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		nonpregnant patients, lifestyle modifications followed by other medications are the initial treatments (Body 2016; Huerta-Iga 2016; Katz 2013; van der Woude 2014). Based on available data, PPIs may be used when clinically indicated (Body 2016; Matok 2012; Pasternak 2010; van der Woude 2014).
Papillomavirus (HPV Vaccines)		Adverse events were not observed in animal reproduction studies. In clinical trials, women who were found to be pregnant before the completion of the 3-dose regimen were instructed to defer any remaining dose until pregnancy resolution. In pregnancies detected within 30 days of vaccination, no cases of congenital abnormalities were noted. Pregnancies with onset beyond 30 days of vaccination had a rate of congenital anomalies consistent with the general population. Administration of the vaccine in pregnancy is not recommended. Until additional information is available, the vaccine series (or completion of the series) should be delayed until pregnancy is completed. Pregnancy testing is not required prior to administration of the vaccine (CDC/ACIP [Petrosky 2015]). A registry has been established for women exposed to the Gardasil 9 HPV vaccine during pregnancy (1-800-986-8999). Administration of the human papillomavirus vaccine during pregnancy is not recommended. Although exposure to human papillomavirus vaccine has not been causally associated with adverse pregnancy outcomes, until additional information is available the vaccine series (or completion of the series) should be delayed until pregnancy is completed (NACI 2017). The manufacturer recommend pregnancy be avoided during the vaccination series. Exposures to quadrivalent human papillomavirus vaccine during pregnancy should be reported to the manufacturer (800-267-2594) or Vaccine Safety Section at Public Health Agency of Canada (866-844-0018 or http://www.phac-aspc.gc.ca/im/vssv/index-eng.php).
Paroxetine	D/X	Paroxetine crosses the placenta (Hendrick Stowe 2003). An increased risk of teratogenic effects, including cardiovascular defects, may be associated with maternal use of paroxetine or other SSRIs; however, available information is conflicting. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of paroxetine may be altered. The maternal CYP2D6 genotype also influences paroxetine plasma concentrations during pregnancy (Hostetter 2000; Ververs 2009). The manufacturer suggests discontinuing paroxetine or switching to another antidepressant unless the benefits of therapy justify continuing treatment during pregnancy; consider other treatment options for women who are planning to become pregnant. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. The ACOG also recommends that therapy with paroxetine be avoided during pregnancy if possible and that fetuses exposed in early pregnancy be assessed with a fetal echocardiography (ACOG 2008). Other guidelines note that treatment with paroxetine should not be initiated in pregnant women (Bauer 2013). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. The use of paroxetine is not recommended as first line therapy during pregnancy. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Menopausal vasomotor symptoms do not occur during pregnancy;

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		therefore, the use of paroxetine for the treatment of menopausal vasomotor symptoms is contraindicated in pregnant women. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
PEG (Polyethylene Glycol 3350 + Electrolytes Solution)		Polyethylene glycol (PEG) has minimal systemic absorption and would be unlikely to cause fetal malformations. However, until additional information is available, use to treat constipation in pregnancy should be avoided unless other preferred methods are inadequate (Mahadevan 2006). Use as a bowel preparation prior to colonoscopy in pregnant women may be considered (Wexner 2006).
Penicillin G Benzathine		Penicillin G crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Penicillin G is the drug of choice for treatment of syphilis during pregnancy and penicillin G (parenteral/aqueous) is the drug of choice for the prevention of early-onset Group B Streptococcal (GBS) disease in newborns (consult current guidelines) (CDC (RR-10) 2010; CDC [Workowski 2015]). When IV therapy is required for anthrax infection in pregnant and postpartum women, penicillin G may be used as an alternative agent (Meaney-Delman 2014).
Penicillin G Procaine		Penicillin G crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Penicillin G is the drug of choice for treatment of syphilis during pregnancy and penicillin G (parenteral/aqueous) is the drug of choice for the prevention of early-onset Group B Streptococcal (GBS) disease in newborns (consult current guidelines) (CDC (RR-10) 2010; CDC [Workowski 2015]). When IV therapy is required for anthrax infection in pregnant and postpartum women, penicillin G may be used as an alternative agent (Meaney-Delman 2014).
Penicillin V Potassium		Penicillin crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of penicillin V may be altered in the second and third trimester (Heikkilä 1993). If treatment for the management of Bacillus anthracis is needed in pregnant women, other agents are preferred (Meaney-Delman 2014)
Pentamidine Isethionate		Animal reproduction studies were not conducted by the manufacturer. Pentamidine crosses the human placenta (Fortunato 1989; Schwebke 1995). Intravenous pentamidine can be used as an alternative treatment in pregnant females with HIV infection for mild to moderate Pneumocystis jirovecii pneumonia (HHS [OI; adult] 2017). Pentamidine may be used to treat stage one trypanosomiasis caused by T. brucei gambiense (CDC 2016); information related to treatment of pregnant females for this indication is limited (Pohlig 2016).
Permethrin	B	Adverse events have not been observed in oral animal reproduction studies. The amount of permethrin available systemically following topical application is ≤2%. The CDC considers the use of permethrin or pyrethrins with piperonyl butoxide the drugs of choice for the treatment of pubic lice during pregnancy; permethrin is the preferred treatment of scabies during pregnancy (CDC [Workowski 2015]).
Perphenazine		Jaundice or hyper- or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. If needed, the minimum effective maternal dose should be used in order to decrease the risk of EPS (ACOG 2008).
Petrolatum		
Phenazopyridine	B	Adverse events have not been observed in animal reproduction studies. Phenazopyridine crosses the placenta and can be detected in amniotic fluid (Meyer 1991).
Phenobarbital	D	Phenobarbital crosses the placenta (Harden 2009b). Barbiturates can be detected in the placenta, fetal liver, and fetal brain. Fetal and maternal blood concentrations may be

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		similar following parenteral administration. An increased incidence of fetal abnormalities may occur following maternal use. When used during the third trimester of pregnancy, withdrawal symptoms may occur in the neonate, including seizures and hyperirritability; symptoms of withdrawal may be delayed in the neonate up to 14 days after birth. Use during labor does not impair uterine activity; however, respiratory depression may occur in the newborn; resuscitation equipment should be available, especially for premature infants. Use for the treatment of epilepsy should be avoided during pregnancy (Harden 2009a). A registry is available for women exposed to phenobarbital during pregnancy: Pregnant women may enroll themselves into the North American Antiepileptic Drug (AED) Pregnancy Registry (888-233-2334 or http://www.aedpregnancyregistry.org).
Phenylephrine	C	Animal reproduction studies have not been conducted. Phenylephrine crosses the placenta at term. Maternal use of phenylephrine during the first trimester of pregnancy is not strongly associated with an increased risk of fetal malformations; maternal dose and duration of therapy were not reported in available publications. Phenylephrine is available over-the-counter (OTC) for the symptomatic relief of nasal congestion. Decongestants are not the preferred agents for the treatment of rhinitis during pregnancy. Oral phenylephrine should be avoided during the first trimester of pregnancy; short-term use (<3 days) of intranasal phenylephrine may be beneficial to some patients although its safety during pregnancy has not been studied. Phenylephrine injection is used at delivery for the prevention and/or treatment of maternal hypotension associated with spinal anesthesia in women undergoing cesarean section. Phenylephrine may be associated with a more favorable fetal acid base status than ephedrine; however, overall fetal outcomes appear to be similar. Nausea or vomiting may be less with phenylephrine than ephedrine but is also dependent upon blood pressure control. Phenylephrine may be preferred in the absence of maternal bradycardia. There is limited information available supporting the use of topical agents for the treatment of hemorrhoids. Products containing phenylephrine should be used with caution in pregnant women, especially patients with hypertension or diabetes.
Phenylephrine/ Mineral Oil/ Petrolatum	C	Animal reproduction studies have not been conducted. Phenylephrine crosses the placenta at term. Maternal use of phenylephrine during the first trimester of pregnancy is not strongly associated with an increased risk of fetal malformations; maternal dose and duration of therapy were not reported in available publications. Phenylephrine is available over-the-counter (OTC) for the symptomatic relief of nasal congestion. Decongestants are not the preferred agents for the treatment of rhinitis during pregnancy. Oral phenylephrine should be avoided during the first trimester of pregnancy; short-term use (<3 days) of intranasal phenylephrine may be beneficial to some patients although its safety during pregnancy has not been studied. Phenylephrine injection is used at delivery for the prevention and/or treatment of maternal hypotension associated with spinal anesthesia in women undergoing cesarean section. Phenylephrine may be associated with a more favorable fetal acid base status than ephedrine; however, overall fetal outcomes appear to be similar. Nausea or vomiting may be less with phenylephrine than ephedrine but is also dependent upon blood pressure control. Phenylephrine may be preferred in the absence of maternal bradycardia. There is limited information available supporting the use of topical agents for the treatment of hemorrhoids. Products containing phenylephrine should be used with caution in pregnant women, especially patients with hypertension or diabetes.
Phenytoin		Phenytoin crosses the placenta (Harden and Pennell 2009). An increased risk of congenital malformations and adverse outcomes may occur following in utero phenytoin exposure. Reported malformations include orofacial clefts, cardiac defects, dysmorphic facial features, nail/digit hypoplasia, growth abnormalities including microcephaly, and mental deficiency. Isolated cases of malignancies (including neuroblastoma) and coagulation defects in the neonate (may be life threatening) following delivery have also been reported. Maternal use of phenytoin should be avoided when possible to decrease the risk of cleft palate and poor cognitive outcomes. Polytherapy may also increase the risk of congenital malformations; monotherapy is

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		recommended (Harden and Meader 2009). The maternal use of folic acid throughout pregnancy is recommended to reduce the risk of major congenital malformations (Harden and Pennell 2009). Potentially life-threatening bleeding disorders in the newborn may also occur due to decreased concentrations of vitamin K-dependent clotting factors following phenytoin exposure in utero; vitamin K administration to the mother prior to delivery and the newborn after birth is recommended. Total plasma concentrations of phenytoin are decreased in the mother during pregnancy; unbound plasma (free) concentrations are also decreased and plasma clearance is increased. Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments of phenytoin in order to maintain clinical response; monitoring during pregnancy should be considered (Harden and Pennell 2009). For women with epilepsy who are planning a pregnancy in advance, baseline serum concentrations should be measured once or twice prior to pregnancy during a period when seizure control is optimal. Monitoring can then be continued once each trimester during pregnancy and postpartum; more frequent monitoring may be needed in some patients. Monitoring of unbound plasma concentrations is recommended (Patsalos 2008). In women taking phenytoin who are trying to avoid pregnancy, potentially significant interactions may exist with hormone-containing contraceptives; consult drug interactions database for more detailed information. Patients exposed to phenytoin during pregnancy are encouraged to enroll themselves into the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling 1-888-233-2334. Additional information is available at https:\\aedpregnancyregistry.org.
Phytonadione		Phytonadione crosses the placenta in limited concentrations (Kazzi 1990). The dietary requirements of vitamin K are the same in pregnant and nonpregnant women (IOM 2000). In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003). Use of preservative free solutions are preferred when the injection is needed during pregnancy.
Pioglitazone		Information related to the use of pioglitazone in pregnant women is limited (Glueck 2003; Ortega-Gonzalez 2005; Ota 2008). Thiazolidinediones may cause ovulation in anovulatory premenopausal women, increasing the risk of unintended pregnancy. In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013). Agents other than pioglitazone are currently recommended to treat diabetes in pregnant women (ADA 2018c).
Piperonyl Butoxide/ Pyrethrins		Pregnant women may be treated with pyrethrins and piperonyl butoxide (CDC [Workowski 2015]).
Pneumococcal Vaccine	C	Animal reproduction studies have not been conducted. Vaccination should be considered in pregnant women at high risk for infection. Inactivated vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]).
Podofilox		Teratogenic events have not been observed in animal reproduction studies with topical administration. Podofilox should not be used during pregnancy (CDC [Workowski 2015])
Podophyllin		Use is contraindicated in women who are or may become pregnant. Reports in pregnant women have shown evidence of fetal abnormalities, fetal death, and stillbirth.
Poliovirus Vaccine		Animal reproduction studies have not been conducted. Although adverse effects of IPV have not been documented in pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. Pregnant women at increased risk for infection and requiring immediate protection against polio may be administered the vaccine (CDC/ACIP [Prevots 2000]).
Polyethylene Glycol 3350		Polyethylene glycol (PEG) has minimal systemic absorption and would be unlikely to cause fetal malformations. However, until additional information is available, use to

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		treat constipation in pregnancy should be avoided unless other preferred methods are inadequate (Mahadevan 2006). Use as a bowel preparation prior to colonoscopy in pregnant women may be considered (Wexner 2006).
Polymyxin B/ Neomycin/ Bacitracin		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006).
Polymyxin B/ Neomycin/ Gramicidin Ophthalmic		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Bacitracin: Bacitracin is not absorbed systemically following ophthalmic administration (Robert, 2001). If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples, 1988).
Polymyxin B/ Trimethoprim Ophthalmic		Adverse events have been observed with trimethoprim in animal reproduction studies; animal reproduction studies have not been conducted with polymyxin B. See individual agents. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples 1988). Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Trimethoprim: Adverse events have been observed in animal reproduction studies. Trimethoprim crosses the placenta and can be detected in the fetal serum and amniotic fluid (Reid 1975). Adverse events may be associated with trimethoprim use during pregnancy (Andersen 2012; Andersen 2013; Mølgaard-Nielsen 2012). Untreated urinary tract infections may cause adverse pregnancy outcomes (Nicolle 2005); because safer options are available for the treatment of UTIs in pregnant women, use of TMP containing products in the first trimester should be avoided (Lee 2008). Studies evaluating the effects of trimethoprim administration in pregnancy have also been conducted with Sulfamethoxazole and Trimethoprim (see the Sulfamethoxazole and Trimethoprim monograph for details).
Potassium Chloride		Potassium requirements are the same in pregnant and nonpregnant women. Adverse events have not been observed following use of potassium supplements in healthy

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		women with normal pregnancies. Use caution in pregnant women with other medical conditions (eg, preeclampsia; may be more likely to develop hyperkalemia) (IOM 2004). Potassium supplementation (that does not cause maternal hyperkalemia) would not be expected to cause adverse fetal events.
Pramipexole		Adverse events were observed in animal reproduction studies. Information related to the use of pramipexole for the treatment of Parkinson disease (Benbir 2013, Mucchiut 2004) or restless legs syndrome (RLS) (Dostal 2013) in pregnant women is limited. Current guidelines note that the available information is insufficient to make a recommendation for the treatment of RLS in pregnant women (Aurora 2012).
Pravastatin	X	Use of pravastatin is contraindicated in pregnancy. Adverse events were observed in some animal reproduction studies. Pravastatin was found to cross the placenta in an ex vivo study using term human placentas (Nanovskaya 2013). There are reports of congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long term outcomes of primary hypercholesterolemia treatment. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Prazosin		Adverse events were observed in some animal reproduction studies. Prazosin crosses the placenta and its pharmacokinetics may be slightly altered during pregnancy (Bourget 1995; Rubin 1983). Limited use in pregnant women has not demonstrated any fetal abnormalities or adverse effects (Dommisse 1983). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are generally preferred (ACOG 2013).
Prednisolone Ophthalmic	C	Adverse events have been observed in animal reproduction studies. Prednisolone crosses the placenta when administered systemically; the amount of prednisolone available systemically following ophthalmic use is unknown. Refer to the Prednisolone (Systemic) monograph for additional information.
Prednisone	C/D	Adverse events have been observed with corticosteroids in animal reproduction studies. Prednisone and its metabolite, prednisolone, cross the human placenta. In the mother, prednisone is converted to the active metabolite prednisolone by the liver. Prior to reaching the fetus, prednisolone is converted by placental enzymes back to prednisone. As a result, the level of prednisone remaining in the maternal serum and reaching the fetus are similar; however, the amount of prednisolone reaching the fetus is ~8 to 10 times lower than the maternal serum concentration (healthy women at term) (Beitins 1972). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant women, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006). Prednisone

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		is preferred by some guidelines when an oral corticosteroid is needed because placental enzymes limit passage to the embryo (Murase 2014). Pregnant women with poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used medications. Uncontrolled asthma is associated with an increased risk of perinatal mortality, preeclampsia, preterm birth, and low birth weight infants. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; however, systemic corticosteroids, including prednisone, should be used to control acute exacerbations or treat severe persistent asthma (ACOG 2008; GINA 2016; Namazy 2016). Prednisone may be used to treat lupus nephritis in pregnant women who have active nephritis or substantial extrarenal disease activity (Hahn 2012). Prednisone is recommended for use in fetal-neonatal alloimmune thrombocytopenia and pregnancy-associated immune thrombocytopenia (ACOG 2016). Prednisone may be used (alternative agent) to treat primary adrenal insufficiency (PAI) in pregnant women. Pregnant women with PAI should be monitored at least once each trimester (Bornstein 2016). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Primaquine	Primaquine is contraindicated in pregnant women.	Primaquine is contraindicated in pregnant women. Sexually active females should have a pregnancy test prior to treatment with primaquine. Females of reproductive potential should use effective contraception during therapy and until the next menses following discontinuation of treatment. Males with female partners of reproductive potential should use condoms during therapy and for 3 months after treatment is discontinued. Malaria infection in pregnant women may be more severe than in nonpregnant women and has a high risk of maternal and perinatal morbidity and mortality. Therefore, pregnant women and women who are likely to become pregnant are advised to avoid travel to malaria-risk areas. When treatment is needed, other agents are preferred (CDC Yellow Book 2016). Consult current CDC guidelines for the treatment of malaria during pregnancy.
Primidone		Primidone and its metabolites (PEMA, phenobarbital, and p-hydroxyphenobarbital) cross the placenta; neonatal serum concentrations at birth are similar to those in the mother. Withdrawal symptoms may occur in the neonate and may be delayed due to the long half-life of primidone and its metabolites. Use may be associated with birth defects and adverse events; the use of folic acid throughout pregnancy and vitamin K during the last month of pregnancy is recommended. Epilepsy itself, number of medications, genetic factors, or a combination of these probably influence the teratogenicity of anticonvulsant therapy. Patients exposed to primidone during pregnancy are encouraged to enroll themselves into the NAAED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Probenecid		Probenecid crosses the placenta. Based on available data, an increased risk of adverse fetal events have not been reported (Gutman, 2012).
Prochlorperazine		Jaundice or hyper- or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The use of prochlorperazine may be considered for adjunctive treatment of nausea and vomiting in pregnant patients when symptoms persist following initial pharmacologic therapy (ACOG 189 2018). Use may interfere with pregnancy tests, causing false positive results.
Promethazine		Adverse effects have not been observed in animal reproduction studies. Promethazine crosses the placenta (Potts 1961). Platelet aggregation may be inhibited in newborns following maternal use of promethazine within 2 weeks of delivery. Promethazine is approved for use as an antiemetic; however, other agents are recommended as initial

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		therapy for the treatment of nausea and vomiting of pregnancy (ACOG 2015). Promethazine is indicated for use during labor for obstetric sedation and may be used alone or as an adjunct to opioid analgesics. Although promethazine is approved for the treatment of allergic conditions (eg, allergic rhinitis, urticaria), other agents are preferred for use in pregnant women (Scadding 2008; Wallace 2008; Zuberbier 2014).
Proparacaine Hydrochloride		Animal reproduction studies have not been conducted.
Propranolol Hydrochloride	C	Adverse events have been observed in some animal reproduction studies. Propranolol crosses the placenta and is measurable in the newborn serum following maternal use during pregnancy (Taylor 1981). According to the manufacturer, congenital abnormalities have been reported following maternal use of propranolol. Bradycardia, hypoglycemia, and/or respiratory depression have been observed in neonates following in utero exposure to propranolol at parturition. Reduced birth weight has also been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth should be available. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). When treatment of hypertension in pregnancy is indicated, beta-blockers may be used. Specific recommendations vary by guideline. Although other agents are preferred (ACOG 2013), use of propranolol may be considered (Magee 2014). Use of propranolol may be considered for some arrhythmias, including SVT, when use of a beta-blocker is needed during pregnancy (ACC/AHA/HRS [Page 2015]; ESC [Regitz-Zagrosek 2011]). Propranolol is recommended for use in controlling hypermetabolic symptoms of thyrotoxicosis in pregnancy (Stagnaro-Green 2011). Propranolol may be used if prophylaxis of migraine is needed in pregnant women; it should be discontinued 2 to 3 days prior to delivery to decrease the risk of adverse events to the fetus/neonate and potential reductions in uterine contraction (Pringsheim 2012).
Propylthiouracil	D	Propylthiouracil has been found to readily cross the placenta. Teratogenic effects have not been observed; however, nonteratogenic adverse effects, including fetal and neonatal hypothyroidism, goiter, and hyperthyroidism, have been reported following maternal propylthiouracil use. The transfer of thyroid-stimulating immunoglobulins can stimulate the fetal thyroid in utero and transiently after delivery and may increase the risk of fetal or neonatal hyperthyroidism (De Groot 2012; Peleg 2002). Antithyroid treatment is recommended for the control of hyperthyroidism during pregnancy (Casey 2006; De Groot 2012). Uncontrolled maternal hyperthyroidism may result in adverse neonatal outcomes (eg, prematurity, low birth weight) and adverse maternal outcomes (eg, preeclampsia, congestive heart failure, stillbirth, and abortion). To prevent adverse fetal and maternal events, normal maternal thyroid function should be maintained prior to conception and throughout pregnancy (De Groot 2012).
Psyllium		Psyllium is not absorbed systemically. When administered with adequate fluids, use is considered safe for the treatment of occasional constipation during pregnancy (Wald, 2003).
Pyrazinamide	C	Adverse events have not been observed in animal reproduction studies. Due to the risk of tuberculosis to the fetus, treatment is recommended when the probability of maternal disease is moderate to high. Drug-susceptible TB guidelines recommend pyrazinamide as part of the initial treatment regimen; however, risks and benefits of use during pregnancy should be considered for each individual patient (Nahid 2016).
Pyridostigmine	B/C	Adverse events have not been observed in animal reproduction studies. Pyridostigmine may cross the placenta (Buckley 1968). Use of pyridostigmine may be continued during pregnancy for the treatment of myasthenia gravis (Norwood 2014; Skeie 2010) and its use should be continued during labor (Norwood 2014). Transient neonatal myasthenia gravis may occur in 10% to 20% of neonates due to placental transfer of maternal antibodies (Skeie 2010; Varner 2013). In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003).

