If the tape is of poor quality, indicate on the MM Tape Request Form (this goes back to the Monitoring Center) that the tape is not available (see below- Proper Packaging and Shipping Information). It is the policy of the Monitoring Center to try to do what they can to hear the tapes. However, if the quality is poor and the coder is having to strain to hear the session, the Site will be notified and the session will not be coded until a good quality audible tape is provided. The original session tapes are kept at the Site. Only copies of the requested sessions are sent to the Monitoring Center.

Proper Labeling of Tapes
Tapes must be properly labeled before they are sent to the Monitoring Center. All tapes and their covers should be labeled with the following information:

1) MM practitioner ID number (i.e., not the name or abbreviation)
2) Participant ID number (in case of role player session, the first name of the pseudo participant. i.e., Gina or Martin)
3) Date of session (i.e., MM/DD/YY)
4) Session week number (i.e., 00 through 16)
5) Session type (i.e., 1 through 7, Initial = 1, Abstinent & Compliant = 2, Non-Abstinent & Compliant = 3, Abstinent & Non-Compliant = 4, Non-Abstinent & Non-Compliant = 5, Medical Attention = 6, Uncertified Practitioner (conducting the session) = 7)

An example of label:

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<tr>
<th>Practitioner ID: 444</th>
<th>Participant ID: 0444444</th>
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<tbody>
<tr>
<td>Session week: 04</td>
<td>Session’s date: 04/04/04</td>
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<tr>
<td>Session type: 4</td>
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Tape Requests
Tape requests are e-mailed and faxed to the Site project coordinator (PC), unless the Site has identified someone else to receive it. The Monitoring Center will update this information (i.e., tape request receiver) annually. If changes at a particular Site are made between the updates, the Site is to notify the Monitoring Center of those changes.
Proper Packaging and Shipping Information

A copy of the MM Tape Request Form must accompany the package of tapes (i.e., appendix A2). The form provides space to indicate the disposition of all session tapes requested. Please take extra precaution in packaging of the tapes to prevent breakage or other types of damage caused by delivery.

Send completed MM tapes and materials to:

    MM monitoring coordinator
    Denise Ernst, MA
    Nariman Arfai
    COMBINE, UNM CASAA
    2650 Yale SE
    Albuquerque, NM 87106

The Monitoring Center will send acknowledgment to the Site of the receipt of the tapes.

Tape Maintenance

All tapes sent to the Monitoring Center are kept for 12 months. The tapes are then destroyed.
Please send the following tapes to the COMBINE Monitoring Center with either a copy of this Request Form with the tapes. Please indicate if there is any problem with recording of the session.

Please send these to:

**Denise Ernst**  
Nariman Arfai  
COMBINE - MM Monitoring Coordinator  
2650 Yale SE  
Albuquerque, NM 87106

<table>
<thead>
<tr>
<th>Practitioner ID #</th>
<th>Participant ID #</th>
<th>Session Week #</th>
<th>Session Date</th>
<th>Session Type</th>
<th>Tape/ Recording status</th>
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