

# **Ryan White Part A Quality Management**

**Ambulatory/Outpatient Medical Care  
Service Delivery Model**

**Palm Beach County**

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Technical assistance provided by:  
Southeast AIDS Education and Training Center

Palm Beach Care Council  
Quality Management Committee  
Medical Services & Support Services Committees

# Ryan White Part A Quality Management

## Ambulatory/Outpatient Medical Care Service Delivery Model

### Statement of Intent

All Ryan White Part A funded practitioners are required by contract to adhere, at a minimum, to the Public Health Service (HHS) Guidelines.

### Service Definition

**Outpatient/Ambulatory medical care (health services)** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). *Primary medical care* for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service's guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies.

### Practitioner Definition

Physicians, Nurse Practitioners, and Physician Assistants with current prescribing privileges in the state Florida.

### Practitioner Continuing Education Recommendation

Practitioners are strongly encouraged to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits within a period of two years. When a new practitioner is working with a contracted practitioner, new practitioner is encouraged to comply within one year.

Additionally, Practitioners are encouraged to seek certification through the American Academy of HIV Medicine. Information can be found at <http://aahivm.org/>.

# STANDARDS OF CARE

## *Documentation of HIV Infection*

Standard	Indicator	Data Source
1. Documentation of HIV Infection <sup>i</sup> is in medical record.	1.1 100% of clients have documentation of a confirmed positive HIV test.	1.1.1 Documentation in client chart

## *Laboratory Testing*

Note: The following is for baseline and follow-up laboratory parameters to monitor prior to and after antiretroviral therapy initiation, for assessment of treatment response and detection of laboratory abnormalities. Some laboratory testing may require more frequent monitoring as clinically indicated. Any variance from the indicators below must be documented in the patient chart.

Standard	Indicator	Data Source
2. Basic laboratory tests shall be obtained.	2.1 100% of client charts have basic screening labs done by second visit. 2.2 100% of client charts have complete labs per protocol. 2.3 100% of client charts screen for Hepatitis A, B, and C.	2.1.1 Documentation in client chart 2.2.1 Documentation in client chart 2.3.1 Documentation in client chart
3. CD4 T-cell count <sup>ii</sup> laboratory tests shall be obtained <i>before and after</i> start of antiretroviral (ART) therapy.	3.1 100% of clients have documentation of CD4 T-Cell count at entry into care and before ART initiation. 3.2 100% of clients have documentation of CD4 T-Cell count at least every 6-12 months if client is documented as adherent with suppressed HIV Viral Load and stable clinical and immunologic status for >2-3 years. 3.3 100% of clients have documentation of CD4 T-Cell count every 3-6 months for all patients not meeting criteria in 3.2. 3.4 100% of clients with a confirmed declining CD4 T-Cell count have documented plan of care.	3.1.1 Documentation in client chart 3.2.1 Documentation in client chart 3.3.1 Documentation in client chart 3.4.1 Documentation in client chart

<p>4. HIV RNA<sup>ii</sup> laboratory tests shall be obtained.</p>	<p>4.1 100% of clients have documentation of HIV RNA at entry into care and before ART initiation.</p> <p>4.2 100% of clients have documentation of HIV RNA every 3-6 months. Interval MAY be extended to 6 months only if patient is documented as adherent with suppressed HIV Viral Load and stable clinical and immunologic status for &gt;2-3 years.</p> <p>4.3 100% of clients with confirmed increasing HIV RNA have documented plan of care.</p>	<p>4.1.1 Documentation in client chart</p> <p>4.2.1 Documentation in client chart</p> <p>4.3.1 Documentation in client chart</p>
<p>5. Resistance tests<sup>ii</sup> shall be obtained.</p>	<p>5.1 100% of naïve clients have documentation of genotype resistance tests at entry into care.</p> <p>5.2 100% of clients have documentation of resistance tests at treatment failure with HIV viral load <math>\geq</math> 1000 copies/mL.  If drug resistance is suspected, client should be on failing regimen at time of test or within 4 weeks of regimen discontinuation. For client with suspected treatment failure due to issues of adherence, medication intolerance, or pharmacokinetic reasons, resistance testing is not warranted until these reasons addressed.</p>	<p>5.1.1 Documentation in client chart</p> <p>5.2.1 Documentation in client chart</p>
<p>6. HLA-B*5701<sup>ii</sup> laboratory test shall be obtained if considering start of abacavir.</p>	<p>6.1 100% of clients have documentation of HLA-B*5701 if considering start of abacavir.</p>	<p>6.1.1 Documentation in client chart</p>
<p>7. Tropism testing<sup>ii</sup> shall be obtained when considering use of CCR5 antagonist.</p>	<p>7.1 100% of clients have documentation of Tropism Testing if considering use of CCR5 antagonist.</p>	<p>7.1.1 Documentation in client chart</p>