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Pyridoxine	A	Water soluble vitamins cross the placenta. Maternal pyridoxine plasma concentrations may decrease as pregnancy progresses and requirements may be increased in pregnant women (IOM 1998). Pyridoxine is used to treat nausea and vomiting of pregnancy (ACOG 189 2018; Neibyl 2010; Campbell [SOGC] 2016).
Pyrimethamine	C	Adverse events have been observed in animal reproduction studies. If administered during pregnancy (ie, for toxoplasmosis), supplementation of folate is strongly recommended. Pregnancy should be avoided during therapy.
Quinidine Sulfate	C	Animal reproduction studies have not been conducted. Quinidine crosses the placenta and can be detected in the amniotic fluid, cord blood, and neonatal serum. Quinidine is indicated for use in the treatment of severe malaria infection in pregnant women (CDC, 2013; Smereck, 2011) and has also been used to treat arrhythmias in pregnancy when other agents are ineffective (European Society of Cardiology, 2003).
Quinine	C	Teratogenic effects have been reported in some animal studies. Quinine crosses the human placenta. Cord plasma to maternal plasma quinine ratios have been reported as 0.18-0.46 and should not be considered therapeutic to the infant. Teratogenic effects, optic nerve hypoplasia, and deafness have been reported in the infant following maternal use of very high doses; however, therapeutic doses used for malaria are generally considered safe. Quinine may also cause significant hypoglycemia when used during pregnancy. Malaria infection in pregnant women may be more severe than in nonpregnant women. Because P. falciparum malaria can cause maternal death and fetal loss, pregnant women traveling to malaria-endemic areas must use personal protection against mosquito bites. Quinine may be used for the treatment of malaria in pregnant women; consult current CDC guidelines. Pregnant women should be advised not to travel to areas of P. falciparum resistance to chloroquine.
Raltegravir Potassium		Raltegravir has high transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines consider raltegravir to be the preferred integrase inhibitor for initial use in antiretroviral-naive pregnant patients and is useful when drug interactions with protease inhibitors are a concern. Because of its ability to rapidly suppress viral load, raltegravir may be useful in women who present late in pregnancy with high viral loads. Dose adjustments are not required in pregnant women; however, once daily dosing is not recommended until more data is available. Reversible elevation of liver enzymes occurred in a patient who initiated raltegravir late in pregnancy; monitor liver enzymes if used during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the

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		National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Ranitidine Hydrochloride		Ranitidine crosses the placenta (Armentano 1989). Histamine H2 antagonists have been evaluated for the treatment of gastroesophageal reflux disease (GERD) as well as gastric and duodenal ulcers during pregnancy. If needed, ranitidine is the agent of choice (Cappell 2003; Richter 2003). Histamine H2 antagonists may be used for aspiration prophylaxis prior to cesarean delivery (ASA 2007).
Rifampin	C	Adverse events have been observed in animal reproduction studies. Rifampin crosses the human placenta. Postnatal hemorrhages have been reported in the infant and mother with administration during the last few weeks of pregnancy. Maternal treatment of tuberculosis is recommended when the probability of maternal disease is moderate to high due to the risk of infection to the fetus (ATC/CDC 2003). Rifampin may be considered for use as an alternative agent in pregnant women for the treatment of mild illness due to human anaplasmosis (also known as human granulocytic anaplasmosis [HGA]); case reports have shown favorable maternal and pregnancy outcomes in small numbers of rifampin-treated pregnant women (CDC [Biggs 2016]).
Rilpivirine		Rilpivirine has moderate to high placental transfer. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines recommend rilpivirine as a component in alternative regimens for initial use in antiretroviral-naïve pregnant females with a pretreatment HIV RNA ≤100,000 copies/mL and CD4 cell count ≥200 cells/mm3. The pharmacokinetics are highly variable in pregnancy; data is insufficient to recommend pregnancy specific dosing; however, viral loads should be monitored more frequently when standard doses are used in pregnant females. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Risperidone	C	Adverse events were observed in animal reproduction studies. In human studies, risperidone and its metabolite cross the placenta (Newport 2007). Agenesis of the corpus callosum has been noted in one case report of an infant exposed to risperidone in utero; relationship to risperidone exposure is not known. Antipsychotic use during the third trimester of pregnancy has a risk for extrapyramidal symptoms (EPS) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress,

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		somnolence, and tremor. These effects may be self-limiting and allow recovery within hours or days with no specific treatment, or they may be severe requiring prolonged hospitalization. When using Risperdal Consta, patients should notify health care provider if they become or intend to become pregnant during therapy or within 12 weeks of last injection. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited. As a result, routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to an agent that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). If treatment is needed in a woman planning a pregnancy or if treatment is initiated during pregnancy, use of an agent other than risperidol is preferred (Larsen 2015). Risperidone may cause hyperprolactinemia, which may decrease reproductive function in both males and females. Healthcare providers are encouraged to enroll women 18 to 45 years of age exposed to risperidone during pregnancy in the Atypical Antipsychotics Pregnancy Registry (1-866-961-2388 or http://www.womensmentalhealth.org/pregnancyregistry).
Ritonavir		Ritonavir has a low level of transfer across the human placenta; no increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with protease inhibitors; it is not clear if pregnancy increases this risk. Ritonavir should only be used as a low-dose booster during pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines consider ritonavir, when used as a booster for other PIs, to be a preferred component of regimens for initial use in antiretroviral-naïve pregnant females. A ritonavir-boosted protease inhibitor regimen is also recommended when acute HIV infection is detected during pregnancy. Early studies have shown lower plasma levels during pregnancy compared to postpartum; however, dosage adjustment is not needed when used as a low-dose booster in pregnant females. Ritonavir is not recommended for initial therapy as a single protease inhibitor in ART naive pregnant females due to inferior efficacy and increased toxicity; females should be switched to a preferred or alternative regimen (ritonavir should only be used as a low-dose booster during pregnancy). The oral solution contains alcohol and therefore is not recommended for use in pregnant patients. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the

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		National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Rosuvastatin		Adverse events have been observed in some animal reproduction studies. There are reports of congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long term outcomes of primary hypercholesterolemia treatment. Use of rosuvastatin is contraindicated in pregnancy. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Rotavirus	C	Reproduction studies have not been conducted. Not indicated for use in women of reproductive age. Infants living in households with pregnant women may be vaccinated (CDC/ACIP [Cortese, 2009]).
Salicylic Acid	C	Adverse events have been observed in animal reproduction studies when administered orally. Salicylates cross the placenta (Østensen 1998). Systemic absorption of topical salicylic acid occurs and varies depending on duration and vehicle (~9% to 25%) and is increased with occlusion (Akhavan 2003). Current guidelines do not recommend salicylic acid for the treatment of psoriasis in pregnant women due to limited safety data and the potential for systemic absorption (Bae 2012). For the topical treatment of acne or warts, salicylic acid can be used in pregnant women if the area of exposure and duration of therapy is limited, although other agents may be preferred (Murase, 2014). Consider maternal/fetal adverse events associated with aspirin if significant systemic exposure occurs (Akhavan 2003).
Salmeterol	C	Adverse events were observed in some animal reproduction studies. Beta-agonists have the potential to affect uterine contractility if administered during labor. Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, pre-eclampsia, preterm birth, low birth weight infants). Although data related to its use in pregnancy is limited, salmeterol may be used when a long-acting beta agonist is needed to treat moderate persistent or severe persistent asthma in pregnant women (NAEPP, 2005).
Saquinavir	B	Saquinavir has a low level of transfer across the human placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend ritonavir-boosted saquinavir for initial use in antiretroviral-naive pregnant females due to potential toxicity, twice-daily dosing requirements, and limited data in pregnancy; use of saquinavir without ritonavir is not recommended in any patient. Based on available data, dose adjustments are not required in pregnant patients. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit

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		of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Selenium Sulfide	C	Animal reproduction studies have not been conducted. The manufacturer's labeling for some products recommend against using selenium sulfide in pregnant women.
Sertraline Hydrochloride		Sertraline crosses the human placenta. Available studies evaluating teratogenic effects following maternal use of sertraline in the first trimester have not shown an overall increased risk of major birth defects. Studies evaluating specific birth defects have provided inconsistent results. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, women who are pregnant may require adjusted doses of sertraline to achieve euthymia. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Sevelamer	C	Adverse events have been observed in animal reproduction studies. Sevelamer is not absorbed systemically; however, it may cause a reduction in the absorption of fat soluble vitamins and folic acid.
Silver Nitrate Applicator		
Silver Sulfadiazine		Adverse events were not observed in animal reproduction studies. Because of the theoretical increased risk for hyperbilirubinemia and kernicterus, silver sulfadiazine is contraindicated for use near term, on premature infants, or on newborn infants during the first 2 months of life (refer to Sulfadiazine monograph).
Simethicone		Simethicone is not absorbed systemically following oral administration. Systemic absorption would be required in order for simethicone to cross the placenta and reach the fetus (Mahadevan 2006).
Simvastatin	X	Studies in pregnant women have shown evidence of fetal abnormalities and use is contraindicated in women who are or may become pregnant. There are reports of

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		congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long-term outcomes of primary hypercholesterolemia treatment. Use of simvastatin is contraindicated in pregnancy. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Sodium Bicarbonate		Animal reproduction studies have not been conducted. Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Campbell 2009; Jeejeebhoy [AHA] 2015). Antacids containing sodium bicarbonate should not be used during pregnancy due to their potential to cause metabolic alkalosis and fluid overload (Mahadevan 2007).
Sodium Chloride	C	Animal reproduction studies have not been conducted. Sodium requirements do not change during pregnancy (IOM 2004). Nasal saline rinses may be used for the treatment of pregnancy rhinitis (Wallace, 2008)
Sodium Phosphate, Rectal	C	Reproduction studies have not been conducted with these products. Use with caution in pregnant women.
Sotalol	B	Adverse events were not observed in the initial animal reproduction studies. Sotalol crosses the placenta and is found in amniotic fluid. Adverse events, such as fetal/neonatal bradycardia, hypoglycemia, and reduced birth weight have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth are generally recommended. Sotalol crosses the placenta in concentrations similar to the maternal serum and it is generally preferred for the treatment of fetal atrial flutter (Namouz-Haddad 2013). The clearance of sotalol is increased during the third trimester of pregnancy, but other pharmacokinetic parameters do not significantly differ from nonpregnant values (O'Hare 1983). Use of sotalol may be considered for some cardiac arrhythmias when use of a beta-blocker is needed during pregnancy (ESC [Regitz-Zagrosek 2011]).
Spironolactone		Spironolactone crosses the placenta (Regitz-Zagrosek 2011). Use of diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. The treatment of heart failure is generally the same in pregnant and nonpregnant women; however, spironolactone should be avoided in the first trimester due to its antiandrogenic effects (Regitz-Zagrosek 2011). The use of mineralocorticoid receptor antagonists is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential. When treatment for hypertension in pregnancy is needed, other agents are preferred (ACOG 2013)
Stavudine	C	Stavudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure to stavudine alone according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is

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		limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. [US Boxed Warning]: Fatal lactic acidosis has been reported in pregnant women using didanosine and stavudine in combination with other antiretroviral agents; co-administration with didanosine is contraindicated. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk. In addition to lactic acidosis, the combination of didanosine and stavudine has been shown to increase the risk of neurodevelopmental disability. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend stavudine for initial therapy in antiretroviral-naive pregnant females due to toxicity; do not use in combination with didanosine or zidovudine. Pharmacokinetics of stavudine are not significantly altered during pregnancy; dose adjustments are not needed. In addition, because of the high risk of toxicity, stavudine should be stopped in females who become pregnant during therapy and women should be switched to a preferred or alternative regimen. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Streptomycin	D	Streptomycin crosses the placenta. Streptomycin may cause fetal harm if administered to a pregnant woman. There are multiple reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Streptomycin should never be substituted as first line therapy for the treatment of tuberculosis in pregnant women (Blumberg 2003).
Sucralfate		Adverse events were not observed in animal reproduction studies. Sucralfate is only minimally absorbed following oral administration. Based on available data, use of sucralfate does not appear to increase the risk of adverse fetal events when used during the first trimester (Mahadevan, 2006).
Sulfacetamide	C	Animal reproduction studies have not been conducted. The amount of sulfacetamide available systemically following topical administration is unknown. Use of systemic sulfonamides during pregnancy may cause kernicterus in the newborn.
Sulfacetamide and Prednisolone Ophthalmic	C/D	Sulfacetamide: Animal reproduction studies have not been conducted. The amount of sulfacetamide available systemically following topical administration is unknown. Use of systemic sulfonamides during pregnancy may cause kernicterus in the newborn. Prednisolone: Adverse events have been observed with corticosteroids in animal reproduction studies. Prednisone and its metabolite, prednisolone, cross the human placenta. In the mother, prednisone is converted to the active metabolite prednisolone by the liver. Prior to reaching the fetus, prednisolone is converted by placental enzymes back to prednisone. As a result, the level of prednisone remaining in the maternal serum and reaching the fetus are similar; however, the amount of prednisolone reaching the fetus is ~8 to 10 times lower than the maternal serum concentration (healthy women at term) (Beitins 1972). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however,

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		information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant women, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006). Prednisone is preferred by some guidelines when an oral corticosteroid is needed because placental enzymes limit passage to the embryo (Murase 2014). Pregnant women with poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used medications. Uncontrolled asthma is associated with an increased risk of perinatal mortality, preeclampsia, preterm birth, and low birth weight infants. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; however, systemic corticosteroids, including prednisone, should be used to control acute exacerbations or treat severe persistent asthma (ACOG 2008; GINA 2016; Namazy 2016). Prednisone may be used to treat lupus nephritis in pregnant women who have active nephritis or substantial extrarenal disease activity (Hahn 2012). Prednisone is recommended for use in fetal-neonatal alloimmune thrombocytopenia and pregnancy-associated immune thrombocytopenia (ACOG 2016). Prednisone may be used (alternative agent) to treat primary adrenal insufficiency (PAI) in pregnant women. Pregnant women with PAI should be monitored at least once each trimester (Bornstein 2016). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Sulfamethoxazole/ Trimethoprim	D	Sulfamethoxazole and trimethoprim cross the placenta. An increased risk of congenital malformations (neural tube defects, cardiovascular malformations, urinary tract defects, oral clefts, club foot) following maternal use of sulfamethoxazole and trimethoprim during pregnancy has been observed in some studies. Folic acid supplementation may decrease this risk (Crider 2009; Czeizel 2001; Hernandez-Diaz 2000; Hernandez-Diaz 2001; Matok 2009). Due to theoretical concerns that sulfonamides pass the placenta and may cause kernicterus in the newborn, neonatal health care providers should be informed if maternal sulfonamide therapy is used near the time of delivery (HHS [OI adult 2017]). The pharmacokinetics of sulfamethoxazole and trimethoprim are similar to nonpregnant values in early pregnancy (Ylikorkala 1973). Sulfamethoxazole and trimethoprim are recommended for the prophylaxis or treatment of Pneumocystis jirovecii pneumonia (PCP), prophylaxis of Toxoplasmic gondii encephalitis (TE), and for the acute and chronic treatment of Q fever in pregnancy (CDC 2013; HHS [OI adult 2017]). Sulfonamides may also be used to treat other infections in pregnant women when clinically appropriate; use during the first trimester should be limited to situations where no alternative therapies are available (ACOG 717 2017).
Sulfasalazine		Sulfasalazine and sulfapyridine cross the placenta. Based on available data, an increase in fetal malformations has not been observed following maternal use of sulfasalazine for the treatment of inflammatory bowel disease. Cases of neural tube defects have been reported (causation undetermined). Agranulocytosis was noted in an infant following maternal use of sulfasalazine during pregnancy. Although sulfapyridine has poor bilirubin-displacing ability, a potential for kernicterus in the newborn exists. Sulfasalazine is known to inhibit the absorption and metabolism of folic acid and may diminish the effects of folic acid supplementation. When treatment for inflammatory bowel disease is needed during pregnancy, sulfasalazine may be used, although supplementation with folic acid is recommended (Flint 2016; Huang 2014; Mahadevan 2015). Sulfasalazine may cause oligospermia and reversible infertility in males (Habal

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		2012). Use is compatible in males with female partners of reproductive potential; however, discontinuing treatment for 3 months may enhance conception (Flint 2016).
Sulfur/ Salicylic Acid	C	Adverse events have been observed in animal reproduction studies when administered orally. Salicylates cross the placenta (Østensen 1998). Systemic absorption of topical salicylic acid occurs and varies depending on duration and vehicle (~9% to 25%) and is increased with occlusion (Akhavan 2003). Current guidelines do not recommend salicylic acid for the treatment of psoriasis in pregnant women due to limited safety data and the potential for systemic absorption (Bae 2012). For the topical treatment of acne or warts, salicylic acid can be used in pregnant women if the area of exposure and duration of therapy is limited, although other agents may be preferred (Murase, 2014). Consider maternal/fetal adverse events associated with aspirin if significant systemic exposure occurs (Akhavan 2003).
Sumatriptan Succinate	C	In a study using full-term, healthy human placentas, limited amounts of sumatriptan were found to cross the placenta (Schenker 1995). Pregnancy outcome information for sumatriptan is available from a pregnancy registry sponsored by GlaxoSmithKline. As of September 2012, data were available for 617 pregnancies (626 infants/fetuses) exposed to sumatriptan (including 7 pregnancies also exposed to naratriptan). Following sumatriptan exposure, the risk of major birth defects following first trimester exposure was 4.2% and no consistent pattern of birth defects was observed. The pregnancy registry was closed to enrollment in January 2012 (Ephross 2014). An analysis of data collected between 1995 and 2008 using the Swedish Medical Birth Register reported pregnancy outcomes following 5-HT1B/1D agonist exposure. An increased risk of major congenital malformations was not observed following sumatriptan exposure (2,229 exposed during the first trimester) (Källén 2011). An increased risk of major congenital malformations was also not observed using data collected from a Norwegian pregnancy registry study. This study included 415 women who used sumatriptan during the first trimester of pregnancy between 2004 and 2007 (Nezvalová-Henriksen 2013). If treatment for cluster headaches is needed during pregnancy, sumatriptan may be used (Jürgens 2009). Other agents are preferred for the initial treatment of migraine in pregnancy (Da Silva 2012; MacGregor 2014; Williams 2012); however, sumatriptan may be considered if first-line agents fail (MacGregor 2014).
Tacrolimus	C	Adverse events were observed in animal reproduction studies. Tacrolimus crosses the human placenta and is measurable in the cord blood, amniotic fluid, and newborn serum. Tacrolimus concentrations in the placenta may be higher than the maternal serum (Jain 1997). Infants with lower birth weights have been found to have higher tacrolimus concentrations (Bramham 2013). Transient neonatal hyperkalemia and renal dysfunction have been reported. Tacrolimus pharmacokinetics are altered during pregnancy. Whole blood concentrations decrease as pregnancy progresses; however, unbound concentrations increase. Measuring unbound concentrations may be preferred, especially in women with anemia or hypoalbuminemia. If unbound concentration measurement is not available, interpretation of whole blood concentrations should account for RBC count and serum albumin concentration (Hebert 2013; Zheng 2012). In general, women who have had a kidney transplant should be instructed that fertility will be restored following the transplant but that pregnancy should be avoided for ~2 years. Tacrolimus may be used as an immunosuppressant during pregnancy. The risk of infection, hypertension, and pre-eclampsia may be increased in pregnant women who have had a kidney transplant (EBPG 2002). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Tamoxifen	D	Animal reproduction studies have demonstrated fetal adverse effects and fetal loss. There have been reports of vaginal bleeding, birth defects and fetal loss in pregnant women. Tamoxifen use during pregnancy may have a potential long term risk to the fetus of a DES-like syndrome. For sexually-active women of childbearing age, initiate during menstruation (negative β-hCG immediately prior to initiation in women with

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		irregular cycles). Tamoxifen may induce ovulation. Barrier or nonhormonal contraceptives are recommended. Pregnancy should be avoided during treatment and for 2 months after treatment has been discontinued.
Tamsulosin	B	Adverse events were not observed in animal reproduction studies. For pregnant women with kidney stones, other treatments such as stents or ureteroscopy, are recommended if stone removal is needed (Preminger 2007; Tan 2013).
Tar Shampoo		Limited application of coal tar during pregnancy for the treatment of psoriasis appears to be safe in pregnant women (Gelmetti, 2009; Landau, 2011).
Tears, Artificial		
Telbivudine	B	Adverse events were not observed in animal reproduction studies. In hepatitis B-infected women (not coinfected with HIV), the AASLD chronic hepatitis B treatment guidelines suggest antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg-positive pregnant women with an HBV DNA >200,000 units/mL. There are limited data on the level of HBV DNA for when antiviral therapy is routinely recommended (>200,000 units/mL is a conservative recommendation); however, the AASLD recommends against antiviral therapy to reduce the risk of perinatal transmission in HBsAg-positive pregnant women with an HBV DNA ≤200,000 units/mL. Telbivudine is one of the antivirals that has been studied in pregnant women, with most studies initiating antiviral therapy at 28 to 32 weeks gestation and discontinuing antiviral therapy between birth to 3 months postpartum (monitor for ALT flares every 3 months for 6 months following discontinuation). There is insufficient long-term safety data in infants born to mothers who took antiviral agents during pregnancy (AASLD [Terrault 2016]). Health professionals are encouraged to contact the antiretroviral pregnancy registry to monitor outcomes of pregnant women exposed to antiretroviral medications (1-800-258-4263).
Tenofovir Disoproxil Fumarate	B	Tenofovir has a high level of transfer across the human placenta following maternal use of tenofovir disoproxil fumarate. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Intrauterine growth has not been affected following use of tenofovir disoproxil fumarate, but data are conflicting about potential growth effects later in infancy. Clinical studies in children have shown bone demineralization with chronic use. Bone mineral content was also decreased in infants following in utero exposure. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general NRTIs are well tolerated and the benefits of use generally outweigh potential risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider tenofovir disoproxil fumarate a component in preferred regimens for initial therapy in antiretroviral-naïve pregnant females. The guidelines also consider emtricitabine plus tenofovir disoproxil fumarate, or lamivudine plus tenofovir disoproxil fumarate as recommended dual NRTI backbone for HIV/HBV coinfected pregnant females. Hepatitis B flare may occur if tenofovir disoproxil fumarate is discontinued. Tenofovir disoproxil fumarate is also a recommended component of a regimen when acute HIV infection is detected during pregnancy. Limited data indicate decreased maternal exposure during the third trimester; dose adjustments are not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as

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		possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Tenofovir disoproxil fumarate is one of the agents recommended for pre-exposure prophylaxis in couples with differing HIV status who are planning a pregnancy. The partner without HIV should begin therapy 1 month prior to attempting conception and continue therapy for 1 month after attempting conception. In hepatitis B-infected women (not coinfected with HIV), the AASLD chronic hepatitis B treatment guidelines suggest antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg-positive pregnant women with an HBV DNA >200,000 units/mL. There are limited data on the level of HBV DNA for when antiviral therapy is routinely recommended (>200,000 units/mL is a conservative recommendation); however, the AASLD recommends against antiviral therapy to reduce the risk of perinatal transmission in HBsAg-positive pregnant women with an HBV DNA ≤200,000 units/mL. Tenofovir is one of the antivirals that has been studied in pregnant women (and may b
Terazosin	C	Adverse events have not been observed in animal studies. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are generally preferred (ACOG 2013).
Terbinafine	B	Adverse events were not observed in animal reproduction studies with systemic terbinafine. Avoid use in pregnancy since treatment of onychomycosis is postponable. Systemic absorption is limited following topical application.
Testosterone (Depo Injection)	X	Use is contraindicated in pregnant women or women who may become pregnant. Exposure to a fetus may cause virilization of varying degrees. Because of the potential for secondary exposure, all children and women should avoid skin-to-skin contact to areas where testosterone has been applied topically on another person. Some products contain benzyl alcohol, which can cross the placenta. Large doses of testosterone may suppress spermatogenesis. Treatment of hypogonadotropic hypogonadism is not recommended for men desiring fertility (Endocrine Society [Bhasin 2018]).
Tetanus/ Diphtheria	C	Reproduction studies have not been conducted. DT is not recommended for use in persons ≥7 years of age. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]). The Advisory Committee on Immunization Practices (ACIP) recommends a single Tdap vaccination during each pregnancy; ideally between 27 and 36 weeks gestation. Pregnant women who are not immunized or are only partially immunized should complete the primary series with Td. Tetanus immune globulin and a tetanus toxoid containing vaccine are recommended by the ACIP as part of the standard wound management to prevent tetanus in pregnant women; the use of a tetanus-toxoid containing vaccine during pregnancy is recommended for wound management if ≥5 years have passed since the last Td vaccination (CDC/ACIP 2013).
Tetanus Toxoid	C	Animal studies have not been conducted. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (CDC, 2011). The ACIP recommends vaccination in previously unvaccinated women or in women with an incomplete vaccination series, whose child may be born in unhygienic conditions. Tetanus immune globulin and a tetanus toxoid-containing vaccine are recommended by the ACIP as part of the standard wound management to prevent tetanus in pregnant women. Vaccination using Td is preferred.
Tetrahydrozoline Ophthalmic		
Thiamine	A	Water soluble vitamins cross the placenta. Thiamine requirements are increased in during pregnancy (IOM 1998). Pregnant females are at increased risk of thiamine deficiency when prolonged nausea and vomiting (including hyperemesis gravidarum) occurs; deficiency may present as a polyneuropathy or Wernicke encephalopathy (Chiossi 2006; Karjalainen 1965; WHO 1999). Thiamine supplementation is

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		recommended in pregnant females with prolonged vomiting. Initial treatment with IV thiamine is needed when Wernicke encephalopathy is suspected. Oral, IM, or IV therapy may be considered depending on severity of thiamine deficiency (Berdai 2016; Chiossi 2006; Palacios-Marqués 2012). When intravenous hydration is used in the management of hyperemesis gravidarum, thiamine should be administered prior to infusing dextrose to prevent Wernicke encephalopathy (ACOG 189 2018).
Thiothixene		Adverse events were observed in some animal reproduction studies. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician. When treating schizophrenia during pregnancy, atypical antipsychotics may be better tolerated by the mother however more information related to fetal effects may be available for agents considered typical (or first generation) antipsychotics (ACOG 2008). Information related to the use of thiothixene in pregnancy is limited and other agents may be preferred.
Timolol Maleate	C	Adverse events were not observed in the initial animal reproduction studies. Timolol crosses the placenta (Schneider 1988) and decreased fetal heart rate has been observed following maternal use of timolol during pregnancy (Devoe 1986). Adverse events, such as fetal/neonatal hypoglycemia and reduced birth weight, have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth is generally recommended. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). Although beta-blockers may be used when treatment of hypertension in pregnancy is indicated, agents other than timolol are preferred (ACOG 2013; Magee 2014). In addition, other agents are preferred when migraine prophylaxis is needed in pregnant women (Pringsheim 2012).
Tipranavir		Tipranavir has a moderate level of transfer across the human placenta (based on one case). Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend tipranavir for initial use in antiretroviral-naive pregnant patients. Available pharmacokinetic data are insufficient to make dosing recommendations. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or

Generic Name	Category	Pregnancy Implications
		http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Titanium Dioxide		
Tizanidine		Adverse events were observed in some animal reproduction studies.
Tobramycin Ophthalmic	B	Adverse events have not been observed in animal reproduction studies. The amount of tobramycin available systemically following topical application of the ophthalmic drops is undetectable (<0.2 mcg/mL) (Filatov 1994). If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctal occlusion to decrease systemic absorption (Samples 1988).
Tolnaftate		
Topiramate	D	Adverse events have been observed in animal reproduction studies. Based on limited data (n=5), topiramate was found to cross the placenta and could be detected in neonatal serum (Ohman 2002). Topiramate may cause fetal harm if administered to a pregnant woman. An increased risk of oral clefts (cleft lip and/or palate) and for being small for gestational age (SGA) has been observed following in utero exposure. Data from the North American Antiepileptic Drug (NAAED) Pregnancy Registry reported that the prevalence of oral clefts was 1.1% for infants exposed to topiramate during the first trimester of pregnancy, versus 0.36% for infants exposed to a reference antiepileptic drug, and 0.12% for infants with no exposure born to mothers without epilepsy; the relative risk of oral clefts in infants exposed to topiramate was calculated to be 9.6 (95% CI: 4 to 23). Data from the NAAED Pregnancy Registry reported that the prevalence of small for gestational age newborns was 19.7% for newborns exposed to topiramate in utero, versus 7.9% for newborns exposed to a reference antiepileptic drug, and 5.4% for newborns with no exposure born to mothers without epilepsy. Although not evaluated during pregnancy, metabolic acidosis may be induced by topiramate. Metabolic acidosis during pregnancy may result in adverse effects and fetal death. Pregnant women and their newborns should be monitored for metabolic acidosis. In general, maternal polytherapy with antiepileptic drugs may increase the risk of congenital malformations; monotherapy with the lowest effective dose is recommended. Newborns of women taking antiepileptic medications may be at an increased risk of a 1 minute APGAR score <7 (Harden 2009). Maternal serum concentrations may decrease during the second and third trimesters of pregnancy; therefore, therapeutic drug monitoring should be considered during pregnancy and postpartum in patients who require therapy (Ohman 2009; Westin 2009). Effective contraception should be used in women who are not planning a pregnancy; consider use of alternative medications in women who wish to become pregnant. Data collection to monitor pregnancy and infant outcomes following exposure to topiramate is ongoing. Patients may enroll themselves into the AED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Tramadol		[US Boxed Warning]: Prolonged maternal use of opioids during pregnancy can cause neonatal withdrawal syndrome in the newborn which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Tramadol crosses the placenta. Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to Infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored.

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		Agents other than tramadol are commonly used to treat maternal pain during labor and immediately postpartum (ACOG 177 2017) as well as chronic noncancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Trazodone	C	Adverse effects were observed in some animal reproduction studies. The ACOG recommends that therapy with antidepressants during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. Consideration should be given to using agents with safety data in pregnancy. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Tretinoin Topical	C	Adverse events were observed in animal reproduction studies following topical application of tretinoin. Teratogenic effects were also observed in pregnant women following topical use; however, a causal association has not been established. When treatment for acne is needed during pregnancy, other agents are preferred (Kong, 2013). These products should not be used for palliation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in women who are pregnant, attempting to conceive, or at high risk for pregnancy.
Triamcinolone Acetonide	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014).
Triamcinolone Dental Paste	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014).
Triamcinolone Hexacetonide		Adverse events have been observed with corticosteroids in animal reproduction studies. Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest

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		effective dose for the shortest duration of time, avoiding high doses during the first trimester. Intra-articular dosing may be used (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant females, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006).
Triamterene/ Hydrochlorothiazide		Triamterene: Adverse events have not been observed in animal reproduction studies. Triamterene crosses the placenta and is found in cord blood. Use of triamterene to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Hydrochlorothiazide: Adverse events have not been observed in animal reproduction studies. Hydrochlorothiazide crosses the placenta. Maternal use may cause may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Use of thiazide diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother (ACOG 2013). Women who required thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use (ACOG 2013).
Trihexyphenidyl	C	Animal reproduction studies have not been conducted. One case report did not show evidence of adverse events after trihexyphenidyl administration during pregnancy (Robottom, 2011).
Trimethobenzamide Hydrochloride		Although use for the treatment of nausea and vomiting in pregnancy has been reported (Milkovich 1976; Pretorius 1961), use of other agents is preferred (ACOG 189 2018).
Tropicamide		Animal reproduction studies have not been conducted. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples, 1988).
Tuberculin Purified Protein Derivative	C	Animal reproduction studies have not been conducted. Pregnancy is not a contraindication to testing (CDC 2005).
Ulipristal		Use is contraindicated during a known or suspected pregnancy. Isolated cases of major malformations have been reported following inadvertent use during pregnancy, however data are not sufficient to determine a causal relationship and no pattern of adverse outcomes has been identified. When used for emergency contraception, exclude pregnancy prior to therapy; ulipristal is not indicated for terminating an existing pregnancy. A rapid return of fertility is expected following use for emergency contraception; routine contraceptive measures should be initiated or continued following use to ensure ongoing prevention of pregnancy. Barrier contraception is recommended immediately following emergency contraception and throughout the same menstrual cycle; efficacy of hormonal contraceptives may be decreased. The manufacturer recommends waiting ≥5 days after taking ulipristal before resuming oral contraceptives. The CDC notes any contraceptive method may be started immediately after taking ulipristal; however, a barrier method should also be used for 14 days following the dose (or until menses occurs, whichever occurs first) (Curtis 2016a). The manufacturer labeling suggests that ulipristal may be less effective in females with BSA >30 kg/m2. When ulipristal is used for treatment of uterine fibroids (Canadian labeling; not in US labeling) a nonhormonal method of contraception is recommended.
Umeclidinium/ Vilanterol	C	Animal reproduction studies have not been conducted with this combination. Beta-agonists have the potential to affect uterine contractility if administered during labor.
Valproic Acid	X (migraine pro-phylaxis)/ D (all other indi-cations)	Adverse events have been observed in animal reproduction studies and in human pregnancies. [US Boxed Warning]: May cause major congenital malformations, such as neural tube defects (eg, spina bifida) and decreased IQ scores following in utero exposure. Use is contraindicated in pregnant women for the prevention of migraine. Use is not recommended in women of childbearing potential for any other condition unless valproate is essential to manage her condition and alternative therapies are not appropriate. Effective contraception should be used during therapy. Valproic acid crosses the placenta (Harden 2009b). Neural tube defects, craniofacial defects,

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		cardiovascular malformations, hypospadias, and limb malformations have been reported. Information from the North American Antiepileptic Drug Pregnancy Registry notes the rate of major malformations to be 9% to 11% following an average exposure to valproate monotherapy 1,000 mg/day; this is an increase in congenital malformations when compared with monotherapy with other antiepileptic drugs (AED). Based on data from the CDC National Birth Defects Prevention Network, the risk of spinal bifida is approximately 1% to 2% following valproate exposure (general population risk estimated to be 0.06% to 0.07%). Nonteratogenic adverse effects have also been reported. Decreased IQ scores have been noted in children exposed to valproate in utero when compared to children exposed to other antiepileptic medications or no antiepileptic medications; the risk of autism spectrum disorders may also be increased. Fatal hepatic failure and hypoglycemia in infants have been noted in case reports following in utero exposure to valproic acid. Clotting factor abnormalities (hypofibrinogenemia, thrombocytopenia, or decrease in other coagulation factors) may develop in the mother following valproate use during pregnancy; close monitoring of coagulation factors is recommended. Current guidelines recommend complete avoidance of valproic acid and derivatives for the treatment of epilepsy in pregnant women whenever possible (Harden 2009a), especially when used for conditions not associated with permanent injury or risk of death. Effective contraception should be used during treatment. When pregnancy is being planned, consider tapering off of therapy prior to conception if appropriate; abrupt discontinuation of therapy may cause status epilepticus and lead to maternal and fetal hypoxia. Folic acid decreases the risk of neural tube defects in the general population; supplementation with folic acid should be used prior to conception and during pregnancy in all women, including those taking valproate. A pregnancy registry is available for women who have been exposed to valproic acid. Patients may enroll themselves in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling (888) 233-2334. Additional information is available at www.aedpregnancyregistry.org.
Valsartan		[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. The use of drugs which act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. Use is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. The exposed fetus should be monitored for fetal growth, amniotic fluid volume, and organ formation. Infants exposed in utero should be monitored for hyperkalemia, hypotension, and oliguria (exchange transfusions or dialysis may be needed). These adverse events are generally associated with maternal use in the second and third trimesters. Untreated chronic maternal hypertension is also associated with adverse events in the fetus, infant, and mother. The use of angiotensin II receptor blockers is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential (ACOG, 2013).
Vancomycin		Adverse events have not been observed in animal reproduction studies. Vancomycin crosses the placenta and can be detected in fetal serum, amniotic fluid, and cord blood (Bourget 1991; Reyes 1989). Adverse fetal effects, including sensorineural hearing loss or nephrotoxicity, have not been reported following maternal use during the second or third trimesters of pregnancy. The pharmacokinetics of vancomycin may be altered during pregnancy and pregnant patients may need a higher dose of vancomycin. Maternal half-life is unchanged, but the volume of distribution and the total plasma clearance may be increased (Bourget 1991). Individualization of therapy through serum concentration monitoring may be warranted. Vancomycin is recommended for the treatment of Clostridium difficile infections in pregnant women (ACG [Surawicz 2013]). Vancomycin is recommended as an alternative agent to prevent the transmission of group B streptococcal (GBS) disease from mothers to newborns (ACOG 2011; CDC 2010).

Generic Name	Category	Pregnancy Implications
Varicella Vaccine		Varicella virus vaccine is contraindicated for use in pregnant females and pregnancy should be avoided for 3 months (per manufacturer labeling; 1 month per ACIP) following vaccination. Information was collected from 1995-2013 using the manufacturer's pregnancy registry, and included 905 women who received a varicella containing vaccine (30% within 3 months prior to conception) and who had known pregnancy outcomes. Among these women, the rates of miscarriage and birth defects was not increased above background rates, and there were no infants born with abnormalities consistent with congenital varicella syndrome. Varicella disease during the 1st or 2nd trimesters may result in congenital varicella syndrome. The onset of maternal varicella infection from 5 days prior to 2 days after delivery may cause varicella infection in the newborn. All women should be assessed for immunity during a prenatal visit; those without evidence of immunity should be vaccinated upon completion or termination of pregnancy (CDC/ACIP [Marin 2007]). Any exposures to the vaccine during pregnancy or within 3 months prior to pregnancy should be reported to the manufacturer (Merck & Co, 877-888-4231) or to VAERS (800-822-7967) as suspected adverse reactions.
Venlafaxine	C	Adverse events have been observed in some animal reproduction studies. Venlafaxine and its active metabolite ODV cross the human placenta. An increased risk of teratogenic effects following venlafaxine exposure during pregnancy has not been observed, based on available data. The risk of spontaneous abortion may be increased. Neonatal seizures and neonatal abstinence syndrome have been noted in case reports following maternal use of venlafaxine during pregnancy. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hyper- or hypotonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SNRI or a discontinuation syndrome and may be consistent with serotonin syndrome associated with treatment. The long-term effects of in utero SNRI/SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of venlafaxine may be altered. Women should be monitored for decreased efficacy. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Verapamil	C	Adverse events have been observed in some animal reproduction studies in doses, which also caused maternal toxicity. Verapamil crosses the placenta. Use during pregnancy may cause adverse fetal effects (bradycardia, heart block, hypotension) (Tan 2001). Women with hypertrophic cardiomyopathy who are controlled with verapamil prior to pregnancy may continue therapy, but increased fetal monitoring is recommended (Gersh 2011). Verapamil may be used IV for the acute treatment of supraventricular tachycardia (SVT) in pregnant women when adenosine or beta-blockers are ineffective or contraindicated. Verapamil may also be used for the ongoing management of SVT in highly symptomatic patients. The lowest effective dose is recommended; avoid use during the first trimester if possible (Page [ACC/AHA/HRS 2015]). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed,

Generic Name	Category	Pregnancy Implications
		other agents are preferred (ACOG 2013). Additional guidelines are available for management of cardiovascular diseases during pregnancy (ESG [Regitz-Zagrosek 2011]).
Vitamin A		Adverse events have been observed in animal reproduction studies. In humans, the critical period of exposure is the first trimester of pregnancy. Excess vitamin A during pregnancy may cause craniofacial malformations, as well as CNS, heart, and thymus abnormalities. Maternal vitamin A deficiency also causes adverse effects in the fetus, and vitamin A requirements are increased in pregnant women (IOM 2000). The manufacturer notes that the safety of doses >6,000 units/day in pregnant women has not been established and doses greater than the RDA are contraindicated in pregnant women or those who may become pregnant. High doses are used in some areas of the world for supplementation where deficiency is a public health problem (eg, to prevent night blindness); however, single doses >25,000 units should be avoided within 60 days of conception. High-dose supplementation is otherwise not recommended as part of routine antenatal care (WHO 2011c).
Vitamin A&D Ointment		
Vitamin D2 & D3		Ergocalciferol: Adverse events were observed in some animal reproduction studies. The ergocalciferol (vitamin D2) metabolite, 25(OH)D, crosses the placenta; maternal serum concentrations correlate with fetal concentrations at birth (Misra, 2008; Wagner, 2008). Vitamin D deficiency in a pregnant woman may lead to a vitamin D deficiency in the neonate (Misra, 2008; Wagner, 2008). Serum 25(OH)D concentrations should be measured in pregnant women considered to be at increased risk of deficiency (ACOG, 2011). The amount of vitamin D contained in prenatal vitamins may not be adequate to treat a deficiency during pregnancy; although larger doses may be needed, current guidelines recommend a total of 1000 to 2000 units/day until more safety data is available (ACOG, 2011; Holick, 2011). In women not at risk for deficiency, doses larger than the RDA should be avoided during pregnancy (ACOG, 2011). Cholecalciferol: The cholecalciferol metabolite, 25(OH)D, crosses the placenta; maternal serum concentrations correlate with fetal concentrations at birth (Misra 2008; Wagner 2008). Vitamin D requirements are the same in pregnant and nonpregnant females (IOM 2011). Vitamin D deficiency in a pregnant woman may lead to a vitamin D deficiency in the neonate (Misra 2008; Wagner 2008). Serum 25(OH)D concentrations should be measured in pregnant women considered to be at increased risk of deficiency (ACOG 2011). The amount of vitamin D contained in prenatal vitamins may not be adequate to treat a deficiency during pregnancy; although larger doses may be needed, current guidelines recommend a total of 1,000 to 2,000 units/day until more safety data is available (ACOG 2011; Holick 2011). In women not at risk for deficiency, doses larger than the RDA should be avoided during pregnancy (ACOG 2011).
Warfarin		Warfarin crosses the placenta; concentrations in the fetal plasma are similar to maternal values. Teratogenic effects have been reported following first trimester exposure and may include coumarin embryopathy (nasal hypoplasia and/or stippled epiphyses; limb hypoplasia may also be present). Adverse CNS events to the fetus have also been observed following exposure during any trimester and may include CNS abnormalities (including ventral midline dysplasia, dorsal midline dysplasia). Spontaneous abortion, fetal hemorrhage, and fetal death may also occur. Use is contraindicated during pregnancy (or in women of reproductive potential) except in women with mechanical heart valves who are at high risk for thromboembolism; use is also contraindicated in women with threatened abortion, eclampsia, or preeclampsia. Frequent pregnancy tests are recommended for women who are planning to become pregnant and adjusted-dose heparin or low molecular weight heparin (LMWH) should be substituted as soon as pregnancy is confirmed or adjusted-dose heparin or LMWH should be used instead of warfarin prior to conception. In pregnant women with high-risk mechanical heart valves, the benefits of warfarin therapy should be discussed with the risks of available treatments (ACCP [Bates 2012]; AHA/ACC [Nishimura 2014]); when possible avoid

Generic Name	Category	Pregnancy Implications
		warfarin use during the first trimester (ACCP [Bates 2012]) and close to delivery (ACCP [Bates 2012]; AHA/ACC [Nishimura 2014]). Use of warfarin during the first trimester may be considered if the therapeutic INR can be achieved with a dose ≤5 mg/day (AHA/ACC [Nishimura 2014]). Adjusted-dose LMWH or adjusted-dose heparin may be used throughout pregnancy or until week 13 of gestation when therapy can be changed to warfarin. LMWH or heparin should be resumed close to delivery. In women who are at a very high risk for thromboembolism (older generation mechanical prosthesis in mitral position or history of thromboembolism), warfarin can be used throughout pregnancy and replaced with LMWH or heparin near term; the use of low-dose aspirin is also recommended (ACCP [Bates 2012] AHA/ACC [Nishimura 2014]). Women who require long-term anticoagulation with warfarin and who are considering pregnancy, LMWH substitution should be done prior to conception when possible. If anti-Xa monitoring cannot be done, do not use LMWH therapy in pregnant patients with a mechanical prosthetic valve (AHA/ACC [Nishimura 2014]). When choosing therapy, fetal outcomes (ie, pregnancy loss, malformations), maternal outcomes (ie, VTE, hemorrhage), burden of therapy, and maternal preference should be considered (ACCP [Bates 2012]).
Zalcitabine		
Zidovudine		* Zidovudine has a high level of transfer across the human placenta; the placenta also metabolizes zidovudine to the active metabolite. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Zidovudine/Lamivudine		* Zidovudine has a high level of transfer across the human placenta; the placenta also metabolizes zidovudine to the active metabolite. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk. * Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is

Generic Name	Category	Pregnancy Implications
		conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Zinc Oxide		Zinc oxide is not expected to be absorbed systemically following topical administration to healthy skin (Newman, 2009). Systemic absorption would be required in order for zinc oxide to cross the placenta and reach the fetus.
Ziprasidone	C	Adverse events were observed in animal reproduction studies. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. Ziprasidone may cause hyperprolactinemia, which may decrease reproductive function in both males and females. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited and routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to a typical antipsychotic that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). Healthcare providers are encouraged to enroll women 18-45 years of age exposed to ziprasidone during pregnancy in the Atypical Antipsychotics Pregnancy Registry (1-866-961-2388 or http://www.womensmentalhealth.org/pregnancyregistry).

Formulary Medications with Contact Precautions

Some oral medications carry with them a risk of untoward or deleterious effects due to unintended absorption. These medications can be chemotherapy, immunosuppressants, enzyme inhibitors, as well as other agents. The National Institute of Occupational Safety and Health recommends using single gloved hands for the administration of intact tablets or capsules.

https://www.cdc.gov/niosh/docket/review/docket233a/pdfs/2016-161finalpublication.pdf

Trade Name	Generic Name	Class No.	Therapeutic Class	Formulation	Contact Precautions
Propecia/ Proscar	finasteride	920800	5 Alpha-Reductase Inhibitor	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Hydrea/ Droxia	hydroxyurea	1000000	Antineoplastic Agents	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Methotrexate	methotrexate	1000000	Antineoplastic Agents	Tablet	Teratogenic potential (FDA Category X); avoid direct contact
CellCept/ Myfortic	mycophenolate	924400	Immunosupressive agents	Capsule/ tablet	Teratogenic potential: Skin contact may enhance tumor production; avoid direct contact

High Alert Medications

High-Alert Medications in Acute Care Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent doublechecks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential highalert medications. During May and June 2014, practitioners responded to an ISMP survey designed to identify which medications were most frequently considered highalert drugs by individuals and organizations. Further, to assure relevance and completeness, the clinical staff at ISMP, members of the ISMP advisory board, and safety experts throughout the US were asked to review the potential list. This list of drugs and drug categories reflects the collective thinking of all who provided input.

Classes/Categories of Medications	
adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)	adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
insulin, subcutaneous and IV	parenteral nutrition preparations
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	moderate sedation agents, IV (e.g., dexmedetomidine, midazolam)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	moderate sedation agents, oral, for children (e.g., chloral hydrate)
antithrombotic agents, including: • anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin) • Factor Xa inhibitors (e.g., fondaparinux, apixaban, rivaroxaban) • direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate) • thrombolytics (e.g., alteplase, reteplase, tenecteplase) • glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)	narcotics/opioids • IV • transdermal • oral (including liquid concentrates, immediate and sustained release formulations)
	neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)
	liposomal forms of drugs (e.g., liposomal amphotericin B) and conventional counterparts (e.g., amphotericin B desoxycholate)
cardioplegic solutions	radiocontrast agents, IV
chemotherapeutic agents, parenteral and oral	dextrose, hypertonic, 20% or greater
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more	sodium chloride for injection, hypertonic, greater than 0.9% concentration
dialysis solutions, peritoneal and hemodialysis	hypoglycemics, oral
epidural or intrathecal medications	inotropic medications, IV (e.g., digoxin, milrinone)

Specific Medications	
EPINEPHrine, subcutaneous	oxytocin, IV
epoprostenol (Flolan), IV	nitroprusside sodium for injection
insulin U-500 (special emphasis)*	potassium chloride for injection concentrate
magnesium sulfate injection	potassium phosphates injection
methotrexate, oral, nononcologic use	promethazine, IV
opium tincture	vasopressin, IV or intraosseous

*All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.

High-Alert Medications in Community and Ambulatory Healthcare Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors and minimize harm. This may include strategies like providing mandatory patient education; improving access to information about these drugs; using auxiliary labels and automated alerts; employing automated or independent double checks when necessary; and standardizing the prescribing, storage, dispensing, and administration of these products.

Background

Based on error reports submitted to the ISMP Medication Errors Reporting Program (ISMP MERP), reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created a list of potential high alert medications. During June-August 2006, 463 practitioners responded to an ISMP survey designed to identify which medications were most frequently considered high alert drugs by individuals and organizations. In 2008, the preliminary list and survey data as well as data about preventable adverse drug events from the ISMP MERP, the Pennsylvania Patient Safety Reporting System, the FDA MedWatch database, databases from participating pharmacies, public litigation data, literature review, and a small focus group of ambulatory care pharmacists and medication safety experts were evaluated as part of a research study funded by an Agency for Healthcare Research and Quality (AHRQ) grant. This list of drugs and drug categories reflects the collective thinking of all who provided input. This list was created as part of the AHRQ funded project “Using risk models to identify and prioritize outpatient high alert medications”

Classes/Categories of Medications	Specific Medications
antiretroviral agents (e.g., efavirenz, lami**VUD**ine, raltegravir, ritonavir, combination antiretroviral products)	car**BAM**azepine
chemotherapeutic agents, oral (excluding hormonal agents) (e.g., cyclophosphamide, mercaptopurine, temozolomide)	heparin, including unfractionated and low molecular weight heparin
hypoglycemic agents, oral	met**FORMIN**
immunosuppressant agents (e.g., aza**THIO**prine, cyclo**SPORINE**, tacrolimus)	methotrexate, non-oncologic use
insulin, all formulations	propylthiouracil
opioids, all formulations	warfarin
pediatric liquid medications that require measurement	
pregnancy category X drugs (e.g., bosentan, **ISO**tretinoin)	

High-Alert Medications in Long-Term Care Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient or resident harm when they are used in error (e.g., wrong drug, wrong dose, wrong route). Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients or residents. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list). Please note that long-term acute care (LTAC) facilities, and LTC facilities with subacute units or where a wide variety of intravenous medications are administered, should also use the ISMP List of High-Alert Medications in Acute Care Settings, which can be found at: www.ismp.org/Tools/institutionalhighAlert.asp. Facilities are also encouraged to use other resources, such as the Beers Criteria1 and STOPP and START Criteria,2 to identify and address medications that should be avoided in the elderly population, which are different from high-alert medications.

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created and will periodically update a list of potential high-alert medications in the long-term care setting. During March 2016, practitioners from LTC facilities responded to an ISMP survey designed to identify which medications were most frequently considered high-alert medications in this setting. Further, to assure relevance and completeness, the clinical staff at ISMP, members of our LTC Advisory Board, and safety experts throughout the US were asked to review the potential list. This list of specific medications and medication classes/categories reflects the collective thinking of all who provided input.

Classes/Categories of Medications
anticoagulants, parenteral and oral. Including warfarin and new agents.
chemotherapeutic agents, parenteral and oral (excluding hormonal agents)
hypoglycemics, oral (including combination products with another drug)
insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)
parenteral nutrition preparations
opioids - parenteral, transdermal, and oral (including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug)

Specific Medications
digoxin, parenteral and oral
EPINEPHrine, parenteral
iron dextran, parenteral
methotrexate, oral, non-oncology use **
concentrated morphine solution, oral ***

** All forms of chemotherapy are considered a class of high-alert medications. Oral methotrexate for non-oncology purposes has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug when used for non-oncology purposes that can result in death.

*** All forms of opioids are considered a class of high-alert medications. Concentrated morphine solution has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug that can result in death.