<p>8. Basic chemistry [Serum Na, K, HCO<sub>3</sub>, Cl, BUN, creatinine, glucose (preferably fasting)]<sup>ii</sup>, Liver function tests (ALT, AST, T.bili, &amp; D. bili)<sup>ii</sup>, CBC with differential<sup>ii</sup> shall be obtained.</p>	<p>8.1 100% of clients have documentation of basic chemistry at entry into care.  8.2 100% of clients have documentation of basic chemistry follow-up at least every 3-6 months.  8.3 100% of clients have documentation of basic chemistry before ART initiation or modification.  8.4 100% of clients have documentation of basic chemistry 2-8 weeks post ART initiation or modification.  8.5 100% of significant abnormal lab values documented with action plan.</p>	<p>8.1.1 Documentation in client chart  8.2.1 Documentation in client chart  8.3.1 Documentation in client chart  8.4.1 Documentation in client chart  8.5.1 Documentation in client chart</p>
<p>9. Fasting lipid profile<sup>ii</sup> (12 hours fasting) shall be obtained.</p>	<p>9.1 100% of clients have documentation of fasting lipid profile at entry into care (May be ordered at second patient visit if patient not fasting).  9.2 100% of clients have documentation of fasting lipid profile annually (if normal at last measurement) or every six months (if abnormal or borderline at last measurement).  9.3 100% of significant abnormal lab values documented with action plan.</p>	<p>9.1.1 Documentation in client chart  9.2.1 Documentation in client chart  9.3.1 Documentation in client chart</p>
<p>10. Urinalysis<sup>ii</sup> shall be obtained.</p>	<p>10.1 100% of clients have documentation of urinalysis at entry into care.  10.2 100% of clients have documentation of urinalysis at least every 12 months.  10.3 100% of significant abnormal lab values documented with action plan.</p>	<p>10.1.1 Documentation in client chart  10.2.1 Documentation in client chart  10.3.1 Documentation in client chart</p>
<p>11. Hepatitis A screening<sup>v</sup> shall be obtained.</p>	<p>11.1 100% of clients have documentation of Hepatitis A Screening - Hepatitis A total antibody (HAVAb) or IgG (not IgM).</p>	<p>11.1.1 Documentation in client chart</p>