Oral Dosage Forms That Should Not Be Crushed

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Effervescent Potassium	------	Tablet	Effervescent tablet (f)
Tylenol Arthritis	acetaminophen	Tablet	Slow-release
Charcoal Plus	activated charcoal	Tablet	Enteric-coated
VoSpire ER	albuterol	Tablet	Slow-release
Fosamax	alendronate	Tablet	Mucous membrane irritant
Uroxatral	alfuzosin	Tablet	Slow-release
ALPRAZolam ER	ALPRAZolam	Tablet	Slow-release
Xanax XR	ALPRAZolam	Tablet	Slow-release
Letairis	ambrisentan	Tablet	Slow-release
Moxatag	amoxicillin	Tablet	Slow-release
Adderall XR	amphetamine salts	Capsule	Slow-release (a)
Otezla	apremilast	Tablet	Film-coated
Aspirin enteric-coated	aspirin	Caplet; Tablet	Slow-release; Enteric-coated
Bayer EC	aspirin	Caplet	Enteric-coated
Bayer Regular	aspirin	Caplet	Enteric-coated
Durlaza	aspirin	Capsule	Slow-release
Easprin	aspirin	Tablet	Enteric-coated
Ecotrin Adult Low Strength	aspirin	Tablet	Enteric-coated
Ecotrin Maximum Strength	aspirin	Tablet	Enteric-coated
Ecotrin Regular Strength	aspirin	Tablet	Enteric-coated
Halfprin 81	aspirin	Tablet	Enteric-coated
Reyataz	atazanavir	Capsule	Note: an oral powder is available, see prescribing information for administration instructions
Strattera	atomoxetine	Capsule	Note: capsule contents can cause ocular irritation
Tessalon Perles	benzonatate	Capsule	Note: swallow whole; local anesthesia of the oral mucosa; choking could occur
Alophen	bisacodyl	Tablet	Enteric-coated
Bisac-Evac	bisacodyl	Tablet	Enteric-coated (c)
Doxidan	bisacodyl	Tablet	Enteric-coated (c)
Dulcolax	bisacodyl	Capsule; Tablet	Enteric-coated (c); Liquid-filled
Feen-a-mint	bisacodyl	Tablet	Enteric-coated (c)
Fleet Laxative	bisacodyl	Tablet	Enteric-coated (c)
Tracleer	bosentan	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Briviact	brivaracetam	Tablet	Film-coated (b)
Lodrane 24	brompheniramine	Capsule	Slow-release
LoHist 12 Hour	brompheniramine	Tablet	Slow-release
Entocort EC	budesonide	Capsule	Enteric-coated (a)
Uceris	budesonide	Tablet	Slow-release (Note: film coating is designed to break down at or above pH of 7.0)
Aplenzin	buPROPion	Tablet	Slow-release
Budeprion SR	buPROPion	Tablet	Slow-release
Wellbutrin SR, XL	buPROPion	Tablet	Slow-release
Zyban	buPROPion	Tablet	Slow-release
Cabometyx	cabozantinib	Tablet	Film-coated
Rayaldee	calcifediol	Capsule	Slow-release
Carbatrol	carBAMazepine	Capsule	Slow-release (a)
Equetro	carBAMazepine	Capsule	Slow-release (a)
TEGretol-XR	carBAMazepine	Tablet	Slow-release
Coreg CR	carvedilol	Capsule	Slow-release (a) (Note: may add contents of capsule to chilled, not warm, applesauce and consume immediately)
Cefaclor ER	Cefaclor	Tablet	Slow-release (b)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Cefuroxime	cefuroxime	Tablet	Taste (b) (Note: use suspension for children)
Ceftin	cefuroxime	Tablet	Taste (b) (Note: use suspension for children)
Somnote	chloral hydrate	Capsule	Liquid filled
Cholbam	cholic acid	Capsule	Note: capsules may be opened and the contents mixed with food/drink
Sensipar	cinacalcet	Tablet	Note: tablets are not scored and cutting may cause variable dosage accuracy
Cipro XR	ciprofloxacin	Tablet	Slow-release (b)
Proquin XR	ciprofloxacin	Tablet	Slow-release
Biaxin-XL	clarithromycin	Tablet	Slow-release
Kapvay	cloNIDine	Tablet	Slow-release
Colestid	colestipol	Tablet	Slow-release
AeroHist Plus	combination	Tablet	Slow-release (h)
Aggrenox	combination	Capsule	Slow-release
Alavert Allergy (Sinus 12 hour)	combination	Tablet	Slow-release
Allegra-D	combination	Tablet	Slow-release
Amibid DM	combination	Tablet	Slow-release
Aquatab C	combination	Tablet	Slow-release (h)
Aquatab D	combination	Tablet	Slow-release (h)
Augmentin XR	combination	Tablet	Slow-release (b,h)
Bidex A	combination	Tablet	Slow-release
Bidhist-D	combination	Tablet	Slow-release
Biohist LA	combination	Tablet	Slow-release (h)
Bisacodyl	combination	Tablet	Enteric-coated (c)
Bisa-Lax	combination	Tablet	Enteric-coated (c)
Bromfed PD	combination	Capsule	Slow-release
Bunavail	combination	Buccal film	Note: chewing or swallowing may result in lower peak concentrations and bioavailability
Chlor-Trimeton 12-H	combination	Tablet	Slow-release (b)
Claritin-D 12 Hour	combination	Tablet	Slow-release
Claritin-D 24 Hour	combination	Tablet	Slow-release
Contrave	combination	Tablet	Slow-release (Note: chewing, dividing, or crushing tablets may alter release rate)
Diclegis	combination	Tablet	Slow-release
EC-Naprosyn	combination	Tablet	Enteric-coated
Extendryl JR	combination	Capsule	Slow-release
Extendryl SR	combination	Capsule	Slow-release (b)
Fero-Grad 500 mg	combination	Tablet	Slow-release
Ferro-Sequels	combination	Tablet	Slow-release
Guaifed	combination	Capsule	Slow-release
Guaifed-PD	combination	Capsule	Slow-release
Guaifenex DM	combination	Tablet	Slow-release (h)
Guaifenex GP	combination	Tablet	Slow-release
Guaifenex PSE	combination	Tablet	Slow-release (h)
GuaiMAX-D	combination	Tablet	Slow-release
Hista-Vent DA	combination	Tablet	Slow-release (h)
Jalyn	combination	Capsule	Mucous membrane irritant (Note: women who are, or may become, pregnant, should not handle crushed or broken tablets [I])
Janumet XR	combination	Tablet	Slow-release
Jentadueto XR	combination	Tablet	Slow-release
Kaletra	combination	Tablet	Film-coated
Kazano	combination	Tablet	Note: not scored; no studies available from company
Korn biglyze XR	combination	Tablet	Slow-release (Note: tablet matrix may remain in stool)
Liquibid-PD	combination	Tablet	Slow-release (h)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Lodrane 240	combination	Capsule	Slow-release
Lovaza	combination	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
Maxifed DM	combination	Tablet	Slow-release (h)
Maxifed OMX	combination	Tablet	Slow-release (h)
Maxiphen DM	combination	Tablet	Slow-release (h)
Medent-DM	combination	Tablet	Slow-release
Miraphen PSE	combination	Tablet	Slow-release
Mucinex DM	combination	Tablet	Slow-release
Namzaric	combination	Capsule	Slow-release
Pre-Hist-D	combination	Tablet	Slow-release (h)
QDALL	combination	Capsule	Slow-release
QDALL AR	combination	Capsule	Slow-release
Rescon	combination	Tablet	Slow-release (h)
Rescon JR	combination	Tablet	Slow-release (h)
Rescon MX	combination	Tablet	Slow-release (h)
Respahist	combination	Capsule	Slow-release (a)
Respaire SR	combination	Capsule	Slow-release
R-Tanna	combination	Tablet	Slow-release
Rytary	combination	Capsule	Slow-release (a)
SINUvent PE	combination	Tablet	Slow-release (h)
Sudafed 12 hour	combination	Capsule	Slow-release (b)
Sudafed 24 hour	combination	Capsule	Slow-release (b)
Targiniq ER	combination	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose of oxyCODONE)
Touro CC-LD	combination	Tablet	Slow-release (h)
Touro LA-LD	combination	Tablet	Slow-release (h)
Treximet	combination	Tablet	Note: unique drug matrix enhances rapid drug absorption
Viekira XR	combination	Tablet	Slow-release
Vimovo	combination	Tablet	Slow-release
Xart XR	combination	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose)
Xigduo XR	combination	Tablet	Slow-release
Zegerid	combination	Capsule	Slow-release (b)
Amrix	cyclobenzaprine	Capsule	Slow-release
Cytoxan	cyclophosphamide	Tablet	Note: drug may be crushed but company recommends using injection
Pradaxa	dabigatran	Capsule	Note: breaking, chewing, or emptying contents of the capsule can result in increased exposure
Ampyra	dalfampridine	Tablet	Slow-release (Note: formerly fampridine-SR)
Enablex	darifenacin	Tablet	Slow-release
Sprycel	dasatinib	Tablet	Film-coated (Note: active ingredients are surrounded by wax matrix to prevent healthcare exposure; women who are, or may become, pregnant, should not handle crushed or broken tablet)
Exjade	deferasirox	Tablet	Note: do not give as whole tablet, tablets are meant to be given as oral suspension; see company insert
Khedezla	desvenlafaxine	Tablet	Slow-release
Pristiq	desvenlafaxine	Tablet	Slow-release
Dexilant	dexlansoprazole	Capsule	Slow-release (a)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Kapidex	dexlansoprazole	Capsule	Slow-release (a) (Note: name changed to Dexilant)
Focalin XR	dexmethylphenidate	Capsule	Slow-release (a)
Arthrotec	diclofenac	Tablet	Enteric-coated
Voltaren XR	diclofenac	Tablet	Slow-release
Videx EC	didanosine	Capsule	Slow-release
Cardizem	diltiazem	Tablet	Note: although not in the package insert the drug has a coating that is intended to release the drug over approximately 3 hours
Cardizem CD	diltiazem	Capsule	Slow-release
Cardizem LA	diltiazem	Tablet	Slow-release
Cartia XT	diltiazem	Capsule	Slow-release
Dilacor XR	diltiazem	Capsule	Slow-release
DiIt-CD	diltiazem	Capsule	Slow-release
Diltia XT	diltiazem	Capsule	Slow-release
Taztia XT	diltiazem	Capsule	Slow-release (a)
Tiazac	diltiazem	Capsule	Slow-release (a)
Tecfidera	dimethyl fumarate	Capsule	Slow-release
Norpace CR	disopyramide	Capsule	Slow-release form within a special capsule
Depakene	divalproex	Capsule	Slow-release; mucus membrane irritant (b)
Depakote	divalproex	Tablet	Slow-release
Depakote ER	divalproex	Tablet	Slow-release
Divalproex ER	divalproex	Tablet	Slow-release
Colace	docusate	Capsule	Taste (e)
Aricept 23 mg	donepezil	Tablet	Note: crushing the 23 mg tablet may significantly increase the rate of absorption; the 5 mg and 10 mg tablets are not affected
Cardura XL	doxazosin	Tablet	Slow-release
Acticlate	doxycycline	Capsule; Tablet	Film-coated (h) (Note: tablet scored in thirds rather than half)
Oracea	doxycycline	Capsule	Slow-release
Northera	droxidopa	Capsule	Note: no studies available from company
Cymbalta	DULoxetine	Capsule	Slow-release (a) (Note: may add contents of capsule to apple juice or applesauce but NOT chocolate)
Avodart	dutasteride	Capsule	Note: drug may cause fetal abnormalities; women who are, or may become, pregnant, should not handle capsules; all women should use caution in handling capsules, especially leaking capsules
Cerdelga	eliglustat	Capsule	Preferably taken with water
Drisdol	ergocalciferol	Capsule	Liquid filled (d)
Ergomar	ergotamine	Tablet	Sublingual form (g)
NexlUM	esomeprazole	Capsule	Slow-release (a)
lntelence	etravirine	Tablet	Note: tablet should be swallowed whole and not crushed; tablet may be dispersed in water
Afinitor	everolimus	Tablet	Mucous membrane irritant
Zort	everolimus	Tablet	Note: crushed powder may cause mucous membrane irritation
Plendil	felodipine	Tablet	Slow-release
Trilipix	fenofibric acid	Capsule	Slow-release
FentaNYL	fentaNYL	Lozenge	Slow-release (Note: this lollipop delivery system requires the patient to slowly dissolve in mouth)
Actiq	fentaNYL	Lozenge	Slow-release (Note: this lollipop delivery system requires the patient to slowly allow dissolution)
Fentora	fentaNYL	Tablet	Note: buccal tablet; swallow whole

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Fergon	ferrous gluconate	Tablet	Enteric-coated
Feosol	ferrous sulfate	Tablet	Enteric-coated (b)
Feratab	ferrous sulfate	Tablet	Enteric-coated (b)
Toviaz	fesoterodine	Tablet	Slow-release
Propecia	finasteride	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Proscar	finasteride	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
PROzac Weekly	FLUoxetine	Tablet	Enteric-coated
Lescol XL	fluvastatin	Tablet	Slow-release
Luvox CR	fluvoxaMINE	Capsule	Slow-release
Gralise	gabapentin	Tablet	Slow-release
Horizant	gabapentin	Tablet	Slow-release
Razadyne ER	galantamine	Capsule	Slow-release
Cytovene	ganciclovir	Capsule	Skin irritant
lressa	gefitinib	Tablet	Note: tablet may be dissolved in 4-8 ounces of water
GlipiZIDE XR	glipiZIDE	Tablet	Slow-release
Glucotrol XL	glipiZIDE	Tablet	Slow-release
Mucinex	guaiFENesin	Tablet	Slow-release
GuaifFENesin/Pseudoephedrine	combination	Tablet	Slow-release
lntuniv	guanFACINE	Tablet	Slow-release
Hysingla ER	HYDROcodone	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose of HYDROcodone)
Zohydro ER	HYDROcodone	Capsule	Slow-release (Note: crushing, chewing, or dissolving capsules may result in overdose or death)
Exalgo	HYDROmorphone	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose)
Droxia	hydroxyurea	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Hydrea	hydroxyurea	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Levbid	hyoscyamine	Tablet	Slow-release (h)
Levsinex Timecaps	hyoscyamine	Capsule	Slow-release
Symax Duotab	hyoscyamine	Tablet	Slow-release
Symax SR	hyoscyamine	Tablet	Slow-release
Boniva	ibandronate	Tablet	Note: chewed, crushed, or sucked tablets may cause oropharyngeal irritation
lmbruvica	ibrutinib	Capsule	Note: not scored; no studies available from company
Motrin	ibuprofen	Tablet	Taste (b,e)
Zydelig	idelalisib	Tablet	Note: not scored; film-coated
Gleevec	imatinib	Tablet	Taste (h) (Note: may be dissolved in water or apple juice)
Crixivan	indinavir	Capsule	Taste (Note: capsule may be opened and mixed with fruit puree [e.g., banana])
lndocin SR	indomethacin	Capsule	Slow-release (a,b)
Dilatrate-SR	isosorbide	Capsule	Slow-release
lmdur	isosorbide	Tablet	Slow-release (h)
lsordil Sublingual	isosorbide	Tablet	Sublingual form (g)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
lsosorbide Dinitrate Sublingual	isosorbide	Tablet	Sublingual form (g)
lsosorbide SR	isosorbide	Tablet	Slow-release
Absorica	isotretinoin	Capsule	Mucous membrane irritant
Accutane	isotretinoin	Capsule	Mucous membrane irritant
DynaCirc CR	isradipine	Tablet	Slow-release
LaMICtal XR	lamoTRlgine	Tablet	Slow-release
Prevacid	lansoprazole	Capsule	Slow-release
Prevacid SoluTab	lansoprazole	Tablet	Note: orally disintegrating do not swallow; dissolve in water only and dispense via dosing syringe of NG tube
Prevacid Suspension	lansoprazole	Suspension	Slow-release (Note: contains enteric-coated granules; mix with water only; not for NG use)
Revlimid	lenalidomide	Capsule	Note: Teratogenic potential; health care workers should avoid contact with capsule contents/body fluids
Lenvima	lenvatinib	Capsule	Note: may be dissolved in a small glass of liquid
Keppra	levETIRAcetam	Tablet	Taste (b) (Note: some extemporaneous formulas are pharmacy prepared)
Keppra XR	levETIRAcetam	Tablet	Slow-release (b)
Sinemet CR	levo/carbidopa	Tablet	Slow-release (h)
Lithobid	lithium	Tablet	Slow-release
Belviq XR	lorcaserin	Tablet	Slow-release
Altoprev	lovastatin	Tablet	Slow-release
Amitiza	lubiprostone	Capsule	Slow-release
Namenda XR	memantine	Capsule	Slow-release (a)
Apriso	mesalamine	Capsule	Slow-release (a) (Note: maintain pH at < 6.0)
Asacol	mesalamine	Tablet	Slow-release
LiaIda	mesalamine	Tablet	Slow-release
Pentasa	mesalamine	Capsule	Slow-release
Fortamet	metFORMIN	Tablet	Slow-release
Glucophage XR	metFORMIN	Tablet	Slow-release
Glumetza	metFORMIN	Tablet	Slow-release
Aptensio XR	methylphenidate	Capsule	Slow-release (a)
Concert	methylphenidate	Tablet	Slow-release
Metadate CD	methylphenidate	Capsule	Slow-release (a)
Metadate ER	methylphenidate	Tablet	Slow-release
Methylin ER	methylphenidate	Tablet	Slow-release
Ritalin LA	methylphenidate	Capsule	Slow-release (a)
Ritalin SR	methylphenidate	Tablet	Slow-release
Metoprolol ER	metoprolol	Tablet	Slow-release
Toprol XL	metoprolol	Tablet	Slow-release (h)
Flagyl ER	metroNIDAZOLE	Tablet	Slow-release
lmpavido	miltefosine	Capsule	Note: not scored; no studies available from company
Solodyn	minocycline	Tablet	Slow-release
Myrbetriq	mirabegron	Tablet	Slow-release
Morphine sulfate extended-release	morphine	Tablet	Slow-release
AVINza	morphine	Capsule	Slow-release (a; not pudding)
Kadian	morphine	Capsule	Slow-release (a) (Note: do not give via NG tubes)
Morphabond	morphine	Tablet	Slow-release (b)
MS Contin	morphine	Tablet	Slow-release (b)
Oramorph SR	morphine	Tablet	Slow-release (b)
Embeda	morphine sulfate	Capsule	Slow-release (a)
CellCept	mycophenolate	Capsule; Tablet	Teratogenic potential (i)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Myfort	mycophenolate	Tablet	Slow-release
Movantik	naloxegol	Tablet	Film-coated
Naprelan	naproxen	Tablet	Slow-release
Viramune XR	nevirapine	Tablet	Slow-release (b)
Afeditab CR	NI FEdipine	Tablet	Slow-release
Cardene SR	niCARdipine	Capsule	Slow-release
Commit	nicotine	Lozenge	Note: integrity compromised by chewing or crushing
Nicotinic Acid	nicotinic acid	Capsule; Tablet	Slow-release (h)
Niaspan	nicotinic acid	Tablet	Slow-release
Slo-Niacin	nicotinic acid	Tablet	Slow-release (h)
Adalat CC	NIFEdipine	Tablet	Slow-release
Nifediac CC	NIFEdipine	Tablet	Slow-release
Nifedical XL	NIFEdipine	Tablet	Slow-release
Procardia XL	NIFEdipine	Tablet	Slow-release
Tasigna	nilotinib	Capsule	Note: disruption of capsule may yield high blood levels causing enhanced toxicity
OFEV	nintedanib	Capsule	Taste
Sular	nisoldipine	Tablet	Slow-release
Nitrostat	nitroglycerin	Tablet	Sublingual form (g)
Omtryg	omega-3-acid ethyl esters A	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
Epanova	omega-3-carboxylic acids	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
PriLOSEC	omeprazole	Capsule	Slow-release
PriLOSEC OTC	omeprazole	Tablet	Slow-release
Norflex ER	orphenadrine	Tablet	Slow-release
Tagrisso	osimertinib	Tablet	Note: tablet may be dissolved in 2 ounces of water
Ditropan XL	oxybutynin	Tablet	Slow-release
OxyCONTIN	oxyCODONE	Tablet	Slow-release (Note: tablet disruption may cause a potentially fatal overdose of oxyCODONE)
Xtampza ER	oxycodone	Tablet	Slow-release (b)
Opana ER	oxymorphone	Tablets	Slow-release (Note: crushing, chewing, or dissolving tablets may result in overdose or death)
lnvega	paliperidone	Tablet	Slow-release
Cotazym-S	pancrelipase	Capsule	Enteric-coated (a)
Creon 5, 10, 20	pancrelipase	Capsule	Slow-release (a)
Pancreaze	pancrelipase	Capsule	Enteric-coated (a)
Pancrecarb	pancrelipase	Capsule	Enteric-coated (a)
Pert	pancrelipase	Capsule	Slow-release (a)
Ultrase	pancrelipase	Capsule	Enteric-coated
Ultresa	pancrelipase	Capsule	Slow-release (a)
Viokace	pancrelipase	Tablet	Mucous membrane irritant
Zenpep	pancrelipase	Capsule	Slow-release (b)
Farydak	panobinostat	Capsule	Irritant
Protonix	pantoprazole	Tablet	Slow-release
Paxil CR	PARoxetine	Tablet	Slow-release
Votrient	pazopanib	Tablet	Note: crushing significantly increases the AUC and Tmax
TRENtal	pentoxifylline	Tablet	Slow-release
Feldene	piroxicam	Capsule	Mucous membrane irritant
Noxafil	posaconazole	Tablet	Slow-release (b)
Kaon-CL-10	potassium	Tablet	Slow-release (b)
K-Dur	potassium	Tablet	Slow-release
Klor-Con	potassium	Tablet	Slow-release (b)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Klor-Con M	potassium	Tablet	Slow-release (b,h)
Klotrix	potassium	Tablet	Slow-release
K-Lyte	potassium	Tablet	Effervescent tablet (f)
K-Lyte CL	potassium	Tablet	Effervescent tablet (f)
K-Lyte DS	potassium	Tablet	Effervescent tablet (f)
K-Tab	potassium	Tablet	Slow-release (b)
Effer-K	potassium bicarbonate	Tablet	Effervescent tablet (f)
Micro K Extencaps	potassium chloride	Capsule	Slow-release (a,b)
Urocit-K	potassium citrate	Tablet	Wax-coated; prevents upper GI release
Biltricide	praziquantel	Tablet	Taste (h)
Rayos	predniSONE	Tablet	Slow-release (Note: delayed release is dependent on an intact coating)
Rythmol SR	propafenone	Capsule	Slow-release
lnderal LA	propranolol	Capsule	Slow-release
lnnoPran XL	propranolol	Capsule	Slow-release
Mestinon ER	pyridostigmine	Tablet	Slow-release (b)
SEROquel XR	QUEtiapine	Tablet	Slow-release
AcipHex	rabeprazole	Tablet	Slow-release
Evista	raloxifene	Tablet	Taste; teratogenic potential (i)
Ranexa	ranolazine	Tablet	Slow-release
Actonel	risedronate	Tablet	Irritant (Note: chewed, crushed, or sucked tablets may cause oropharyngeal irritation)
Atelvia	risedronate	Tablet	Slow-release (Note: tablet coating is an important part of the slow-release; chewed, cut, or crushed tablets may cause oropharyngeal irritation)
Norvir	ritonavir	Tablet	Note: crushing tablets has resulted in decreased bioavailability of drug (b)
Xarelto	rivaroxaban	Tablet	Note: crushed tablet must be given within 4 hours
Requip XL	ropinirole	Tablet	Slow-release
Jakafi	ruxolitinib	Tablet	Note: see prescribing information for making a suspension
Uptravi	selexipag	Tablet	Film-coated
RenageI	sevelamer	Tablet	Note: tablets expand in liquid if broken or crushed
Renvela	sevelamer carbonate	Tablet	Note: tablets expand in liquid if broken or crushed (b)
Rapamune	sirolimus	Tablet	Note: pharmacokinetic parameters may be affected (b)
VESlcare	solifenacin	Tablet	Enteric-coated
Azulfidine EN-Tabs	sulfasalazine	Tablet	Slow-release (b)
Belsomra	suvorexant	Tablet	Note: not scored; no studies available from company
Envarsus XR	tacrolimus	Tablet	Slow-release
Flomax	tamsulosin	Capsule	Slow-release
Nucynta ER	tapentadole	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets may result in overdose or death)
Hetlioz	tasimelteon	Capsule	Note: not scored; no studies available from company
Ketek	telithromycin	Tablet	Slow-release (b)
Temodar	temozolomide	Capsule	Slow-release (Note: accidentally opened or damaged capsules require rigorous precautions to avoid inhalation or contact with the skin or mucous membranes [i])
Theo-24	theophylline	Capsule	Slow-release (Note: contains beads that dissolve throughout the GI tract)

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Theochron	theophylline	Tablet	Slow-release
Uniphyl	theophylline	Tablet	Slow-release
Aptivus	tipranavir	Capsule	Note: oil emulsion within spheres; taste
Xeljanz XR	tofacitinib	Tablet	Slow-release
Detrol LA	tolterodine	Capsule	Slow-release
Qudexy XR	topiramate	Capsule	Slow-release (a)
Topamax	topiramate	Capsule; Tablet	Taste; Taste (a)
Ryzolt	traMADol	Tablet	Slow-release (Note: crushing may cause overdose)
Ultram ER	traMADol	Tablet	Slow-release (Note: tablet disruption may cause a potentially fatal overdose of drug)
Oleptro	traZODone	Tablet	Slow-release (h)
Valcyte	valGANCiclovir	Tablet	Teratogenic and irritant potential (i, b)
Effexor XR	venlafaxine	Capsule	Slow-release
Verapamil SR	verapamil	Tablet	Slow-release (h)
Calan SR	verapamil	Tablet	Slow-release (h)
Covera-HS	verapamil	Tablet	Slow-release
Isoptin SR	verapamil	Tablet	Slow-release (h)
VereIan	verapamil	Capsule	Slow-release (a)
Verelan PM	verapamil	Capsule	Slow-release (a)
Erivedge	vismodegib	Capsule	Note: package insert indicates potential teratogenic effects; material safety data sheet warns against skin contact; health care workers should take appropriate precautions
Zolinza	vorinostat	Capsule	Note: irritant; avoid contact with skin or mucous membranes; avoid contact with crushed or broken tablets
Zyflo CR	zileuton	Tablet	Slow-release
Ambien CR	zolpidem	Tablet	Slow-release
Intermezzo	zolpidem	Tablet	Sublingual form (g)
Pancrelipase		Capsule	Enteric-coated (a)

(a) Capsule may be opened and the contents taken without crushing or chewing; soft food such as applesauce or pudding may facilitate administration; contents may generally be administered via nasogastric tube using an appropriate fluid provided entire contents are washed down the tube.
(b) Liquid dosage forms of the product are available; however, dose, frequency of administration and manufacturers may differ from that of the solid dosage form.
(c) Antacids and/or milk may prematurely dissolve the coating of the tablet.
(d) Capsule may be opened and the liquid contents removed for administration.
(e) The taste of this product form would likely be unacceptable to the patient; administration via nasogastric tube should be acceptable.
(f) Effervescent tablets must be dissolved in the amount of diluent recommended by the manufacturer
(g) Tablets are made to disintegrate under the tongue.
(h) Tablet is scored and may be broken in half without affecting release characteristics.
(i) Skin contact may enhance tumor production; avoid direct contact.

Disclaimer: This list is not meant to represent all products, either by generic or trade name. While every effort has been made to ensure the accuracy and completeness of the information presented in this chart the reader is advised that the authors, editor, or publisher cannot be responsible for the currency of the information, for any errors or omissions, or for any consequences that may arise.
Two official USP terms are used to designate special-release medication forms: "extended release" and "delayed release." Others (e.g., sustained release, controlled release) are commonly used on package labeling. The term "Slow-release" is being used here to signify all such drugs with a special-release mechanism.

Look-Alike Sound-Alike Medication Names

Drug Name	Confused Drug Name
acetaZOLAMIDE	acetoHEXAMIDE
acetoHEXAMIDE	acetaZOLAMIDE
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Inderal
ALPRAZolam	LORazepam
amantadine	amiodarone
aMILoride	amLODIPine
amiodarone	amantadine
amLODIPine	aMILoride
Antivert	Axert
Apresoline	Priscoline
ARIPiprazole	proton pump inhibitors
ARIPiprazole	RABEprazole
atomoxetine	atorvastatin
atorvastatin	atomoxetine
Atrovent	Natru-Vent
Avandia	Coumadin
Axert	Antivert
azaCITIDine	azaTHIOprine
azaTHIOprine	azaCITIDine
Benadryl	benazepril
benazepril	Benadryl
Bidex	Videx
buPROPion	busPIRone
busPIRone	buPROPion
captopril	carvedilol
carBAMazepine	OXcarbazepine
Cardene	Cardizem
Cardizem	Cardene
Cardura	Coumadin
carvedilol	captopril
ceFAZolin	cefTRIAXone
cefTRIAXone	ceFAZolin
CeleBREX	CeleXA
CeleXA	ZyPREXA
CeleXA	CeleBREX
CeleXA	Cerebyx
Cerebyx	CeleXA
cetirizine	sertraline
cetirizine	stavudine
clobazam	clonazePAM
clonazePAM	clobazam
clonazePAM	cloNIDine
clonazePAM	LORazepam
cloNIDine	clonazePAM
cloNIDine	KlonoPIN
Colace	Cozaar
colchicine	Cortrosyn
Comvax	Recombivax HB
Cortrosyn	colchicine
Coumadin	Avandia
Coumadin	Cardura
Cozaar	Colace
Cozaar	Zocor

Drug Name	Confused Drug Name
cyclophosphamide	cycloSPORINE
cycloSERINE	cycloSPORINE
cycloSPORINE	cyclophosphamide
cycloSPORINE	cycloSERINE
Cymbalta	Symbyax
Daptacel (DTaP)	Adacel (Tdap)
Darvocet	Percocet
Darvon	Diovan
Denavir	indinavir
Depakote	Depakote ER
Depakote ER	Depakote
Depo-Medrol	Solu-MEDROL
desipramine	disopyramide
Desyrel	SEROquel
Diabenese	Diamox
Diamox	Diabenese
Diflucan	Diprivan
dimenhyDRINATE	diphenhydrAMINE
Dioval	Diovan
Diovan	Dioval
Diovan	Zyban
Diovan	Darvon
diphenhydrAMINE	dimenhyDRINATE
Diprivan	Diflucan
Diprivan	Ditropan
disopyramide	desipramine
Ditropan	Diprivan
Doribax	Zovirax
Doxil	Paxil
Dulcolax (bisacodyl)	Dulcolax (docusate sodium)
Dulcolax (docusate sodium)	Dulcolax (bisacodyl)
DULoxetine	FLUoxetine
Effexor	Effexor XR
Effexor XR	Enablex
Effexor XR	Effexor
Enablex	Effexor XR
Engerix-B adult	Engerix-B pediatric/adolescent
Engerix-B pediatric/adolescent	Engerix-B adult
ePHEDrine	EPINEPHrine
EPINEPHrine	ePHEDrine
ethambutol	Ethmozine
ethaverine [non-US name]	etravirine
Ethmozine	ethambutol
etravirine	ethaverine [non-US name]
Fanapt	Xanax
Flonase	Flovent
Flovent	Flonase
flumazenil	influenza virus vaccine
FLUoxetine	PARoxetine
FLUoxetine	DULoxetine
FLUoxetine	Loxitane
folic acid	folinic acid (leucovorin calcium)

Drug Name	Confused Drug Name
folinic acid (leucovorin calcium)	folic acid
fomepizole	omeprazole
Foradil	Toradol
gentamicin	gentian violet
gentian violet	gentamicin
glacial acetic acid	acetic acid for irrigation
glipiZIDE	glyBURIDE
Glucotrol	Glycotrol
glyBURIDE	glipiZIDE
Glycotrol	Glucotrol
guaiFENesin	guanFACINE
guanFACINE	guaiFENesin
HMG-CoA reductase inhibitors ("statins")	nystatin
HumaLOG	HumuLIN
HumaLOG	NovoLOG
HumuLIN	NovoLIN
HumuLIN	HumaLOG
HumuLIN 70/30	HumaLOG Mix 75/25
HumuLIN R U-100	HumuLIN R U-500
HumuLIN R U-500	HumuLIN R U-100
hydrALAZINE	hydrOXYzine
Hydrea	Lyrica
HYDROcodone	oxyCODONE
Hydrogesic	hydrOXYzine
HYDROmorphone	morphine
hydrOXYzine	Hydrogesic
hydrOXYzine	hydrALAZINE
Inderal	Adderall
indinavir	Denavir
influenza virus vaccine	flumazenil
influenza virus vaccine	perflutren lipid microspheres
influenza virus vaccine	tuberculin purified protein derivative (PPD)
Isordil	Plendil
Janumet	Sinemet
Kaletra	Keppra
Keflex	Keppra
Keppra	Kaletra
Keppra	Keflex
Ketalar	ketorolac
ketorolac	Ketalar
ketorolac	methadone
KlonoPIN	cloNIDine
K-Phos Neutral	Neutra-Phos-K
LaMICtal	LamISIL
LamISIL	LaMICtal
lamiVUDine	lamoTRIgine
lamoTRIgine	lamiVUDine
lamoTRIgine	levETIRAcetam
lamoTRIgine	levothyroxine
Lanoxin	levothyroxine
Lanoxin	naloxone
lanthanum carbonate	lithium carbonate
Lantus	Latuda
Lantus	Lente
Lariam	Levaquin
Lasix	Luvox
Latuda	Lantus
Lente	Lantus
leucovorin calcium	Leukeran
leucovorin calcium	levoleucovorin
Leukeran	leucovorin calcium
Levaquin	Lariam
Levemir	Lovenox
levETIRAcetam	lamoTRIgine
levETIRAcetam	levOCARNitine
levETIRAcetam	levofloxacin
levOCARNitine	levETIRAcetam
levofloxacin	levETIRAcetam
levoleucovorin	leucovorin calcium
levothyroxine	lamoTRIgine
levothyroxine	Lanoxin
levothyroxine	liothyronine
Lexapro	Loxitane
Lexiva	Pexeva
liothyronine	levothyroxine
Lipitor	Loniten
Lipitor	ZyrTEC
lithium	Ultram
lithium carbonate	lanthanum carbonate
Lodine	codeine
Lodine	iodine
Loniten	Lipitor
Lopressor	Lyrica
LORazepam	ALPRAZolam
LORazepam	clonazePAM
LORazepam	Lovaza
Lotronex	Protonix
Lovaza	LORazepam
Lovenox	Levemir
Loxitane	Lexapro
Loxitane	FLUoxetine
Luvox	Lasix
Lyrica	Hydrea
Lyrica	Lopressor
Maalox	Maalox Total Stomach Relief
Maalox Total Stomach Relief	Maalox
Maxzide	Microzide
Menactra	Menomune
Menomune	Menactra
metFORMIN	metroNIDAZOLE
methimazole	metolazone
metolazone	methimazole
metoprolol succinate	metoprolol tartrate
metoprolol tartrate	metoprolol succinate
metroNIDAZOLE	metFORMIN
Micronase	Microzide
Microzide	Maxzide
Microzide	Micronase
Miralax	Mirapex
Mirapex	Miralax
morphine	HYDROmorphone

Drug Name	Confused Drug Name
morphine - non-concentrated oral liquid	morphine - oral liquid concentrate
morphine - oral liquid concentrate	morphine - non-concentrated oral liquid
Motrin	Neurontin
MS Contin	OxyCONTIN
nalbuphine	naloxone
naloxone	Lanoxin
naloxone	nalbuphine
Narcan	Norcuron
Natru-Vent	Atrovent
Navane	Norvasc
Neo-Synephrine (oxymetazoline)	Neo-Synephrine (phenylephrine)
Neo-Synephrine (phenylephrine)	Neo-Synephrine (oxymetazoline)
Neumega	Neupogen
Neupogen	Neumega
Neurontin	Motrin
Neurontin	Noroxin
niCARdipine	NIFEdipine
NIFEdipine	niCARdipine
NIFEdipine	niMODipine
niMODipine	NIFEdipine
Norcuron	Narcan
Normodyne	Norpramin
Noroxin	Neurontin
Norpramin	Normodyne
Norvasc	Navane
NovoLIN	HumuLIN
NovoLIN	NovoLOG
NovoLIN 70/30	NovoLOG Mix 70/30
NovoLOG	HumaLOG
NovoLOG	NovoLIN
NovoLOG Flexpen	NovoLOG Mix 70/30 Flexpen
NovoLOG Mix 70/30	NovoLIN 70/30
NovoLOG Mix 70/30 Flexpen	NovoLOG Flexpen
nystatin	HMG-CoA reductase inhibitors ("statins")
Occlusal-HP	Ocuflox
Ocuflox	Occlusal-HP
OLANZapine	QUEtiapine
omeprazole	fomepizole
oxaprozin	OXcarbazepine
OXcarbazepine	oxaprozin
OXcarbazepine	carBAMazepine
oxyCODONE	HYDROcodone
oxyCODONE	OxyCONTIN
OxyCONTIN	MS Contin
OxyCONTIN	oxyCODONE
PARoxetine	FLUoxetine
PARoxetine	piroxicam
Paxil	Doxil
Paxil	Taxol
Paxil	Plavix
penicillAMINE	penicillin
penicillin	penicillAMINE
PENTobarbital	PHENobarbital
Percocet	Darvocet
Percocet	Procet
perflutren lipid microspheres	influenza virus vaccine
Pexeva	Lexiva
PHENobarbital	PENTobarbital
piroxicam	PARoxetine
Plavix	Paxil
Plavix	Pradax [Non-US Product]
Plavix	Pradaxa
pneumococcal 7-valent vaccine	pneumococcal polyvalent vaccine
pneumococcal polyvalent vaccine	pneumococcal 7-valent vaccine
Pradax [Non-US Product]	Plavix
Pradaxa	Plavix
prednisoLONE	predniSONE
predniSONE	prednisoLONE
PriLOSEC	Pristiq
PriLOSEC	PROzac
Priscoline	Apresoline
Pristiq	PriLOSEC
probenecid	Procanbid
Procanbid	probenecid
Procardia XL	Protain XL
Procet	Percocet
Prograf	PROzac
propylthiouracil	Purinethol
Proscar	Provera
Protain XL	Procardia XL
protamine	Protonix
proton pump inhibitors	ARIPiprazole
Protonix	Lotronex
Protonix	protamine
Provera	Proscar
Provera	PROzac
PROzac	Prograf
PROzac	PriLOSEC
PROzac	Provera
Purinethol	propylthiouracil
Pyridium	pyridoxine
pyridoxine	Pyridium
QUEtiapine	OLANZapine
quiNIDine	quiNINE
quiNINE	quiNIDine
RABEprazole	ARIPiprazole
Renagel	Renvela
Renvela	Renagel
Reprexain	ZyPREXA
Retrovir	ritonavir
Rifadin	Rifater
Rifamate	rifampin
rifampin	Rifamate
rifampin	rifaximin
Rifater	Rifadin
rifaximin	rifampin

Drug Name	Confused Drug Name
RisperDAL	Restoril
risperiDONE	rOPINIRole
ritonavir	Retrovir
rOPINIRole	risperiDONE
saquinavir	SINEquan
SEROquel	Desyrel
SEROquel	SINEquan
sertraline	cetirizine
sertraline	Soriatane
Sinemet	Janumet
SINEquan	saquinavir
SINEquan	SEROquel
SINEquan	Singulair
SINEquan	Zonegran
Singulair	SINEquan
sitaGLIPtin	SUMAtriptan
Solu-CORTEF	Solu-MEDROL
Solu-MEDROL	Depo-Medrol
Solu-MEDROL	Solu-CORTEF
Soriatane	sertraline
sotalol	Sudafed
stavudine	cetirizine
Sudafed	sotalol
SUFentanil	fentaNYL
sulfADIAZINE	sulfaSALAzine
sulfaSALAzine	sulfADIAZINE
SUMAtriptan	sitaGLIPtin
SUMAtriptan	ZOLMitriptan
Symbyax	Cymbalta
Taxol	Paxil
TEGretol	TEGretol XR
TEGretol	Tequin
TEGretol	TRENtal
TEGretol XR	TEGretol
Tenex	Xanax
Tequin	TEGretol
tetanus diptheria toxoid (Td)	tuberculin purified protein derivative (PPD)
Thalomid	Thiamine
Thiamine	Thalomid
tiaGABine	tiZANidine
tiZANidine	tiaGABine
Tobradex	Tobrex
Tobrex	Tobradex
Topamax	Toprol-XL
Toprol-XL	Topamax
Toradol	Foradil
traMADol	traZODone
traZODone	traMADol
TRENtal	TEGretol
tuberculin purified protein derivative (PPD)	influenza virus vaccine
tuberculin purified protein derivative (PPD)	tetanus diptheria toxoid (Td)

Drug Name	Confused Drug Name
Tylenol	Tylenol PM
Tylenol PM	Tylenol
Ultram	lithium
Varivax	VZIG (varicella-zoster immune globulin)
Viagra	Allegra
Videx	Bidex
Viracept	Viramune
Viramune	Viracept
VZIG (varicella-zoster immune globulin)	Varivax
Wellbutrin SR	Wellbutrin XL
Wellbutrin XL	Wellbutrin SR
Xanax	Fanapt
Xanax	Tenex
Xanax	Zantac
Yasmin	Yaz
Yaz	Yasmin
Zantac	Xanax
Zantac	ZyrTEC
Zerit	ZyrTEC
Zestril	Zegerid
Zestril	Zetia
Zestril	ZyPREXA
Zetia	Zebeta
Zetia	Zestril
Zocor	Cozaar
Zocor	ZyrTEC
ZOLMitriptan	SUMAtriptan
zolpidem	Zyloprim
Zonegran	SINEquan
Zostrix	Zovirax
Zovirax	Doribax
Zovirax	Zyvox
Zovirax	Zostrix
Zyban	Diovan
Zyloprim	zolpidem
ZyPREXA	CeleXA
ZyPREXA	Reprexain
ZyPREXA	Zestril
ZyPREXA	ZyrTEC
ZyPREXA Zydis	Zelapar (Zydis formulation)
ZyrTEC	Lipitor
ZyrTEC	Zantac
ZyrTEC	Zerit
ZyrTEC	Zocor
ZyrTEC	ZyPREXA
ZyrTEC	ZyrTEC-D
ZyrTEC (cetirizine)	ZyrTEC Itchy Eye Drops (ketotifen fumarate)
ZyrTEC Itchy Eye Drops (ketolifen fumarate)	ZyrTEC (cetirizine)
ZyrTEC-D	ZyrTEC
Zyvox	Zovirax

SECTION C:
DESCRIPTION/SPECIFICATIONS/PERFO
RMANCE WORK STATEMENT

U.S. Department of Homeland Security
Immigration and Customs Enforcement

Performance Work Statement
Detention Services
(Texas-Wide RFP)

See Attached PWS
And Addendum B – PWS Addendum

SECTION D:
PACKAGING & MARKING

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[END OF SECTION D]

SECTION E:
INSPECTION AND ACCEPTANCE

E.1 CLAUSES INCORPORATED BY REFERENCE (FAR 52.252-2) (FEB 1998)

This contract incorporates the following clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text can be accessed electronically at this internet address: http://acquisition.gov/far/index.html.

Clause Number	Clause Title	Date
52.246-4	Inspection of Services – Fixed Price	Aug 1996
52.246-6	Inspection of Services – Time and Material and Labor Hour	May 2001

E.2 INSPECTION REQUIREMENTS

Review of Deliverables ---

a. The Contracting Officer or Contracting Officer's Representative will provide written acceptance, comments and/or change requests, if any, within thirty (30) business days from receipt by the Government of the initial deliverable.

b. Upon receipt of the Government comments, the Contractor shall have fifteen (15) business days to incorporate the Government's comments and/or change requests and to resubmit the deliverable in its final form.

c. If written acceptance, comments and/or change requests are not issued by the Government within thirty (30) calendar days of submission, the draft deliverable shall be deemed acceptable as written and the Contractor may proceed with the submission of the final deliverable product. The Contractor shall provide all deliverables to the COR in Microsoft Excel, PowerPoint or Word format.

E.3 DELIVERABLES CHART

#	Deliverable	Due Date
1	Quality Control Plan	With Proposal Submission; Updated as Needed

2	Plans, Policy and Procedures Manual	Plan and Policy: as required with Proposal Submission; Procedures Manual: 5 days after award
3	Standard Operating Procedures	Within 30 calendar days of award of contract
4	Post Orders	Within 30 calendar days of award of contract, annually and as requested by the COR.
5	Communication Plan	With Proposal Submission; Updated as Needed
6	Resumes of Key Personnel	Submitted within 5 days after award. For all new candidates, prior to Entry on Duty (EOD)
7	Organizational Chart	With Proposal Submission and after that, anytime as requested.
8	Staffing Plan	With Proposal Submission and after that anytime as requested by the COR.
9	Documentation of employee receipt of ICE Operations Policy/Procedure Manual	As requested by COR
10	Contractor employee certification for standards of conduct	As requested by COR
11	Contractor employee violation of standards of conduct and disciplinary action	Reported immediately* to COR
12	Notification of change in employee's health status	Notification immediately to COR (immediate verbal report, with written follow-up)

13	Employee termination, transfer, suspension, personnel action relating to disqualifying information or incidents of delinquency	Notification immediately to COR (immediate verbal report, with written follow-up)
14	Report of any on contract employee misconduct	Notification immediately to COR (immediate verbal report, with written follow-up)
15	e-QIP Security Process	Prior to Entry on Duty (EOD)
16	Physical Force Incident Reports	Reported to COR immediately (immediate verbal report, with written report within two (2) hours of incident)
17	Report of escapes	Reported to COR immediately (immediate verbal report, with written report within two (2) hours of incident)
18	Physical harm or threat to safety, health or welfare	Reported to COR immediately (immediate verbal report, with written report within 24 hours of incident)
19	Drug Test Results	Upon EOD and as requested by COR, or reported immediately to COR upon found violation
20	Emergency Call Back Roster	Quarterly or as needed
21	Training Plan, with Curriculum	Within 30 calendar days of award of contract; Updated as Needed
22	Quarterly Training Forecast	Quarterly
23	Training certification and reports for formal and on the job training (including Supervisors and refresher)	As requested by COR
24	Daily Time Sheet	As requested by COR

25	Emergency Action Plan to include Auxiliary Power procedures	Within 30 calendar days of award of contract; Updated as Needed
26	Sexual Assault & Suicide Prevention Program	No later than the post award conference
27	Firearms Training Certificates	Annually
28	Employee Weapon Permit	To COR 3 days prior to EOD, and then after as requested by COR
29	Notification of employee criminal activity	Reported immediately to COR and appropriate law enforcement agency.
30	Officer Testing Questions and Results	Post award, as needed by the COR
31	Key, Tool Cabinet Inventory Class A and Class B Log	At the beginning of day and end of each shift
32	Equipment Inventory	Within 30 calendar days after award of contract, then annually or as requested by COR
33	Intervention Equipment Inventory	Within 30 calendar days after award of contract, then annually or as requested by COR
34	Regular Tool Control Log	Monthly
35	Detainee Volunteer Work Screening Form (Request Form)	As required
36	Detainee Volunteer Work Program Training Form	As required
37	ACA Accreditation	Within 18 months of contract award

38	Proposed daily transportation routes	Within 30 calendar days of contract award
39	Safety Devices/Equipment Training Plan	Quarterly
40	Chemical Perpetual Inventory Sheet	As requested by COR
41	Compliance and Independent Audit Report	Annually
42	Key Indicators Report	Monthly, by 5th of each month for previous month's data
43	General Supply/Inventory Plan	Within 30 calendar days after award of contract, then annually or as requested by COR
44	Commissary Inventory List	As requested by COR
45	Statement of Detainee Funds Accounts	As requested by COR
46	IT Security Plan	Within 30 calendar days after award of contract
47	Finalized List of Approved Food Vendors	Within 30 calendar days after award of contract and upon any changes thereafter
48	Prime Vendor/Food Service Expenditures	As requested by COR
49	Employee Meal Ticket Sales Report	As requested by COR
50	Number of Meals Served/Daily Meal Count	Quarterly or as requested by COR
51	Detainee Records	Continuous

52	Detainee Death	Reported immediately to COR (immediate verbal report, with written report within two (2) hours of incident)
53	Detainee Departure Documents	Continuous, prior to detainee departing.
54	Detainee Volunteer Food Service Worker Contingency Plan	Within 30 calendar days of award of contract and after that anytime as requested by the COR.
55	35 Day Regular Menu	Monthly
56	Physical damage to the facility documentation	Immediate verbal report to COR, with written report within five (5) days.
57	Detainee Special Needs Menu	As requested by COR
58	Daily Diet List (Medical & Religious)	As requested by COR
59	Holiday Menus	Annually
60	Emergency Food Preparation and Service Schedule	Within 30 calendar days of award of contract
61	ACA Temperature Log Report (refrigerators, freezers, dishwasher temperatures and water)	As requested by COR
62	Food Service Weekly Inspection Log	Weekly or as requested by COR
63	Food Handler Certification	Maintained for all food service employees at all times, and as requested by COR
64	Food and Non-Food Inventory	Monthly or as requested by COR

65	Maintenance Service Work Orders	As requested by COR
66	Common Fare Cost for Detainees	Quarterly, or as requested by COR
67	Authorized Detainee Worker List Weekly Schedule	Weekly, or as requested by COR
68	Detainee Volunteer Food Service Work Detail Pay List	Monthly
69	Monthly Medical Inspection Corrective Actions	Monthly
70	Certified Dietician In- Service Staff Training and Department Inspection	Quarterly, or as requested by the COR
71	Medical Clearance including TB test	For all new employees and after diagnosed with illness or communicable disease. Employees must be re-examined and medically cleared before returning to work. TB test certification annually.
72	Vehicle inventory log and interior specification for each vehicle type	Within 30 calendar days of award of contract, annually and as requested by COR
73	Menu Cycle (Revisions and Registered Dietician Recertification of all menus)	Annually
74	End of Month Food Service Cost Report, including Cost Per Meal Data	Annually
75	Firearms Control Register	As requested by COR

76	Surveillance Video	As requested by COR
77	Detainee or Contractor Employee Contraband Found Report	Immediately to COR (immediate verbal report, with written follow-up)
78	Staff Vacancy Report	To COR by 5th of each month for previous month's data
79	Additional Reports as requested by the COR	As needed
80	Notice of facility readiness	10 days prior to the end of the Transition Period
81	Records related to performance by contractor	As requested by CO or COR at any time during the term of the contract or at termination/expiration.
82	Litigation	As requested by CO or COR at any time during the term of the contract or at/after termination/expiration.
83	Congressional Inquiry	Immediately to COR and CO (immediate verbal report, with written follow-up) to FOD, DFOD, COR, and CO
84	Press statements and/or releases	To FOD, DFOD & COR prior to release
85	Correctional Officer assignment, Names of Supervisory Correctional Officers, and Shift Rosters	As requested by COR
86	Overnight lodging requests	Advance of commencement of overnight trip
87	Non-returned ID Badges/Credentials	Immediately to COR
88	Intelligence Information	Immediately to COR
89	Serious Incidents	Immediately to COR

90	Contractor Employee Manual	Within 30 calendar days of award of contract and after that anytime as requested by the COR.
91	Any requested Detainee medical documentation	Immediately to COR
92	Medical and Personnel Records of Contractor Employees	As requested by COR
93	Contractor Business Permits and Licenses	Within 30 calendar days of award of contract and after that anytime as directed by COR.
94	Contractor Employee Registrations, Commissions, Permits, and Licenses	Prior to EOD and then after, as requested by COR
95	Correctional Officer Post Assignment Record	As requested by COR
96	Count Records	As requested by COR
97	GSA Form 139 or ICE equivalent	As requested by COR
98	Authorization to exceed a change in duty	To COR for approval prior to commencement of change of duty
99	Lost and Found	As requested by COR
100	Security incidents – computers	To COR within four (4) hours of incident
101	Daily Detainee Manifest	As requested by COR
102	Contract Discrepancy Report, Corrective Action Plan, or outcome measures required by any inspection or accreditation review, QASP or PBNDS requirements	As outlined within the requiring document

103	Spill Report	Immediately to COR
104	Transition-Out	1 week after notification of Transition to New Vendor
105	Small Business Subcontracting Plan	Submitted with Proposal
106	Operational Data/Metrics Summary	Due within three (3) days of request
107	Renovation Progress Meetings	Monthly

** The word "immediately" or "immediate," as used above in the Deliverables Chart is defined as "as soon as reasonably possible". The Contractor should use prudent and reasonable judgement to determine the timeframe necessary to notify the Government as defined above based on the situation, but it should not exceed a reasonable timeframe to notify the Government. For example, a reasonable timeframe for a physical force incident is as soon as the incident that required a physical force response has been contained. A reasonable timeframe to notify the Government of an attempted escape is after the detainee is safely within the confines of the building. A reasonable timeframe to report an actual escape in which the Contractor does not know the location of the detainee is as soon as the Contractor realizes there has been an escape. In the case of a conflict between the Program Office and the Contractor on a reasonable timeframe, the Contracting Officer will determine the appropriate reasonable timeframe.*

E.4 ACCEPTANCE CRITERIA

The Government will provide written notification of acceptance or rejection of all final deliverables within thirty (30) calendar days. Absent written notification, final deliverables may be construed as accepted. All notifications of rejection will be accompanied with an explanation of the specific deficiencies causing the rejection.