<p>12. Hepatitis B screening<sup>iv</sup> shall be obtained.</p>	<p>12.1 100% of clients have documentation of Hepatitis B Screening - Hepatitis B core antibody (HBcAb) total or IgG (not IgM), Hepatitis B surface antibody (HBsAb), and Hepatitis B surface antigen (HBsAg).</p> <p>12.2 100% of clients with documentation of positive HBsAg, have further Hepatitis B testing; Viral Load by DNA PCR, and Hep Be Ag and Ab obtained and documented.</p>	<p>12.1.1 Documentation in client chart 12.2.1 Documentation in client chart</p>
<p>13. Hepatitis C screening<sup>iv</sup> shall be obtained.</p>	<p>13.1 100% of clients have documentation of Hepatitis C Screening - Hepatitis C antibody (HCVAb).</p> <p>13.2 100% of clients with documentation of positive HCVAb, have Hepatitis C (HCV) Viral Load, HCV genotype, and a treatment plan in the record.</p> <p>13.3 100% of active Injection Drug User or other HCV risk factor clients with documentation of negative HCVAb, have yearly documentation of repeat HCVAb.</p> <p>13.4 100% of clients with documentation of unexplained chronic LFT elevation, have at least one evaluation for Hepatitis C viral load (even if HCVAb is negative).</p>	<p>13.1.1 Documentation in client chart 13.2.1 Documentation in client chart 13.3.1 Documentation in client chart 13.4.1 Documentation in client chart</p>
<p>14. Syphilis, N. gonorrhoeae (GC), and C. trachomatis (Chlamydia) screening shall be obtained<sup>vi</sup>.</p>	<p>14.1 100% of clients have documentation of Syphilis screening at baseline and annually thereafter.</p> <p>14.2 100% of female clients who report sexual activity since their last screening have documentation of N. gonorrhea (GC), and C. trachomatis (Chlamydia) screening annually.</p>	<p>14.1.1 Documentation in client chart 14.2.1 Documentation in client chart</p>

## *Immunizations/Treatments*

Standard	Indicator	Data Source
15. Clients are offered immunizations.	<p>15.1 100% of clients are offered pneumococcal vaccine<sup>vii</sup> and a follow up booster 5 years later.</p> <p>15.2 100% of clients are offered influenza immunization<sup>viii</sup>.</p> <p>15.3 100% of non immune clients are offered Hepatitis A and B vaccine<sup>vii</sup>.</p> <p>15.4 100% of clients are offered Tetanus, diphtheria, pertussis (Td/Tdap) <sup>ix</sup> vaccination and a follow up booster 10 years later.</p>	<p>15.1.1 Documentation in client chart</p> <p>15.2.1 Documentation in client chart</p> <p>15.3.1 Documentation in client chart</p> <p>15.4.1 Documentation in client chart</p>
16. ART therapy shall be provided.	<p>16.1 100% of clients have documentation of consideration and discussion of ART therapy at the times of CD4 T-Cell count and HIV RNA monitoring.</p> <p>16.2 100% of pregnant women have documentation of prescribed ART Therapy or explanation as to why not.</p>	<p>16.1.1 Documentation in client chart</p> <p>16.2.1 Documentation in client chart</p>
17. Treatment for opportunistic infections and prophylaxis for opportunistic infections shall be provided. <sup>x</sup>	<p>17.1 100% of clients have documentation of treatment, when indicated, for opportunistic infections.</p> <p>17.2 100% of clients have documentation of prophylaxis for opportunistic infections, when indicated, and prophylaxis is discontinued, when indicated.</p>	<p>17.1.1 Documentation in client chart</p> <p>17.2.1 Documentation in client chart</p>



## *Additional Assessments*

<b>Standard</b>	<b>Indicator</b>	<b>Data Source</b>
18. Pregnancy test <sup>ii</sup> (females) shall be obtained if starting an efavirenz-containing regimen.	<p>18.1 100% of female clients have documentation of pregnancy test if starting an efavirenz (EFV)-containing regimen.</p> <p>18.2 100% of female patients started on EFV will have birth control and last normal menstrual period documented on each visit as long as they are on EFV.</p>	<p>18.1.1 Documentation in client chart</p> <p>18.2.1 Documentation in client chart</p>
19. Gynecological Exam <sup>xi xii</sup> (females), including Pap smear and pelvic, shall be offered.	<p>19.1 100% of charts of female clients show a PAP test and pelvic exam offered annually.</p> <p>19.2 100% of female clients have documentation of follow-up Pap smear and pelvic exam offered 1 year later, as indicated.</p> <p>19.3 100% of charts of female clients with abnormal PAP tests or with lesions present show referral to a gynecologist and the outcome will be documented.</p>	<p>19.1.1 Documentation in client chart</p> <p>19.2.1 Documentation in client chart</p> <p>19.3.1 Documentation in client chart</p>
20. Mammogram <sup>vi</sup> (females) shall be provided.	<p>20.1 100% of female clients have documentation of mammogram offered annually, as indicated.</p> <p>20.2 100% of female clients with documentation of abnormal mammogram have documented plan of care in record.</p> <p>20.3 100% of female clients have Breast Self Examination education and encouraged to self-examine monthly documented in chart.</p>	<p>20.1.1 Documentation in client chart</p> <p>20.2.1 Documentation in client chart</p> <p>20.3.1 Documentation in client chart</p>
21. Colon and Rectal Cancer Screening <sup>ix</sup> shall be provided.	<p>21.1 100% of clients have documentation of colorectal cancer screening offered annually, as indicated.</p> <p>21.2 100% of clients with documentation of abnormal screening have documented plan of care in record.</p>	<p>21.1.1 Documentation in client chart</p> <p>21.2.1 Documentation in client chart</p>

22. Client is tested or assessed for Tuberculosis (TB) annually.	22.1 100% of clients have documentation of TB test or assessment annually. 22.2 100% of clients with documentation of abnormal test results have documented plan of treatment.	22.1.1 Documentation in client chart 22.2.1 Documentation in client chart
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*Care Assessments*

<b>Standard</b>	<b>Indicator</b>	<b>Data Source</b>
23. Clients with HIV infection attend 2 or more medical visits annually.	23.1 90% of clients with HIV infection attend 2 or more medical visits annually. 23.2 100% of clients not adherent to 23.1 have documentation of attempts to re-establish in care.	23.1.1 Documentation in client chart 23.2.1 Documentation in client chart
24. Adherence education shall be provided.	24.1 100% of clients have documentation of medication adherence assessment and/or education at each visit.	24.1.1 Documentation in client chart
25. Cytomegalovirus (CMV) screening for patients with CD4 T-cell count <50mm <sup>3</sup> .	25.1 100% of clients with CD4 T-cell count <50mm <sup>3</sup> , have documentation of referral to ophthalmology.	25.1.1 Documentation in client chart
26. Nutritional health education shall be assessed.	26.1 100% of clients have documentation of annual nutritional assessment.	26.1.1 Documentation in client chart
27. Oral health education/care shall be provided.	27.1 100% of clients have documentation of annual oral health referral, as indicated.	27.1.1 Documentation in client chart
28. Mental health assessment/care shall be provided.	28.1 100% of clients have documentation of being assessed annually for mental health needs. 28.2 100% of clients with documentation of depression have documented plan of care in record.	28.1.1 Documentation in client chart 28.2.1 Documentation in client chart
29. Exercise education/assessment shall be provided.	29.1 100% of clients have documentation of exercise education/assessment at least annually.	29.1.1 Documentation in client chart

<p>30. Drugs/Alcohol/Tobacco (including smoke-less) assessment/education shall be performed.</p>	<p>30.1 100% of clients have documentation of drug/alcohol tobacco (including smoke-less) education/assessment at least annually.</p>	<p>30.1.1 Documentation in client chart</p>
<p>31. Domestic violence assessment shall be provided.</p>	<p>31.1 100% of clients have documentation of domestic violence assessment at least annually; provide education and referral as indicated.</p>	<p>31.1.1 Documentation in client chart</p>
<p>32. Sexual health education, to include birth control method, discussion of condom use, risk identification, and family/pregnancy planning shall be provided.</p>	<p>32.1 100% of clients have documentation of sexual health education, to include birth control method, discussion of condom use, risk identification, and family/pregnancy planning, as appropriate at each visit.</p>	<p>32.1.1 Documentation in client chart</p>
<p>33. Advanced Directive (Living Will) shall be offered, to include education regarding its importance.</p>	<p>33.1 100% of clients have documentation of discussion regarding advanced directive (living will) at least annually.</p>	<p>33.1.1 Documentation in client chart</p>
<p>34. Transgender health care.</p>	<p>34.1 100% of transgender clients will have documentation of birth sex and self-reported gender identity.</p> <p>34.2 100% of transgender clients are assessed for additional medical and mental health needs in addition to those inherent in birth sex and including those incurred from additional anatomical changes.</p>	<p>34.1.1 Documentation in client chart 34.1.1 Documentation in client chart</p>