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[END OF SECTION E]

SECTION F:
DELIVERIES OR PERFORMANCE

F.1 CLAUSES INCORPORATED BY REFERENCE (FAR 52.252-2) (FEB 1998)

This contract incorporates the following clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text can be accessed electronically at this internet address: http://acquisition.gov/far/index.html.

Clause Number	Clause Title	Date
52.242-15	Stop Work Order	Aug 1989
52.242-17	Government Delay of Work	Apr 1984

F.2 PERIOD OF PERFORMANCE

Period of Performance	Dates
Base Period	*08/01/2020 – 07/31/2021*
In Accordance with FAR 52.217-9	
Option 1	*08/01/2021 – 07/31/2022*
Option 2	*08/01/2022 – 07/31/2023*
Option 3	*08/01/2023 – 07/31/2024*
Option 4	*08/01/2024 – 07/31/2025*
Option 5	*08/01/2025 – 07/31/2026*
Option 6	*08/01/2026 – 07/31/2027*
Option 7	*08/01/2027 – 07/31/2028*
Option 8	*08/01/2028 – 07/31/2029*
Option 9	*08/01/2029 – 07/31/2030*

F.3 PLACE OF PERFORMANCE:

T. Don Hutto Residential Center
1001 Welch St.
Taylor, TX 76574

No single facility described below should provide housing of less than 250 adults. The facilities' requirements are as follows:

- A facility or facilities is required to house approximately 520 adult female detainees within the San Antonio AOR. The facility(ies) must be located within 50 driving miles from Austin-Bergstrom International Airport and no more than 30 driving miles from a major hospital and emergency services. The facility(ies) shall have access to public and

commercial transportation routes and services. The facility(ies) is (are) expected to house Level 1 risk detainees. Please see the PWS Addendum for additional specific requirements.

The facility shall be managed and operable 24 hours a day, 7 days a week for 365 days a year and 366 days a year for any leap years. The services shall be conducted in accordance with industry standards and ICE's Performance Based National Detention Standards (PBNDS) 2011, as revised in 2016, as well as applicable federal, state, and local laws, regulations, codes, guidelines, policies and standards. The facilities must meet the requirements of the DHS Final Rule, 6 CFR Part 115, Standards to Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities, also known as the DHS Prison Rape Elimination Act (PREA) Standards applicable to immigration detention facilities.

F.4 CONTRACTOR EVALUATING PROCEDURES:

The Government will issue Contractor performance ratings for each awarded requirement from this solicitation via the Contractor Performance Assessment Reporting System (CPARS) in accordance with FAR 42.1502. The CPARS website is located: http://www.cpars.gov.

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[END OF SECTION F]

SECTION G:
CONTRACT ADMINISTRATION DATA

G.1 CONTRACT ADMINISTRATION

Notwithstanding the Contractor's responsibility for total management responsibility during the performance of this contract, the administration of the contract will require maximum coordination between the ICE and the Contractor.

The Government points of contact for this resulting contract are identified above.

G.2 CONTRACTING OFFICER'S REPRESENTATIVE

The following individual is designated and authorized by the CO to perform contract administration functions related to the technical performance of this contract.

The Government points of contact for this resulting contract are identified above.

(a) The Contracting Officer (CO) may designate Government personnel to act as the Contracting Officer's Representative (COR) to perform functions under the contract such as review or inspection and acceptance of supplies, services, including construction, and other functions of a technical nature. The CO will provide a written notice of such designation to the Contractor within five working days after contract award or for construction, not less than five working days prior to giving the contractor the notice to proceed. The designation letter will set forth the authorities and limitations of the COR under the contract.

(b) The CO cannot authorize the COR or any other representative to sign documents, such as contracts, contract modifications, etc., that require the signature of the CO.

G.3 INVOICE REQUIREMENTS

Invoices shall be submitted as follows:

Service Providers/Contractors shall use these procedures when submitting an invoice.

1. Invoice Submission: Invoices shall be submitted monthly in a ".pdf" format in accordance with the contract terms and conditions via email, United States Postal Service (USPS) or facsimile as follows:

a) Email:

- (b)(7)(E) @ice.dhs.gov
- Contracting Officer Representative (COR) or Government Point of Contact (GPOC)

• Contract Specialist/Contracting Officer

Each email shall contain only (1) invoice and the invoice number shall be indicated on the subject line of the email.

b) USPS:

DHS, ICE
Financial Operations - Burlington
P.O. Box 1620
Williston, VT 05495-1620

ATTN: (b)(7)(E)

The Contractors Data Universal Numbering System (DUNS) Number must be registered and active in the System for Award Management (SAM) at https://www.sam.gov prior to award and shall be notated on every invoice submitted to ensure prompt payment provisions are met. The ICE program office identified in the task order/contract shall also be notated on every invoice.

c) Facsimile:

Alternative Invoices shall be submitted to: (802)-288-7658

Submissions by facsimile shall include a cover sheet, point of contact and the number of total pages.
Note: The Service Provider's or Contractor's Dunn and Bradstreet (D&B) DUNS Number must be registered in the System for Award Management (SAM) at https://www.sam.gov prior to award and shall be notated on every invoice submitted to ensure prompt payment provisions are met. The ICE program office identified in the task order/contract shall also be notated on every invoice.

2. Content of Invoices: Each invoice shall contain the following information in accordance with 52.212-4 (g), as applicable:

(i). Name and address of the Service Provider/Contractor. Note: the name, address and DUNS number on the invoice MUST match the information in both the Contract/Agreement and the information in the SAM. If payment is remitted to another entity, the name, address and DUNS information of that entity must also be provided which will require Government verification before payment can be processed;

(ii). Dunn and Bradstreet (D&B) DUNS Number;

(iii). Invoice date and invoice number;

(iv). Agreement/Contract number, contract line item number and, if applicable, the order number;

(v). Description, quantity, unit of measure, unit price, extended price and period of performance of the items or services delivered;

(vi). If applicable, shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vii). Terms of any discount for prompt payment offered;

(viii). Remit to Address;

(ix). Name, title, and phone number of person to resolve invoicing issues;

(x). ICE program office designated on order/contract/agreement and

(xi). Mark invoice as "Interim" (Ongoing performance and additional billing expected) and "Final" (performance complete and no additional billing)

(xii). Electronic Funds Transfer (EFT) banking information in accordance with 52.232-33 Payment by Electronic Funds Transfer – System for Award Management or 52-232-34, Payment by Electronic Funds Transfer – Other than System for Award Management.

3. Invoice Supporting Documentation. To ensure payment, the vendor must submit supporting documentation which provides substantiation for the invoiced costs to the Contracting Officer Representative (COR) or Point of Contact (POC) identified in the contract. Invoice charges must align with the contract CLINs. Supporting documentation is required when guaranteed minimums are exceeded and when allowable costs are incurred. Details are as follows:

(i). Guaranteed Minimums. If a guaranteed minimum is not exceeded on a CLIN(s) for the invoice period, no supporting documentation is required. When a guaranteed minimum is exceeded on a CLIN (s) for the invoice period, the Contractor is required to submit invoice supporting documentation for all detention services provided during the invoice period which provides the information described below:

a. Detention Bed Space Services
- Bed day rate;
- Detainees check-in and check-out dates;
- Number of bed days multiplied by the bed day rate;
- Name of each detainee;
- Detainees identification information

(ii). Allowable Incurred Cost. Fixed Unit Price Items (items for allowable incurred costs, such as transportation services, stationary guard or escort services, transportation mileage or other

Minor Charges such as sack lunches and detainee wages): shall be fully supported with documentation substantiating the costs and/or reflecting the established price in the contract and shall be submitted in .pdf format:

a. Detention Bed Space Services. For detention bed space CLINs without a GM, the supporting documentation must include:

- Bed day rate;
- Detainees check-in and check-out dates;
- Number of bed days multiplied by the bed day rate;
- Name of each detainee;
- Detainees identification information

b. Transportation Services: For transportation CLINs without a GM, the supporting documentation must include:

- Mileage rate being applied for that invoice;
- Number of miles;
- Transportation routes provided;
- Locations serviced;
- Names of detainees transported;
- Itemized listing of all other charges; and,
- for reimbursable expenses (e.g. travel expenses, special meals, etc.) copies of all receipts.

c. Stationary Guard Services: The itemized monthly invoice shall state:

- The location where the guard services were provided,
- The employee guard names and number of hours being billed,
- The employee guard names and duration of the billing (times and dates), and
- for individual or detainee group escort services only, the name of the detainee(s) that was/were escorted.

d. Other Direct Charges (e.g. VTC support, transportation meals/sack lunches, volunteer detainee wages, etc.):

1) The invoice shall include appropriate supporting documentation for any direct charge billed for reimbursement. For charges for detainee support items (e.g. meals, wages, etc.), the supporting documentation should include the name of the detainee(s) supported and the date(s) and amount(s) of support.

(iii) Firm Fixed-Price CLINs. Supporting documentation is not required for charges for FFP CLINs.

4. Safeguarding Information: As a contractor or vendor conducting business with Immigration and Customs Enforcement (ICE), you are required to comply with DHS Policy regarding the safeguarding of Sensitive Personally Identifiable Information (PII). Sensitive PII is information that identifies an individual, including an alien, and could result in harm, embarrassment, inconvenience or unfairness. Examples of Sensitive PII include information

such as: Social Security Numbers, Alien Registration Numbers (A-Numbers), or combinations of information such as the individuals name or other unique identifier and full date of birth, citizenship, or immigration status.

As part of your obligation to safeguard information, the follow precautions are required:

(i) Email supporting documents containing Sensitive PII in an encrypted attachment with password sent separately to the Contracting Officer Representative assigned to the contract.

(ii) Never leave paper documents containing Sensitive PII unattended and unsecure. When not in use, these documents will be locked in drawers, cabinets, desks, etc. so the information is not accessible to those without a need to know.

(iii) Use shredders when discarding paper documents containing Sensitive PII.

(iv) Refer to the DHS Handbook for Safeguarding Sensitive Personally Identifiable Information (March 2012) found at http://www.dhs.gov/xlibrary/assets/privacy/dhs-privacy-safeguardingsensitivepiihandbook-march2012.pdf for more information on and/or examples of Sensitive PII.

5. Invoice Inquiries. If you have questions regarding payment, please contact ICE Financial Operations at 1-877-491-(b)(7)(E) or by e-mail at (b)(7)(E)@ice.dhs.gov.

Invoices without the above information may be returned for resubmission.

The preferred method of submittal is email.

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SECTION H:
SPECIAL CONTRACT REQUIREMENTS

H.1. CONTRACTOR'S INSURANCE

The Contractor shall maintain insurance in an amount not less than $3,000,000 to protect the Contractor from claims under workman's compensation acts and from any other claims for damages for personal injury, including death which may arise from operations under this contract whether such operations by the Contractor itself or by any subcontractor or anyone directly or indirectly employed by either business entity. The Contractor shall maintain General Liability insurance: bodily injury liability coverage written on a comprehensive form of policy of at least $500,000 per occurrence is required.

Additionally, an automobile liability insurance policy providing for bodily injury and property damage liability covering automobiles operated in the United States shall provide coverage of at least $200,000 per person and $500,000 per occurrence for bodily injury and $20,000 per occurrence for property coverage. Certificates of such insurance shall be subject to the approval of the CO for adequacy of protection. All insurance certificates required under this contract shall provide 30 days' notice to the Government of any contemplated cancellation.

The Contractor shall provide that all staff having access to detainee monies and valuables are bonded in an amount sufficient to ensure reimbursement to the detainee by the Contractor in case of loss.

H.2. SECURITY REQUIREMENTS - REQUIRED SECURITY LANGUAGE FOR SENSITIVE /BUT UNCLASSIFED (SBU) CONTRACT DETENTION FACILITY

General: Performance under this Contract Detention Facility requires access to sensitive DHS information and will involve direct contact with ICE Detainees. The Contractor shall adhere to the following.

Contractor Employee Fitness Screening: Screening criteria under DHS Instruction 121-01-007-001 (Personnel Security, Suitability and Fitness Program), or successor thereto, that may exclude contractor employees from consideration to perform under this agreement includes:

- Misconduct or negligence in employment;
- Criminal or dishonest conduct;
- Material, intentional false statement or deception of fraud in examination or appointment;
- Refusal to furnish testimony as required by 5 CFR § 5.4 (i.e., a refusal to provide testimony to the Merit Systems Protection Board or the Office of Special Counsel);
- Illegal use of narcotics, drugs, or other controlled substances without evidence of substantial rehabilitation.
- Alcohol abuse, without evidence of substantial rehabilitation, of a nature and duration that suggests that the applicant or appointee would be prevented from performing the

duties of the position in question, or would constitute a direct threat to the property or safety of the applicant or appointee or others;
- Illegal use of narcotics, drugs, or other controlled substances, without evidence of substantial rehabilitation;
- Knowing and willful engagement in acts or activities designed to overthrow the U.S. Government by force;
- Any statutory or regulatory bar which prevents the lawful employment of the person involved in the position in question (for Excepted Service employees); and
- Any other nondiscriminatory reason that an individual's employment (or work on a contract) would not protect the integrity of promote the efficiency of the service.

Contractor Employee Fitness Screening: Screening criteria under 6 CFR § 115.117 (Sexual Abuse and Assault Prevention Standards) implemented pursuant to Public Law 108-79 (Prison Rape Elimination Act (PREA) of 2003) or successor thereto, that WILL exclude contractor employees from consideration to perform under this agreement includes:

- Engaged in Sexual Abuse in a Prison, Jail, Holding Facility, Community Confinement Facility, Juvenile Facility, or other Institution as defined under 42 USC 1997;
- Convicted of engaging or attempting to engage in sexual activity facilitated by force, overt or implied threats of force, or coercion, or if the victim did not consent or was unable to consent or refuse;
- Civilly or administratively adjudicated to have in engaged in such activity.

Subject to existing law, regulations and/or other provisions of this Agreement, illegal or undocumented aliens shall not be employed by the Service Provider.

1.2.1 GENERAL

The United States Immigration and Customs Enforcement (ICE) has determined that performance of the tasks as described in contract agreement (#) 70CDCR20D00000013 requires that the Contractor, subcontractor(s), vendor(s), etc. (herein known as Contractor) have access to sensitive DHS information and ICE Detainees, and that the Contractor will adhere to the following:

1.2.2 PRELIMINARY FITNESS DETERMINATION

ICE will exercise full control over granting, denying, withholding or terminating unescorted government facility and/or sensitive Government information access for contractor employees, based upon the results of a Fitness screening process. ICE may, as it deems appropriate, authorize and make a favorable expedited preliminary Fitness determination based on preliminary security checks. The preliminary Fitness determination will allow the contractor employee to commence work temporarily prior to the completion of a Full Field Background Investigation. The granting of a favorable preliminary Fitness shall not be considered as assurance that a favorable final Fitness determination will follow as a result thereof. The granting of preliminary Fitness or final Fitness shall in no way prevent, preclude, or bar the withdrawal or termination of any such access by ICE, at any time during the term of the contract. No employee

of the Contractor shall be allowed to enter on duty and/or access sensitive information or systems without a favorable preliminary Fitness determination or final Fitness determination by the Office of Professional Responsibility, Personnel Security Unit (OPR-PSU). No employee of the Contractor shall be allowed unescorted access to a Government facility without a favorable preliminary Fitness determination or final Fitness determination by OPR-PSU. Contract employees are processed under DHS Instruction 121-01-007-001 (Personnel Security, Suitability and Fitness Program), or successor thereto; those having direct contact with Detainees will also have 6 CFR § 115.117 considerations made as part of the Fitness screening process.

1.2.3 BACKGROUND INVESTIGATIONS

Contractor employees (to include applicants, temporaries, part-time and replacement employees) under the contract, needing access to sensitive information and/or ICE Detainees, shall undergo a position sensitivity analysis based on the duties each individual will perform on the contract. The results of the position sensitivity analysis shall identify the appropriate background investigation to be conducted. Background investigations will be processed through the Personnel Security Unit. Contractor employees nominated by a Contracting Officer Representative for consideration to support this contract shall submit the following security vetting documentation to OPR-PSU, through the Contracting Officer Representative (COR), within 10 days of notification by OPR-PSU of nomination by the COR and initiation of an Electronic Questionnaire for Investigation Processing (e-QIP) in the Office of Personnel Management (OPM) automated on-line system.

1. Standard Form 85P (Standard Form 85PS (With supplement to 85P required for armed positions)), "Questionnaire for Public Trust Positions" Form completed on-line and archived by the contractor employee in their OPM e-QIP account.

2. Signature Release Forms (Three total) generated by OPM e-QIP upon completion of Questionnaire (e-signature recommended/acceptable – instructions provided to applicant by OPR-PSU). Completed on-line and archived by the contractor employee in their OPM e-QIP account.

3. Two (2) SF 87 (Rev. December 2017) Fingerprint Cards. **(Two Original Cards sent via COR to OPR-PSU)**

4. Foreign National Relatives or Associates Statement. (This document sent as an attachment in an e-mail to contractor employee from OPR-PSU – must be signed and archived into contractor employee's OPM e-QIP account prior to electronic "Release" of data via on-line account)

5. DHS 11000-9, "Disclosure and Authorization Pertaining to Consumer Reports Pursuant to the Fair Credit Reporting Act" (This document sent as an attachment in an e-mail to contractor employee from OPR-PSU – must be signed and archived into contractor employee's OPM e-QIP account prior to electronic "Release" of data via on-line account)

6. Optional Form 306 Declaration for Federal Employment (This document sent as an attachment in an e-mail to contractor employee from OPR-PSU – must be signed and archived into contractor employee's OPM e-QIP account prior to electronic "Release" of data via on-line account)

7. Questionnaire regarding conduct defined under 6 CFR § 115.117 (Sexual Abuse and Assault Prevention Standards) (This document sent as an attachment in an e-mail to contractor employee from OPR-PSU – must be signed and archived into contractor employee's OPM e-QIP account prior to electronic "Release" of data via on-line account)

8. One additional document may be applicable if contractor employee was born abroad. If applicable, additional form and instructions will be provided to contractor employee. (If applicable, the document will be sent as an attachment in an e-mail to contractor employee from OPR-PSU – must be signed and archived into contractor employee's OPM e-QIP account prior to electronic "Release" of data via on-line account)

Contractor employees who have an adequate, current investigation by another Federal Agency may not be required to submit complete security packages; the investigation may be accepted under reciprocity. The questionnaire related to 6 CFR § 115.117 listed above in item 7 will be required for positions designated under PREA.

An adequate and current investigation is one where the investigation is not more than five years old, meets the contract risk level requirement, and applicant has not had a break in service of more than two years. (Executive Order 13488 amended under Executive Order 13764/DHS Instruction 121-01-007-01).

Required information for submission of security packet will be provided by OPR-PSU at the time of award of the contract. Only complete packages will be accepted by the OPR-PSU as notified by the COR.

To ensure adequate background investigative coverage, contractor employees must currently reside in the United States or its Territories. Additionally, contractor employees are required to have resided within the Unites States or its Territories for three or more years out of the last five (ICE retains the right to deem a contractor employee ineligible due to insufficient background coverage). This time-line is assessed based on the signature date of the standard form questionnaire submitted for the applied position. Contractor employees falling under the following situations may be exempt from the residency requirement: 1) work or worked for the U.S. Government in foreign countries in federal civilian or military capacities; 2) were or are dependents accompanying a federal civilian or a military employee serving in foreign countries so long as they were or are authorized by the U.S. Government to accompany their federal civilian or military sponsor in the foreign location; 3) worked as a contractor employee, volunteer, consultant or intern on behalf of the federal government overseas, where stateside coverage can be obtained to complete the background investigation; 4) studied abroad at a U.S. affiliated college or university; or 5) have a current and adequate background investigation (commensurate with the position risk/sensitivity levels) completed for a federal or contractor employee position, barring any break in federal employment or federal sponsorship.

Only U.S. Citizens and Legal Permanent Residents are eligible for employment on contracts requiring access to DHS sensitive information unless an exception is granted as outlined under DHS Instruction 121-01-007-001. Per DHS Sensitive Systems Policy Directive 4300A, only U.S. citizens are eligible for positions requiring access to DHS Information Technology (IT) systems or positions that are involved in the development, operation, management, or maintenance of DHS IT systems, unless an exception is granted as outlined under DHS Instruction 121-01-007-001.

1.2.4 TRANSFERS FROM OTHER DHS CONTRACTS:

Contractor employees may be eligible for transfer from other DHS Component contracts provided they have an adequate and current investigation meeting the new assignment requirement. If the contractor employee does not meet the new assignment requirement a DHS 11000-25 with ICE supplemental page will be submitted to OPR-PSU to initiate a new investigation.

Transfers will be accomplished by submitting a DHS 11000-25 with ICE supplemental page indicating "Contract Change." The questionnaire related to 6 CFR § 115.117 listed above in item 7 will be required for positions designated under PREA.

1.2.5 CONTINUED ELIGIBILITY

ICE reserves the right and prerogative to deny and/or restrict facility and information access of any contractor employee whose actions conflict with Fitness standards contained in DHS Instruction 121-01-007-01, Chapter 3, paragraph 6.B or who violate standards of conduct under 6 CFR § 115.117. The Contracting Officer or their representative can determine if a risk of compromising sensitive Government information exists or if the efficiency of service is at risk and may direct immediate removal of a contractor employee from contract support. The OPR-PSU will conduct periodic reinvestigations every 5 years, or when derogatory information is received, to evaluate continued Fitness of contractor employees.

1.2.6 REQUIRED REPORTS

The Contractor will notify OPR-PSU, via the COR, of all terminations/resignations of contractor employees under the contract within five days of occurrence. The Contractor will return any expired ICE issued identification cards and building passes of terminated/ resigned employees to the COR. If an identification card or building pass is not available to be returned, a report must be submitted to the COR referencing the pass or card number, name of individual to whom issued, the last known location and disposition of the pass or card. The COR will return the identification cards and building passes to the responsible ID Unit.

The Contractor will report any adverse information coming to their attention concerning contractor employees under the contract to the OPR-PSU, via the COR, as soon as possible. Reports based on rumor or innuendo should not be made. The subsequent termination of employment of an employee does not obviate the requirement to submit this report. The report

shall include the contractor employees' name and social security number, along with the adverse information being reported.