### *Charting/Documentation*

<b>Standard</b>	<b>Indicator</b>	<b>Data Source</b>
35. Client chart shall contain complete and up-to-date problem list.	35.1 100% of client charts contain a complete and up-to-date problem list.	35.1.1 Documentation in client chart
36. Client chart shall contain complete and up-to-date medication list to include start dates, stop dates, and dosages with patient instructions.	36.1 100% of client charts contain a complete and up-to-date list to include start dates, stop dates, and dosages with patient instructions.	36.1.1 Documentation in client chart
37. Client chart shall contain complete and up-to-date allergy list.	37.1 100% of client charts contain a complete and up-to-date allergy list to include a brief description of the allergic reaction.	37.1.1 Documentation in client chart
38. Client chart shall contain complete and up-to-date immunization list.	38.1 100% of client charts contain a complete and up-to-date immunization list. 38.2 100% of client charts show consent for each vaccine received.	38.1.1 Documentation in client chart 38.2.1 Documentation in client chart

## References

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- <sup>ii</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. November 3, 2008; Page 6; Table 3. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed October 10, 2009.
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- <sup>iv</sup> <http://www.clinicalcalculator.com/english/nephrology/cockroft/cca.htm>. Accessed October 11, 2009.
- <sup>v</sup> <http://www.aidsetc.org/pdf/workgroups/pcare/pcwg-heptools.pdf>. Accessed October 11, 2009.
- <sup>vi</sup> Counseling for Patients with HIV Infection and Referral to Support Services, page 18, Sexually Transmitted Diseases Treatment Guidelines, 2006, <http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/rr5511a1.htm>. Accessed July 21, 2009.
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- <sup>viii</sup> <http://www.faetc.org/PDF/Newsletter/Newsletter-Volume10-2009/HIVCareLink-Vol10-Issue-5-April-15.pdf>
- <sup>ix</sup> <http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/2009/adult-schedule-11x17.pdf>. Accessed July 22, 2009.
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- <sup>xi</sup> Routine pelvic examination and cervical cytology screening. ACOG Committee Opinion No. 431. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;113:1190–3.
- <sup>xii</sup> <http://www3.niaid.nih.gov/topics/HIVAIDS/Understanding/Population+Specific+Information/womenHiv.htm> Accessed July 22, 2009.
- <sup>xiii</sup> [http://my.clevelandclinic.org/services/fecal\\_occult\\_blood\\_test/hic\\_fecal\\_occult\\_blood\\_test.aspx](http://my.clevelandclinic.org/services/fecal_occult_blood_test/hic_fecal_occult_blood_test.aspx). Accessed July 22, 2009.
- <sup>xiv</sup> Centers for Disease Control and Prevention. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR 2009;58(No. RR-4):20

Appendix A – Quick Guideline for Laboratory Testing

**Table 3. Laboratory Testing Schedule for Monitoring HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy<sup>a</sup>** (page 1 of 2)

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	ART Initiation <sup>b</sup> or Modification	2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated	If ART Initiation is Delayed <sup>c</sup>
HIV Serology	√ If HIV diagnosis has not been confirmed								
CD4 Count	√	√		√ During first 2 years of ART or if viremia develops while patient on ART or CD4 count <300 cells/mm <sup>3</sup>		√ <u>After 2 years on ART with Consistently Suppressed Viral Load:</u> CD4 Count 300–500 cells/mm <sup>3</sup> : • Every 12 months  CD4 Count >500 cells/mm <sup>3</sup> : • CD4 monitoring is optional	√	√	√ Every 3-6 months
HIV Viral Load	√	√	√ <sup>d</sup>	√ <sup>e</sup>	√ <sup>e</sup>		√	√	Repeat testing is optional
Resistance Testing	√	√ <sup>f</sup>					√	√	√ <sup>f</sup>
HLA-B*5701 Testing		√ If considering ABC							
Tropism Testing		√ If considering a CCR5 antagonist					√ If considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	√	

**Table 3. Laboratory Testing Schedule for Monitoring HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy<sup>a</sup>** (page 2 of 2)

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	ART Initiation <sup>b</sup> or Modification	2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated	If ART Initiation is Delayed <sup>c</sup>
Hepatitis B Serology <sup>g,h</sup>	√	√ May repeat if patient is nonimmune and not chronically infected with HBV <sup>b</sup>				√ May repeat if patient is nonimmune and not chronically infected with HBV <sup>b</sup>		√	
Hepatitis C Antibody Test (if positive, confirm with HCV RNA test)	√	√ May repeat for at-risk patients if negative result at baseline				√ May repeat for at-risk patients if negative result at baseline		√	
Basic Chemistry <sup>i,j</sup>	√	√	√	√				√	√ Every 6-12 months
ALT, AST, T. bilirubin	√	√	√	√				√	√ Every 6-12 months
CBC with Differential	√	√	√ If on ZDV	√ If on ZDV or if CD4 testing is done	√			√	√ Every 3-6 months
Fasting Lipid Profile <sup>k</sup>	√	√			√ If abnormal at last measurement	√ If normal at last measurement		√	√ If normal at baseline, annually
Fasting Glucose or Hemoglobin A1C	√	√		√ If abnormal at last measurement		√ If normal at last measurement		√	√ If normal at baseline, annually
Urinalysis <sup>l,j</sup>	√	√			√ If on TAF or TDF <sup>l</sup>	√		√	
Pregnancy Test		√ In women with child-bearing potential						√	

<sup>a</sup> This table pertains to laboratory tests done to select an ARV regimen and monitor for treatment responses or ART toxicities. Please refer to the HIV Primary Care guidelines for guidance on other laboratory tests generally recommended for primary health care maintenance of HIV patients.<sup>1</sup>

<sup>b</sup> If ART initiation occurs soon after HIV diagnosis and entry into care, repeat baseline laboratory testing is not necessary.

<sup>c</sup> ART is indicated for all HIV-infected individuals and should be started as soon as possible. However, if ART initiation is delayed, patients should be retained in care, with periodic monitoring as noted above.

<sup>d</sup> If HIV RNA is detectable at 2 to 8 weeks, repeat every 4 to 8 weeks until viral load is suppressed to <200 copies/mL, and thereafter, every 3 to 6 months.

<sup>e</sup> In patients on ART, viral load typically is measured every 3 to 4 months. However, for adherent patients with consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended to 6-month intervals.

<sup>f</sup> Based on current rates of transmitted drug resistance to different ARV medications, standard genotypic drug-resistance testing in ARV-naïve persons should focus on testing for mutations in the reverse transcriptase (RT) and protease (PR) genes. If transmitted integrase strand transfer inhibitor (INSTI) resistance is a concern, providers should also test for resistance mutations to this class of drugs. In ART-naïve patients who do not immediately begin ART, repeat testing before initiation of ART is optional if resistance testing was performed at entry into care. In virologically suppressed patients who are switching therapy because of toxicity or for convenience, viral amplification will not be possible; therefore, resistance testing should not be performed. Results from prior resistance testing can be helpful in constructing a new regimen.

<sup>g</sup> If HBsAg is positive, TDF or TAF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections. Preliminary data from clinical trials have demonstrated TAF activity against HBV. Final results from ongoing clinical trials will help to define the role of TAF in the treatment of HBV/HIV coinfection.

<sup>h</sup> If HBsAg, HBsAb, and anti-HBc are negative, hepatitis B vaccine series should be administered. Refer to HIV Primary Care and Opportunistic Infections guidelines for more detailed recommendations.<sup>1,2</sup>

<sup>i</sup> Serum Na, K, HCO<sub>3</sub>, Cl, BUN, creatinine, glucose (preferably fasting), and creatinine-based estimated glomerular filtration rate. Serum phosphorus should be monitored in patients with chronic kidney disease who are on TAF- or TDF-containing regimens.<sup>3</sup>

<sup>j</sup> Consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America for recommendations on managing patients with renal disease.<sup>3</sup> More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g., proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension).