The Contractor will provide, through the COR a Quarterly Report containing the names of contractor employees who are active, pending hire, have departed within the quarter or have had a legal name change (Submitted with documentation). The list shall include the Name, Position and SSN (Last Four) and should be derived from system(s) used for contractor payroll/voucher processing to ensure accuracy.

CORs will submit reports to (b)(7)(E) @ice.dhs.gov

Contractors, who are involved with management and/or use of information/data deemed "sensitive" to include 'law enforcement sensitive" are required to complete the DHS Form 11000-6-Sensitive but Unclassified Information NDA for contractor access to sensitive information. The NDA will be administered by the COR to the all contract personnel within 10 calendar days of the entry on duty date. The completed form shall remain on file with the COR for purpose of administration and inspection.

Sensitive information as defined under the Computer Security Act of 1987, Public Law 100-235 is information not otherwise categorized by statute or regulation that if disclosed could have an adverse impact on the welfare or privacy of individuals or on the welfare or conduct of Federal programs or other programs or operations essential to the national interest. Examples of sensitive information include personal data such as Social Security numbers; trade secrets; system vulnerability information; pre-solicitation procurement documents, such as statements of work; and information pertaining to law enforcement investigative methods; similarly, detailed reports related to computer security deficiencies in internal controls are also sensitive information because of the potential damage that could be caused by the misuse of this information. All sensitive information must be protected from loss, misuse, modification, and unauthorized access in accordance with DHS Management Directive 11042.1, *DHS Policy for Sensitive Information* and ICE Policy 4003, *Safeguarding Law Enforcement Sensitive Information*."

Any unauthorized disclosure of information should be reported to ICE.ADSEC@ICE.dhs.gov.

1.2.7 SECURITY MANAGEMENT

The Contractor shall appoint a senior official to act as the Corporate Security Officer. The individual will interface with the OPR-PSU through the COR on all security matters, to include physical, personnel, and protection of all Government information and data accessed by the Contractor.

The COR and the OPR-PSU shall have the right to inspect the procedures, methods, and facilities utilized by the Contractor in complying with the security requirements under this contract. Should the COR determine that the Contractor is not complying with the security requirements of this contract, the Contractor will be informed in writing by the Contracting Officer of the proper action to be taken in order to effect compliance with such requirements.

The computer security requirements as described in paragraphs 1.2.8 and 1.2.9 of this section

apply to both Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) operations and to the former Immigration and Naturalization Service operations (FINS). These entities are hereafter referred to as the Department.

1.2.8 INFORMATION TECHNOLOGY SECURITY CLEARANCE

When sensitive government information is processed on Department telecommunications and automated information systems, the Contractor agrees to provide for the administrative control of sensitive data being processed and to adhere to the procedures governing such data as outlined in DHS MD 4300.1*, Information Technology Systems Security.* or its replacement. Contractor employees must have favorably adjudicated background investigations commensurate with the defined sensitivity level.

Contractor employees who fail to comply with Department security policy are subject to having their access to Department IT systems and facilities terminated, whether or not the failure results in criminal prosecution. Any person who improperly discloses sensitive information is subject to criminal and civil penalties and sanctions under a variety of laws (e.g., Privacy Act).

1.2.9 INFORMATION TECHNOLOGY SECURITY TRAINING AND OVERSIGHT

In accordance with Chief Information Office requirements and provisions, all contractor employees accessing Department IT systems or processing DHS sensitive data via an IT system will require an ICE issued/provisioned Personal Identity Verification (PIV) card. Additionally, Information Assurance Awareness Training (IAAT) will be required upon initial access and annually thereafter. IAAT training will be provided by the appropriate component agency of DHS.

Contractor employees, who are involved with management, use, or operation of any IT systems that handle sensitive information within or under the supervision of the Department, shall receive periodic training at least annually in security awareness and accepted security practices, systems rules of behavior, to include Unauthorized Disclosure Training, available on PALMS or by contacting (b)(7)(E) @ICE.dhs.gov. Department contractor employees, with significant security responsibilities, shall receive specialized training specific to their security responsibilities annually. The level of training shall be commensurate with the individual's duties and responsibilities and is intended to promote a consistent understanding of the principles and concepts of telecommunications and IT systems security.

All personnel who access Department information systems will be continually evaluated while performing these duties. System Administrators should be aware of any unusual or inappropriate behavior by personnel accessing systems. Any unauthorized access, sharing of passwords, or other questionable security procedures should be reported to the local Security Office or Information System Security Officer (ISSO).

H.3. ICE INFORMATION GOVERNANCE AND PRIVACY REQUIREMENTS CLAUSE (JUL 2017)

No section of this clause may be read as self-deleting unless the terms of the contract meet the requirements for self-deletion as specified in this clause.

A. Limiting Access to Privacy Act and Other Sensitive Information

(1) Privacy Act Information
In accordance with FAR 52.224-1 Privacy Act Notification (APR 1984), and FAR 52.224-2 Privacy Act (APR 1984), if this contract requires contractor personnel to have access to information protected by the Privacy Act of 1974 the contractor is advised that the relevant DHS system of records notices (SORNs) applicable to this Privacy Act information may be found at www.dhs.gov/privacy. Applicable SORNS of other agencies may be accessed through the agencies' websites or by searching FDsys, the Federal Digital System, available at http://www.gpo.gov/fdsys/. SORNs may be updated at any time.

(3) Prior Approval Required to Hire Subcontractors
The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (Subcontractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under or relating to this contract. The Contractor (and any Subcontractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

(4) Separation Checklist for Contractor Employees
Contractor shall complete a separation checklist before any employee or Subcontractor employee terminates working on the contract. The separation checklist must verify: (1) return of any Government-furnished equipment; (2) return or proper disposal of sensitive personally identifiable information (PII), in paper or electronic form, in the custody of the employee or Subcontractor employee including the sanitization of data on any computer systems or media as appropriate; and (3) termination of any technological access to the Contractor's facilities or systems that would permit the terminated employee's access to sensitive PII.

In the event of adverse job actions resulting in the dismissal of an employee or Subcontractor employee, the Contractor shall notify the Contracting Officer's Representative (COR) within 24 hours. For normal separations, the Contractor shall submit the checklist on the last day of employment or work on the contract.

As requested, contractors shall assist the ICE Point of Contact (ICE/POC), Contracting Officer, or COR with completing ICE Form 50-005/Contractor Employee Separation Clearance Checklist by returning all Government-furnished property including but not limited to computer equipment, media, credentials and passports, smart cards, mobile devices, PIV cards, calling cards, and keys and terminating access to all user accounts and systems.

B. Privacy Training, Safeguarding, and Remediation

If the Safeguarding of Sensitive Information (MAR 2015) and Information Technology Security and Privacy Training (MAR 2015) clauses are included in this contract, section B of

this clause is deemed self- deleting.

(1) Required Security and Privacy Training for Contractors
Contractor shall provide training for all employees, including Subcontractors and independent contractors who have access to sensitive personally identifiable information (PII) as well as the creation, use, dissemination and/or destruction of sensitive PII at the outset of the employee's work on the contract and every year thereafter. Training must include procedures on how to properly handle sensitive PII, including security requirements for the transporting or transmission of sensitive PII, and reporting requirements for a suspected breach or loss of sensitive PII. All Contractor employees are required to take the *Privacy at DHS: Protecting Personal Information* training course. This course, along with more information about DHS security and training requirements for Contractors, is available at www.dhs.gov/dhs-security-and-training-requirements-contractors. The Federal Information Security Management Act (FISMA) requires all individuals accessing ICE information to take the annual Information Assurance Awareness Training course. These courses are available through the ICE intranet site or the Agency may also make the training available through hypertext links or CD. The Contractor shall maintain copies of employees' certificates of completion as a record of compliance and must submit an annual e-mail notification to the ICE Contracting Officer's Representative that the required training has been completed for all the Contractor's employees.

(2) Safeguarding Sensitive PII Requirement
Contractor employees shall comply with the Handbook for Safeguarding sensitive PII at DHS at all times when handling sensitive PII, including the encryption of sensitive PII as required in the Handbook. This requirement will be flowed down to all subcontracts and lower tiered subcontracts as well.

(3) Non-Disclosure Agreement Requirement
All Contractor personnel that may have access to PII or other sensitive information shall be required to sign a Non-Disclosure Agreement (DHS Form 11000-6) prior to commencing work. The Contractor shall maintain signed copies of the NDA for all employees as a record of compliance. The Contractor shall provide copies of the signed NDA to the Contracting Officer's Representative (COR) no later than two (2) days after execution of the form.

(4) Prohibition on Use of PII in Vendor Billing and Administrative Records
The Contractor's invoicing, billing, and other financial/administrative records/databases may not store or include any sensitive Government information, such as PII that is created, obtained, or provided during the performance of the contract. It is acceptable to list the names, titles and contact information for the Contracting Officer, Contracting Officer's Representative, or other ICE personnel associated with the administration of the contract in the invoices as needed.

(5) Reporting Suspected Loss of Sensitive PII
Contractors must report the suspected loss or compromise of sensitive PII to ICE in a timely manner and cooperate with ICE's inquiry into the incident and efforts to remediate any harm to potential victims.

1. The Contractor must develop and include in its security plan (which is submitted to ICE) an

internal system by which its employees and Subcontractors are trained to identify and report the potential loss or compromise of sensitive PII.

2. The Contractor must report the suspected loss or compromise of sensitive PII by its employees or Subcontractors to the ICE Security Operations Center (480-496-(b)(7)(E), the Contracting Officer's Representative (COR), and the Contracting Officer within one (1) hour of the initial discovery.

3. The Contractor must provide a written report to ICE within 24 hours of the suspected loss or compromise of sensitive PII by its employees or Subcontractors. The report must contain the following information:

a. Narrative or detailed description of the events surrounding the suspected loss or compromise of information.
b. Date, time, and location of the incident.
c. Type of information lost or compromised.
d. Contractor's assessment of the likelihood that the information was compromised or lost and the reasons behind the assessment.
e. Names of person(s) involved, including victim, Contractor employee/Subcontractor and any witnesses.
f. Cause of the incident and whether the company's security plan was followed and, if not, which specific provisions were not followed.
g. Actions that have been or will be taken to minimize damage and/or mitigate further compromise.
h. Recommendations to prevent similar situations in the future, including whether the security plan needs to be modified in any way and whether additional training may be required.

4. The Contractor shall provide full access and cooperation for all activities determined by the Government to be required to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents.

5. At the Government's discretion, Contractor employees or Subcontractor employees may be identified as no longer eligible to access sensitive PII or to work on that contract based on their actions related to the loss or compromise of sensitive PII.

(6) Victim Remediation

The Contractor is responsible for notifying victims and providing victim remediation services in the event of a loss or compromise of sensitive PII held by the Contractor, its agents, or its Subcontractors, under this contract. Victim remediation services shall include at least 18 months of credit monitoring and, for serious or large incidents as determined by the Government, call center help desk services for the individuals whose sensitive PII was lost or compromised. The Contractor and ICE will collaborate and agree on the method and content of any notification that may be required to be sent to individuals whose sensitive PII was lost or compromised.

C. Government Records Training, Ownership, and Management

(1) Records Management Training and Compliance

(a) The Contractor shall provide DHS basic records management training for all employees and Subcontractors that have access to sensitive PII as well as to those involved in the creation, use, dissemination and/or destruction of sensitive PII. This training will be provided at the outset of the Subcontractor's/employee's work on the contract and every year thereafter. This training can be obtained via links on the ICE intranet site or it may be made available through other means (e.g., CD or online). The Contractor shall maintain copies of certificates as a record of compliance and must submit an e-mail notification annually to the Contracting Officer's Representative verifying that all employees working under this contract have completed the required records management training.

(b) The Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format, mode of transmission, or state of completion.

(2) Records Creation, Ownership, and Disposition

(a) The Contractor shall not create or maintain any records not specifically tied to or authorized by the contract using Government IT equipment and/or Government records or that contain Government Agency data. The Contractor shall certify in writing the destruction or return of all Government data at the conclusion of the contract or at a time otherwise specified in the contract.

(b) Except as stated in the Performance Work Statement and, where applicable, the Contractor's Commercial License Agreement, the Government Agency owns the rights to all electronic information (electronic data, electronic information systems or electronic databases) and all supporting documentation and associated metadata created as part of this contract. All deliverables (including all data and records) under the contract are the property of the U.S. Government and are considered federal records, for which the Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein. The Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.

(c) The Contractor shall not retain, use, sell, disseminate, or dispose of any government data/records or deliverables without the express written permission of the Contracting Officer or Contracting Officer's Representative. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. § 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the Agency records schedules.

D. Data Privacy and Oversight

Section D applies to information technology (IT) contracts. If this is not an IT contract, section D may read as self-deleting.

(1) Restrictions on Testing or Training Using Real Data Containing PII
The use of real data containing sensitive PII from any source for testing or training purposes is generally prohibited. The Contractor shall use synthetic or de-identified real data for testing or training whenever feasible. ICE policy requires that any proposal to use of real data or de-identified data for IT system testing or training be approved by the ICE Privacy Officer and Chief Information Security Officer (CISO) in advance. In the event performance of the contract requires or necessitates the use of real data for system-testing or training purposes, the Contractor in coordination with the Contracting Officer or Contracting Officer's Representative and Government program manager shall obtain approval from the ICE Privacy Office and CISO and complete any required documentation.

If this IT contract contains the Safeguarding of Sensitive Information (MAR 2015) and Information Technology Security and Privacy Training (MAR 2015) clauses, section D(2) of this clause is deemed self-deleting.

(2) Requirements for Contractor IT Systems Hosting Government Data
The Contractor is required to obtain a Certification and Accreditation for any IT environment owned or controlled by the Contractor or any Subcontractor on which Government data shall reside for the purposes of IT system development, design, data migration, testing, training, maintenance, use, or disposal.

(3) Requirement to Support Privacy Compliance

(a) The Contractor shall support the completion of the Privacy Threshold Analysis (PTA) document when it is required. PTAs are triggered by the creation, modification, upgrade, or disposition of an IT system, and must be renewed at least every three years. Upon review of the PTA, the DHS Privacy Office determines whether a Privacy Impact Assessment (PIA) and/or Privacy Act System of Records Notice (SORN), or modifications thereto, are required. The Contractor shall provide adequate support to complete the PIA in a timely manner, and shall ensure that project management plans and schedules include the PTA, PIA, and SORN (to the extent required) as milestones. Additional information on the privacy compliance process at DHS, including PTAs, PIAs, and SORNs, is located on the DHS Privacy Office website (www.dhs.gov/privacy) under "Compliance." DHS Privacy Policy Guidance Memorandum 2008-02 sets forth when a PIA will be required at DHS, and the Privacy Impact Assessment Guidance and Template outline the requirements and format for the PIA.

(b) If the contract involves an IT system build or substantial development or changes to an IT system that may require privacy documentation, the Contractor shall assign or procure a Privacy Lead, to be listed under "Key Personnel." The Privacy Lead shall be responsible for providing adequate support to DHS to ensure DHS can complete any required PTA, PIA, SORN, or other supporting documentation to support privacy compliance. The Privacy Lead shall work with personnel from the program office, the ICE Privacy Office, the Office of the Chief Information Officer, and the Records Management Branch to ensure that the privacy

documentation is kept on schedule, that the answers to questions in the PIA are thorough and complete, and that questions asked by the ICE Privacy Office and other offices are answered in a timely fashion. The Privacy Lead:

- Must have excellent writing skills, the ability to explain technology clearly for a non-technical audience, and the ability to synthesize information from a variety of sources.
- Must have excellent verbal communication and organizational skills.
- Must have experience writing PIAs. Ideally the candidate would have experience writing PIAs for DHS.
- Must be knowledgeable about the Privacy Act of 1974 and the E-Government Act of 2002.
- Must be able to work well with others.

(c) If a Privacy Lead is already in place with the program office and the contract involves IT system builds or substantial changes that may require privacy documentation, the requirement for a separate Private Lead specifically assigned under this contract may be waived provided the Contractor agrees to have the existing Privacy Lead coordinate with and support the ICE Privacy POC to ensure privacy concerns are proactively reviewed and so ICE can complete any required PTA, PIA, SORN, or other supporting documentation to support privacy compliance if required. The Contractor shall work with personnel from the program office, the ICE Office of Information Governance and Privacy, and the Office of the Chief Information Officer to ensure that the privacy documentation is kept on schedule, that the answers to questions in any privacy documents are thorough and complete, that all records management requirements are met, and that questions asked by the ICE Privacy Office and other offices are answered in a timely fashion.

H.4. INFORMATION TECHNOLOGY SECURITY AND PRIVACY TRAINING (MAR 2015)

(a) *Applicability.* This clause applies to the Contractor, its subcontractors, and Contractor employees (hereafter referred to collectively as "Contractor"). The Contractor shall insert the substance of this clause in all subcontracts.

(b) *Security Training Requirements*.

(1) All users of Federal information systems are required by Title 5, Code of Federal Regulations, Part 930.301, Subpart C, as amended, to be exposed to security awareness materials annually or whenever system security changes occur, or when the user's responsibilities change. The Department of Homeland Security (DHS) requires that Contractor employees take an annual Information Technology Security Awareness Training course before accessing sensitive information under the contract. Unless otherwise specified, the training shall be completed within thirty (30) days of contract award and be completed on an annual basis thereafter not later than October 31st of each year. Any new Contractor employees assigned to the contract shall complete the training before accessing sensitive information under the contract. The training is accessible at http://www.dhs.gov/dhs-security-and-training-requirements-contractors. The Contractor shall maintain copies of training certificates for all Contractor and subcontractor

employees as a record of compliance. Unless otherwise specified, initial training certificates for each Contractor and subcontractor employee shall be provided to the Contracting Officer's Representative (COR) not later than thirty (30) days after contract award. Subsequent training certificates to satisfy the annual training requirement shall be submitted to the COR via e-mail notification not later than October 31st of each year. The e-mail notification shall state the required training has been completed for all Contractor and subcontractor employees.

(2) The DHS Rules of Behavior apply to every DHS employee, Contractor and subcontractor that will have access to DHS systems and sensitive information. The DHS Rules of Behavior shall be signed before accessing DHS systems and sensitive information. The DHS Rules of Behavior is a document that informs users of their responsibilities when accessing DHS systems and holds users accountable for actions taken while accessing DHS systems and using DHS Information Technology resources capable of inputting, storing, processing, outputting, and/or transmitting sensitive information. The DHS Rules of Behavior is accessible at http://www.dhs.gov/dhs-security-and-training-requirements-contractors. Unless otherwise specified, the DHS Rules of Behavior shall be signed within thirty (30) days of contract award. Any new Contractor employees assigned to the contract shall also sign the DHS Rules of Behavior before accessing DHS systems and sensitive information. The Contractor shall maintain signed copies of the DHS Rules of Behavior for all Contractor and subcontractor employees as a record of compliance. Unless otherwise specified, the Contractor shall e-mail copies of the signed DHS Rules of Behavior to the COR not later than thirty (30) days after contract award for each employee. The DHS Rules of Behavior will be reviewed annually and the COR will provide notification when a review is required.

(c) *Privacy Training Requirements.* All Contractor and subcontractor employees that will have access to Personally Identifiable Information (PII) and/or Sensitive PII (SPII) are required to take *Privacy at DHS: Protecting Personal Information* before accessing PII and/or SPII. The training is accessible at http://www.dhs.gov/dhs-security-and-training-requirements-contractors.

Training shall be completed within thirty (30) days of contract award and be completed on an annual basis thereafter not later than October 31st of each year. Any new Contractor employees assigned to the contract shall also complete the training before accessing PII and/or SPII. The Contractor shall maintain copies of training certificates for all Contractor and subcontractor employees as a record of compliance. Initial training certificates for each Contractor and subcontractor employee shall be provided to the COR not later than thirty (30) days after contract award. Subsequent training certificates to satisfy the annual training requirement shall be submitted to the COR via e-mail notification not later than October 31st of each year. The e-mail notification shall state the required training has been completed for all Contractor and subcontractor employees.

H.5. SAFEGUARDING OF SENSITIVE INFORMATION (MAR 2015)

(a) *Applicability.* This clause applies to the Contractor, its subcontractors, and Contractor employees (hereafter referred to collectively as "Contractor"). The Contractor shall insert the substance of this clause in all subcontracts.

(b) *Definitions*. As used in this clause—

“Personally Identifiable Information (PII)” means information that can be used to distinguish or trace an individual's identity, such as name, social security number, or biometric records, either alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth, or mother’s maiden name. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. In performing this assessment, it is important for an agency to recognize that non-personally identifiable information can become personally identifiable information whenever additional information is made publicly available—in any medium and from any source—that, combined with other available information, could be used to identify an individual.

PII is a subset of sensitive information. Examples of PII include, but are not limited to: name, date of birth, mailing address, telephone number, Social Security number (SSN), email address, zip code, account numbers, certificate/license numbers, vehicle identifiers including license plates, uniform resource locators (URLs), static Internet protocol addresses, biometric identifiers such as fingerprint, voiceprint, iris scan, photographic facial images, or any other unique identifying number or characteristic, and any information where it is reasonably foreseeable that the information will be linked with other information to identify the individual.

“Sensitive Information” is defined in HSAR clause 3052.204-71, Contractor Employee Access, as any information, which if lost, misused, disclosed, or, without authorization is accessed, or modified, could adversely affect the national or homeland security interest, the conduct of Federal programs, or the privacy to which individuals are entitled under section 552a of Title 5, United States Code (the Privacy Act), but which has not been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept secret in the interest of national defense, homeland security or foreign policy. This definition includes the following categories of information:

(1) Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107-296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, Part 29) as amended, the applicable PCII Procedures Manual, as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the PCII Program Manager or his/her designee);

(2) Sensitive Security Information (SSI), as defined in Title 49, Code of Federal Regulations, Part 1520, as amended, “Policies and Procedures of Safeguarding and Control of SSI,” as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the Assistant Secretary for the Transportation Security Administration or his/her designee);

(3) Information designated as “For Official Use Only,” which is unclassified information of a sensitive nature and the unauthorized disclosure of which could adversely impact a person’s privacy or welfare, the conduct of Federal programs, or other programs or operations essential to

the national or homeland security interest; and

(4) Any information that is designated "sensitive" or subject to other controls, safeguards or protections in accordance with subsequently adopted homeland security information handling procedures.

"Sensitive Information Incident" is an incident that includes the known, potential, or suspected exposure, loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or unauthorized access or attempted access of any Government system, Contractor system, or sensitive information.

"Sensitive Personally Identifiable Information (SPII)" is a subset of PII, which if lost, compromised or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Some forms of PII are sensitive as stand-alone elements. Examples of such PII include: Social Security numbers (SSN), driver's license or state identification number, Alien Registration Numbers (A-number), financial account number, and biometric identifiers such as fingerprint, voiceprint, or iris scan. Additional examples include any groupings of information that contain an individual's name or other unique identifier plus one or more of the following elements:

(1) Truncated SSN (such as last 4 digits)
(2) Date of birth (month, day, and year)
(3) Citizenship or immigration status
(4) Ethnic or religious affiliation
(5) Sexual orientation
(6) Criminal History
(7) Medical Information
(8) System authentication information such as mother's maiden name, account passwords or personal identification numbers (PIN)

Other PII may be "sensitive" depending on its context, such as a list of employees and their performance ratings or an unlisted home address or phone number. In contrast, a business card or public telephone directory of agency employees contains PII but is not sensitive.

(c) *Authorities*. The Contractor shall follow all current versions of Government policies and guidance accessible at http://www.dhs.gov/dhs-security-and-training-requirements-contractors, or available upon request from the Contracting Officer, including but not limited to:

(1) DHS Management Directive 11042.1 Safeguarding Sensitive But Unclassified (for Official Use Only) Information

(2) DHS Sensitive Systems Policy Directive 4300A
(3) DHS 4300A Sensitive Systems Handbook and Attachments
(4) DHS Security Authorization Process Guide
(5) DHS Handbook for Safeguarding Sensitive Personally Identifiable Information
(6) DHS Instruction Handbook 121-01-007 Department of Homeland Security Personnel Suitability and Security Program

(7) DHS Information Security Performance Plan (current fiscal year)
(8) DHS Privacy Incident Handling Guidance
(9) Federal Information Processing Standard (FIPS) 140-2 Security Requirements for Cryptographic Modules accessible at http://csrc.nist.gov/groups/STM/cmvp/standards.html
(10) National Institute of Standards and Technology (NIST) Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations accessible at http://csrc.nist.gov/publications/PubsSPs.html
(11) NIST Special Publication 800-88 Guidelines for Media Sanitization accessible at http://csrc.nist.gov/publications/PubsSPs.html

(d) *Handling of Sensitive Information.* Contractor compliance with this clause, as well as the policies and procedures described below, is required.