<sup>k</sup> Consult the National Lipid Association's recommendations for management of patients with dyslipidemia.<sup>4</sup>

<sup>l</sup> Urine glucose and protein should be assessed before initiating TAF- or TDF-containing regimens, and monitored during treatment with these regimens.

**Key to Acronyms:** 3TC = lamivudine; ABC = abacavir; ALT = alanine aminotransferase; ART = antiretroviral therapy; AST = aspartate aminotransferase; BUN = blood urea nitrogen; CBC = complete blood count; Cl = chloride; CrCl = creatinine clearance; EFV = efavirenz; FTC = emtricitabine; HBsAb = hepatitis B surface antibody; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCO<sub>3</sub> = bicarbonate; K = potassium; NA = sodium; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine



**Appendix B – Medical Visit Components**

1. **Initial** – At initial visit
  - a. Comprehensive initial history
  - b. Physical examination, including review of systems
  - c. Vital signs, including weight and Body Mass Index (BMI) <http://www.globalrph.com/bmi.htm>
  - d. Gynecological exam including pap smear and pelvic for females
  - e. Rectal examination
  - f. Sexual transmitted infection assessment
  - g. Age appropriate cancer screening
  - h. Adherence to medications
  - i. Risk reduction/harm reduction (including safer sex practices)
  
2. **Interim Monitoring and Problem-Oriented visits** - At every visit:
  - a. Vital signs, including weight and BMI
  - b. Symptom targeted physical exam
  - c. Interval changes in vital signs addressed, especially trend in weight over time
  - d. Adherence to medications
  - e. Risk reduction/harm reduction (including safer sex practices); if at risk since last STI screen, repeat STI screening
  
3. **Annual** – At each annual visit:
  - a. Update comprehensive initial history, as appropriate
  - b. Physical examination, including review of systems
  - c. Vital signs, including weight and BMI
  - d. Interval changes in vital signs addressed, especially trend in weight over time
  - e. Assessments related to issues of aging
  - f. Gynecological exam including pap smear and pelvic for females
  - g. Rectal examination and stool guaiac testing
  - h. Sexual transmitted infection assessment
  - i. Age appropriate cancer screening
  - j. Adherence to medications
  - k. Risk reduction/harm reduction (including safer sex practices)

## Appendix C – HIV Treatment Guidelines & Other Useful Links

- Treat and monitor patients in adherence with current DHHS Guidelines and other standards of care, to include, but not limited to:
  - a. DHHS Clinical Guidelines  
<http://www.aidsinfo.nih.gov/Guidelines/>
  - b. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.  
[https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa\\_tables.pdf](https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_tables.pdf)
  - c. Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus. AETC National Resource Center. 2013.  
<http://www.aidsetc.org/resource/primary-care-guidelines-management-persons-infected-human-immunodeficiency-virus>
  - d. American Cancer Society Guidelines for the Early Detection of Cancer  
<http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer>
  - e. European AIDS Clinical Society (EACS) guidelines on the prevention and management of metabolic diseases in HIV  
<http://www.ncbi.nlm.nih.gov/pubmed/18257770>
  - f. Dyslipidemia. AETC National Resource Center. 2014.  
<http://www.aidsetc.org/guide/dyslipidemia>
  - g. CDC Recommended Adult/Pediatric Immunization Schedule  
<http://www.cdc.gov/vaccines/schedules/index.html>
  - h. Incorporating HIV Prevention into the Medical Care of Persons Living with HIV  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm>
  - i. Counseling for Patients with HIV Infection and Referral to Support Services, page 18, Sexually Transmitted Diseases Treatment Guidelines, 2006,  
<http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/rr5511a1.htm>
  - j. Cervical Dysplasia. AETC National Resource Center. 2014.  
<http://www.aidsetc.org/guide/cervical-dysplasia>