(1) Department of Homeland Security (DHS) policies and procedures on Contractor personnel security requirements are set forth in various Management Directives (MDs), Directives, and Instructions. *MD 11042.1, Safeguarding Sensitive But Unclassified (For Official Use Only) Information* describes how Contractors must handle sensitive but unclassified information. DHS uses the term "FOR OFFICIAL USE ONLY" to identify sensitive but unclassified information that is not otherwise categorized by statute or regulation. Examples of sensitive information that are categorized by statute or regulation are PCII, SSI, etc. The *DHS Sensitive Systems Policy Directive 4300A* and the *DHS 4300A Sensitive Systems Handbook* provide the policies and procedures on security for Information Technology (IT) resources. The *DHS Handbook for Safeguarding Sensitive Personally Identifiable Information* provides guidelines to help safeguard SPII in both paper and electronic form. *DHS Instruction Handbook 121-01-007 Department of Homeland Security Personnel Suitability and Security Program* establishes procedures, program responsibilities, minimum standards, and reporting protocols for the DHS Personnel Suitability and Security Program.

(2) The Contractor shall not use or redistribute any sensitive information processed, stored, and/or transmitted by the Contractor except as specified in the contract.

(3) All Contractor employees with access to sensitive information shall execute *DHS Form 11000-6, Department of Homeland Security Non-Disclosure Agreement (NDA),* as a condition of access to such information. The Contractor shall maintain signed copies of the NDA for all employees as a record of compliance. The Contractor shall provide copies of the signed NDA to the Contracting Officer's Representative (COR) no later than two (2) days after execution of the form.

(4) The Contractor's invoicing, billing, and other recordkeeping systems maintained to support financial or other administrative functions shall not maintain SPII. It is acceptable to maintain in these systems the names, titles and contact information for the COR or other Government personnel associated with the administration of the contract, as needed.

(e) *Authority to Operate*. The Contractor shall not input, store, process, output, and/or transmit sensitive information within a Contractor IT system without an Authority to Operate (ATO) signed by the Headquarters or Component CIO, or designee, in consultation with the

Headquarters or Component Privacy Officer. Unless otherwise specified in the ATO letter, the ATO is valid for three (3) years. The Contractor shall adhere to current Government policies, procedures, and guidance for the Security Authorization (SA) process as defined below.

(1) Complete the Security Authorization process. The SA process shall proceed according to the *DHS Sensitive Systems Policy Directive 4300A* (Version 11.0, April 30, 2014), or any successor publication, *DHS 4300A Sensitive Systems Handbook* (Version 9.1, July 24, 2012), or any successor publication, and the *Security Authorization Process Guide* including templates.

(i) Security Authorization Process Documentation. SA documentation shall be developed using the Government provided Requirements Traceability Matrix and Government security documentation templates. SA documentation consists of the following: Security Plan, Contingency Plan, Contingency Plan Test Results, Configuration Management Plan, Security Assessment Plan, Security Assessment Report, and Authorization to Operate Letter. Additional documents that may be required include a Plan(s) of Action and Milestones and Interconnection Security Agreement(s). During the development of SA documentation, the Contractor shall submit a signed SA package, validated by an independent third party, to the COR for acceptance by the Headquarters or Component CIO, or designee, at least thirty (30) days prior to the date of operation of the IT system. The Government is the final authority on the compliance of the SA package and may limit the number of resubmissions of a modified SA package. Once the ATO has been accepted by the Headquarters or Component CIO, or designee, the Contracting Officer shall incorporate the ATO into the contract as a compliance document. The Government's acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the IT system controls are implemented and operating effectively.

(ii) Independent Assessment. Contractors shall have an independent third party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the SA package, and report on technical, operational, and management level deficiencies as outlined in *NIST Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations*. The Contractor shall address all deficiencies before submitting the SA package to the Government for acceptance.

(iii) Support the completion of the Privacy Threshold Analysis (PTA) as needed. As part of the SA process, the Contractor may be required to support the Government in the completion of the PTA. The requirement to complete a PTA is triggered by the creation, use, modification, upgrade, or disposition of a Contractor IT system that will store, maintain and use PII, and must be renewed at least every three (3) years. Upon review of the PTA, the DHS Privacy Office determines whether a Privacy Impact Assessment (PIA) and/or Privacy Act System of Records Notice (SORN), or modifications thereto, are required. The Contractor shall provide all support necessary to assist the Department in completing the PIA in a timely manner and shall ensure that project management plans and schedules include time for the completion of the PTA, PIA, and SORN (to the extent required) as milestones. Support in this context includes responding timely to requests for information from the Government about the use, access, storage, and maintenance of PII on the Contractor's system, and providing timely review of relevant compliance documents for

factual accuracy. Information on the DHS privacy compliance process, including PTAs, PIAs, and SORNs, is accessible at http://www.dhs.gov/privacy-compliance.

(2) *Renewal of ATO.* Unless otherwise specified in the ATO letter, the ATO shall be renewed every three (3) years. The Contractor is required to update its SA package as part of the ATO renewal process. The Contractor shall update its SA package by one of the following methods: (1) Updating the SA documentation in the DHS automated information assurance tool for acceptance by the Headquarters or Component CIO, or designee, at least 90 days before the ATO expiration date for review and verification of security controls; or (2) Submitting an updated SA package directly to the COR for approval by the Headquarters or Component CIO, or designee, at least 90 days before the ATO expiration date for review and verification of security controls. The 90-day review process is independent of the system production date and therefore it is important that the Contractor build the review into project schedules. The reviews may include onsite visits that involve physical or logical inspection of the Contractor environment to ensure controls are in place.
(3) *Security Review.* The Government may elect to conduct random periodic reviews to ensure that the security requirements contained in this contract are being implemented and enforced. The Contractor shall afford DHS, the Office of the Inspector General, and other Government organizations access to the Contractor's facilities, installations, operations, documentation, databases and personnel used in the performance of this contract. The Contractor shall, through the Contracting Officer and COR, contact the Headquarters or Component CIO, or designee, to coordinate and participate in review and inspection activity by Government organizations external to the DHS. Access shall be provided, to the extent necessary as determined by the Government, for the Government to carry out a program of inspection, investigation, and audit to safeguard against threats and hazards to the integrity, availability and confidentiality of Government data or the function of computer systems used in performance of this contract and to preserve evidence of computer crime.

(4) *Continuous Monitoring.* All Contractor-operated systems that input, store, process, output, and/or transmit sensitive information shall meet or exceed the continuous monitoring requirements identified in the *Fiscal Year 2014 DHS Information Security Performance Plan,* or successor publication. The plan is updated on an annual basis. The Contractor shall also store monthly continuous monitoring data at its location for a period not less than one year from the date the data is created. The data shall be encrypted in accordance with *FIPS 140-2 Security Requirements for Cryptographic Modules* and shall not be stored on systems that are shared with other commercial or Government entities. The Government may elect to perform continuous monitoring and IT security scanning of Contractor systems from Government tools and infrastructure.

(5) *Revocation of ATO.* In the event of a sensitive information incident, the Government may suspend or revoke an existing ATO (either in part or in whole). If an ATO is suspended or revoked in accordance with this provision, the Contracting Officer may direct the Contractor to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor IT system under this contract. Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

(6) *Federal Reporting Requirements*. Contractors operating information systems on behalf of the Government or operating systems containing sensitive information shall comply with Federal reporting requirements. Annual and quarterly data collection will be coordinated by the Government. Contractors shall provide the COR with requested information within three (3) business days of receipt of the request. Reporting requirements are determined by the Government and are defined in the *Fiscal Year 2014 DHS Information Security Performance Plan,* or successor publication. The Contractor shall provide the Government with all information to fully satisfy Federal reporting requirements for Contractor systems.

(f) Sensitive Information Incident Reporting Requirements.

(1) All known or suspected sensitive information incidents shall be reported to the Headquarters or Component Security Operations Center (SOC) within one hour of discovery in accordance with *4300A Sensitive Systems Handbook Incident Response and Reporting* requirements. When notifying the Headquarters or Component SOC, the Contractor shall also notify the Contracting Officer, COR, Headquarters or Component Privacy Officer, and US-CERT using the contact information identified in the contract. If the incident is reported by phone or the Contracting Officer's email address is not immediately available, the Contractor shall contact the Contracting Officer immediately after reporting the incident to the Headquarters or Component SOC. The Contractor shall not include any sensitive information in the subject or body of any e-mail. To transmit sensitive information, the Contractor shall use *FIPS 140-2 Security Requirements for Cryptographic Modules* compliant encryption methods to protect sensitive information in attachments to email. Passwords shall not be communicated in the same email as the attachment. A sensitive information incident shall not, by itself, be interpreted as evidence that the Contractor has failed to provide adequate information security safeguards for sensitive information, or has otherwise failed to meet the requirements of the contract.

(2) If a sensitive information incident involves PII or SPII, in addition to the reporting requirements in *4300A Sensitive Systems Handbook Incident Response and Reporting*, Contractors shall also provide as many of the following data elements that are available at the time the incident is reported, with any remaining data elements provided within 24 hours of submission of the initial incident report:

(i) Data Universal Numbering System (DUNS);
(ii) Contract numbers affected unless all contracts by the company are affected;
(iii) Facility CAGE code if the location of the event is different than the prime contractor location;
(iv) Point of contact (POC) if different than the POC recorded in the System for Award Management (address, position, telephone, email);
(v) Contracting Officer POC (address, telephone, email);
(vi) Contract clearance level;
(vii) Name of subcontractor and CAGE code if this was an incident on a subcontractor network;
(viii) Government programs, platforms or systems involved;
(ix) Location(s) of incident;

(x) Date and time the incident was discovered;
(xi) Server names where sensitive information resided at the time of the incident, both at the Contractor and subcontractor level;
(xii) Description of the Government PII and/or SPII contained within the system;
(xiii) Number of people potentially affected and the estimate or actual number of records exposed and/or contained within the system; and
(xiv) Any additional information relevant to the incident.

(g) Sensitive Information Incident Response Requirements.

(1) All determinations related to sensitive information incidents, including response activities, notifications to affected individuals and/or Federal agencies, and related services (e.g., credit monitoring) will be made in writing by the Contracting Officer in consultation with the Headquarters or Component CIO and Headquarters or Component Privacy Officer.

(2) The Contractor shall provide full access and cooperation for all activities determined by the Government to be required to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents.

(3) Incident response activities determined to be required by the Government may include, but are not limited to, the following:

(i) Inspections,
(ii) Investigations,
(iii) Forensic reviews, and
(iv) Data analyses and processing.

(4) The Government, at its sole discretion, may obtain the assistance from other Federal agencies and/or third-party firms to aid in incident response activities.

(h) *Additional PII and/or SPII Notification Requirements.*

(1) The Contractor shall have in place procedures and the capability to notify any individual whose PIIresided in the Contractor IT system at the time of the sensitive information incident not later than 5 business days after being directed to notify individuals, unless otherwise approved by the Contracting Officer. The method and content of any notification by the Contractor shall be coordinated with, and subject to prior written approval by theContracting Officer, in consultation with the Headquarters or Component Privacy Officer, utilizing the *DHS Privacy Incident Handling Guidance*. The Contractor shall not proceed with notification unless the Contracting Officer, in consultation with the Headquarters or Component Privacy Officer, has determined in writing that notification is appropriate.

(2) Subject to Government analysis of the incident and the terms of its instructions to the Contractor regarding any resulting notification, the notification method may consist of letters to affected individuals sent by first class mail, electronic means, or general public notice, as

approved by the Government. Notification may require the Contractor's use of address verification and/or address location services. At a minimum, the notification shall include:

(i) A brief description of the incident;
(ii) A description of the types of PII and SPII involved;
(iii) A statement as to whether the PII or SPII was encrypted or protected by other means;
(iv) Steps individuals may take to protect themselves;
(v) What the Contractor and/or the Government are doing to investigate the incident, to mitigate the incident, and to protect against any future incidents; and
(vi) Information identifying who individuals may contact for additional information.

(i) *Credit Monitoring Requirements*. In the event that a sensitive information incident involves PII or SPII, the Contractor may be required to, as directed by the Contracting Officer:

(1) Provide notification to affected individuals as described above; and/or

(2) Provide credit monitoring services to individuals whose data was under the control of the Contractor or resided in the Contractor IT system at the time of the sensitive information incident for a period beginning the date of the incident and extending not less than 18 months from the date the individual is notified. Credit monitoring services shall be provided from a company with which the Contractor has no affiliation. At a minimum, credit monitoring services shall include:

(i) Triple credit bureau monitoring;
(ii) Daily customer service;
(iii) Alerts provided to the individual for changes and fraud; and
(iv) Assistance to the individual with enrollment in the services and the use of fraud alerts; and/or

(3) Establish a dedicated call center. Call center services shall include:

(i) A dedicated telephone number to contact customer service within a fixed period;
(ii) Information necessary for registrants/enrollees to access credit reports and credit scores;
(iii) Weekly reports on call center volume, issue escalation (i.e., those calls that cannot be handled by call center staff and must be resolved by call center management or DHS, as appropriate), and other key metrics;
(iv) Escalation of calls that cannot be handled by call center staff to call center management or DHS, as appropriate;
(v) Customized FAQs, approved in writing by the Contracting Officer in coordination with the Headquarters or Component Chief Privacy Officer; and
(vi) Information for registrants to contact customer service representatives and fraud resolution representatives for credit monitoring assistance.

(i) *Certification of Sanitization of Government and Government-Activity-Related Files and Information.* As part of contract closeout, the Contractor shall submit the certification to the

COR and the Contracting Officer following the template provided in *NIST Special Publication 800-88 Guidelines for Media Sanitization*.

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[END OF SECTION H]

SECTION I:
CONTRACT CLAUSES

I.1 CLAUSES INCORPORATED BY REFERENCE (FAR 52.252-2) (FEB 1998)

This contract incorporates the following clauses by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. Also, the full text can be accessed electronically at this internet address:
http://acquisition.gov/far/index.html.

Number	Titles	DATE
52.202-1	Definitions	Jun 2020
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Jun 2020
52.203-12	Limitations on Payments to Influence Certain Federal Transactions	Jun 2020
52.203-13	Contractor Code of Business Ethics and Conduct	Jun 2020
52.203-17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights	Jun 2020
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	May 2011
52.204-9	Personal Identity Verification of Contractor Personnel	Jan 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Jun 2020
52.204-13	System for Award Management Maintenance	Oct 2018
52.204-15	Service Contract Reporting Requirements for Indefinite - Delivery Contracts	Oct 2016
52.204-18	Commercial and Government Entity Code Maintenance	Jul 2016
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	Jul 2016
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	Jul 2018
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	Aug 2019
52.208-9	Contractor Use of Mandatory Sources of Supply or Services	May 2014
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	Jun 2020
52.209-9	Updates of Publicly Available Information Regarding	Oct 2018

	Responsibility Matters	
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2015
52.215-2	Audit and Records – Negotiations	Jun 2020
52.215-8	Order of Precedence – Uniform Contract Format	Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	Aug 2011
52.215-12	Subcontractor Cost or Pricing Data	Jun 2020
52.215-14	Integrity of Unit Prices	Jun 2020
52.215-15	Pension Adjustments and Asset Reversions	Oct 2010
52.215-18	Revisions for Adjustment of Plans for Postretirement Benefits (PRB) Other than Pension	Jul 2005
52.215-19	Notification of Ownership Changes	Oct 1997
52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns	Mar 2020
52.219-8	Utilization of Small Business Concerns	Nov 2016
52.219-9	Small Business Subcontracting Plan, Alternate II	Jun 2020
52.219-16	Liquidated Damages-Subcontracting Plan	Jan 1999
52.219-28	Post-Award Small Business Program Representation	May 2020
52.222-1	Notice to the Government of Labor Disputes	Feb 1997
52.222-3	Convict Labor	Jun 2003
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-26	Equal Opportunity	Sept 2016
52.222-37	Employment Reports on Veterans	Jun 2020
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-41	Service Contract Labor Standards	Aug 2018
52.222-43	Fair Labor Standards Act and Service Contract Labor Standards - Price Adjustment (Multiple Year and Option Contracts)	Aug 2018
52.222-50	Combating Trafficking in Persons	Jan 2019
52.222-54	Employment Eligibility Verification	Oct 2015
52.222-55	Minimum Wages Under Executive Order 13658	Dec 2015
52.222-62	Paid Sick Leave Under Executive Order 13706	Jan 2017
52.223-2	Affirmative Procurement of Bio-based Products Under Service or Construction Contracts	Sep 2013
52.223-5	Pollution Prevention and Right-To-Know Information	May 2011
52.223-6	Drug-Free Workplace	May 2001
52.223-15	Energy Efficiency in Energy-Consuming Products	May 2020
52.223-17	Affirmative Procurement of EPA-Designated Items in Service and Construction Contracts	Aug 2018
52.223-18	Contractor Policies to Ban Text Messaging While Driving	Jun 2020
52.223-19	Compliance with Environmental Management Systems	May 2011
52.224-1	Privacy Act Notification	Apr 1984
52.224-2	Privacy Act	Apr 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008

52.226-6	Promoting Excess Food Donation to Nonprofit Organizations	Jun 2020
52.227-1	Authorization and Consent	Jun 2020
52.229-3	Federal, State, and Local Taxes	Feb 2013
52.230-2	Cost Accounting Standards	Jun 2020
52.230-6	Administration of Cost Accounting Standards	Jun 2010
52.232-1	Payments	Apr 1984
52.232-7	Payments under Time-and-Materials and Labor-Hour Contracts	Aug 2012
52.232-8	Discounts for Prompt Payment	Feb 2002
52.232-9	Limitation on Withholding of Payments	Apr 1984
52.232-11	Extras	Apr 1984
52.232-17	Interest	May 2014
52.232-18	Availability of Funds	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment	Jan 2017
53.232-33	Payment by Electronic Funds - System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Dec 2013
52.233-1	Disputes	May 2014
52.233-3	Protest after Award	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.239-1	Privacy or Security Safeguards	Aug 1996
52.242-5	Payments to Small Business Subcontractors	Jan 2017
52.242-13	Bankruptcy	Jul 1995
52.243-1	Changes – Fixed Price, Alternate I (Apr 1984)	Aug 1987
52.243-3	Changes – Time-and-Materials or Labor Hours	Sep 2000
52.244-5	Competition in Subcontracting	Dec 1996
52.245-1	Government Property	Jan 2017
52.245-9	Use and Charges	Apr 2012
52.249-2	Termination for Convenience of the Government –Fixed Price	Apr 2012
52.249-8	Default (Fixed-Price Supply and Service)	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

I.2 CLAUSES INCORPORATED IN FULL TEXT

52.204-1 Approval of Contract (Dec 1989)

This contract is subject to the written approval of the Contracting Officer and shall not be binding until so approved.

(End of Clause)

52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--
"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.
"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.
(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
(iii) Verify and control/limit connections to and use of external information systems.
(iv) Control information posted or processed on publicly accessible information systems.
(v) Identify information system users, processes acting on behalf of users, or devices.
(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
(xii) Identify, report, and correct information and information system flaws in a timely manner.
(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
(xiv) Update malicious code protection mechanisms when new releases are available.
(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of Clause)

(End of Clause)

52.216-18 Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from August 1, 2020 – July 31, 2030.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

52.216-19 Ordering Limitations (Oct 1995)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than (b)(4) the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor --

(1) Any order for a single item in excess of *the total value of the CLIN set forth in this Contract for the applicable period of performance pursuant to which such services are being ordered under;*

(2) Any order for a combination of items in excess of *the total combined value of the CLINs set forth in this Contract for the applicable period of performance which such services are being ordered under*; or

(3) A series of orders from the same ordering office within 365 days that together call for quantities exceeding the limitation in subparagraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.*, includes the Requirements clause at subsection 52.216- 21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 5 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

52.216-22 Indefinite Quantity (Oct 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum," (see page 3 hereof). The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum," (see page 3 hereof).

(c) Except for any limitations on quantities in the Delivery-Order Limitations clause or

in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; *provided*, that the Contractor shall not be required to make any deliveries under this contact after the period of performance end date of the IDIQ.

(End of Clause)

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of contract expiration.

(End of Clause)

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within the performance period provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 Years and 6 Months.

(End of Clause)

52.222-35 Equal Opportunity Veterans (Jun 2020)

(a) *Definitions*. As used in this clause--

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran," and "recently separated veteran" have the meanings given at Federal Acquisition Regulation (FAR) 22.1301.

(b) *Equal opportunity clause*. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

(c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts valued at or above the threshold specified in FAR 22.1303(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

52.222-36 Equal Opportunity for Workers with Disabilities (Jun 2020)

(a) *Equal opportunity clause.* The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.

(b) *Subcontracts*. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of the threshold specified in Federal Acquisition Regulation (FAR) 22.1408(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

52.222-42 Statement of Equivalent Rates for Federal Hires (May 2014)

In compliance with the Service Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

This Statement is for Information Only:
It is not a Wage Determination

Employee Class	**Monetary Wage -- Fringe Benefits**

(End of Clause)

I.3 HSAR CLAUSES INCORPORATED BY REFERENCE

Number	Titles	DATE
3052.203-70	Instructions for Contractor Disclosure of Violations	Sep 2012
3052.225-70	Requirement for Use of Certain Domestic Commodities	Aug 2009

I.4 HSAR CLAUSES INCORPORATED IN FULL TEXT

3052.204-71 Contractor Employee Access (Sep 2012)

(a) *Sensitive Information,* as used in this clause, means any information, which if lost, misused, disclosed, or, without authorization is accessed, or modified, could adversely affect the national or homeland security interest, the conduct of Federal programs, or the privacy to which individuals are entitled under section 552a of title 5, United States Code (the Privacy Act), but which has not been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept secret in the interest of national defense, homeland security or foreign policy. This definition includes the following categories of information:

(1) Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107-296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, Part 29) as amended, the applicable PCII Procedures Manual, as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the PCII Program Manager or his/her designee);

(2) Sensitive Security Information (SSI), as defined in Title 49, Code of Federal Regulations, Part 1520, as amended, "Policies and Procedures of Safeguarding and Control of SSI," as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the Assistant Secretary for the Transportation Security Administration or his/her designee);

(3) Information designated as "For Official Use Only," which is unclassified information of a sensitive nature and the unauthorized disclosure of which could adversely impact a person's privacy or welfare, the conduct of Federal programs, or other programs or operations essential to the national or homeland security interest; and

(4) Any information that is designated “sensitive” or subject to other controls, safeguards or protections in accordance with subsequently adopted homeland security information handling procedures.

(b) “Information Technology Resources” include, but are not limited to, computer equipment, networking equipment, telecommunications equipment, cabling, network drives, computer drives, network software, computer software, software programs, intranet sites, and internet sites.

(c) Contractor employees working on this contract must complete such forms as may be necessary for security or other reasons, including the conduct of background investigations to determine suitability. Completed forms shall be submitted as directed by the Contracting Officer. Upon the Contracting Officer's request, the Contractor's employees shall be fingerprinted, or subject to other investigations as required. All Contractor employees requiring recurring access to Government facilities or access to sensitive information or IT resources are required to have a favorably adjudicated background investigation prior to commencing work on this contract unless this requirement is waived under Departmental procedures.

(d) The Contracting Officer may require the Contractor to prohibit individuals from working on the contract if the Government deems their initial or continued employment contrary to the public interest for any reason, including, but not limited to, carelessness, insubordination, incompetence, or security concerns.

(e) Work under this contract may involve access to sensitive information. Therefore, the Contractor shall not disclose, orally or in writing, any sensitive information to any person unless authorized in writing by the Contracting Officer. For those Contractor employees authorized access to sensitive information, the Contractor shall ensure that these persons receive training concerning the protection and disclosure of sensitive information both during and after contract performance.

(f) The Contractor shall include the substance of this clause in all subcontracts at any tier where the subcontractor may have access to Government facilities, sensitive information, or resources.

(End of Clause)

3052.204-71 Contractor Employee Access ALTERNATE I (SEP 2012)

(g) Before receiving access to IT resources under this contract the individual must receive a security briefing, which the Contracting Officer’s Technical Representative (COTR) will arrange, and complete any nondisclosure agreement furnished by DHS.

(h) The Contractor shall have access only to those areas of DHS information technology resources explicitly stated in this contract or approved by the COTR in writing as necessary for performance of the work under this contract. Any attempts by Contractor personnel to

gain access to any information technology resources not expressly authorized by the statement of work, other terms and conditions in this contract, or as approved in writing by the COTR, is strictly prohibited. In the event of violation of this provision, DHS will take appropriate actions with regard to the contract and the individual(s) involved.

(i) Contractor access to DHS networks from a remote location is a temporary privilege for mutual convenience while the Contractor performs business for the DHS Component. It is not a right, a guarantee of access, a condition of the contract, or Government Furnished Equipment (GFE).

(j) Contractor access will be terminated for unauthorized use. The Contractor agrees to hold and save DHS harmless from any unauthorized use and agrees not to request additional time or money under the contract for any delays resulting from unauthorized use or access.

(k) Non-U.S. citizens shall not be authorized to access or assist in the development, operation, management or maintenance of Department IT systems under the contract, unless a waiver has been granted by the Head of the Component or designee, with the concurrence of both the Department's Chief Security Officer (CSO) and the Chief Information Officer (CIO) or their designees. Within DHS Headquarters, the waiver may be granted only with the approval of both the CSO and the CIO or their designees. In order for a waiver to be granted:

(1) There must be a compelling reason for using this individual as opposed to a U. S. citizen; and
(2) The waiver must be in the best interest of the Government.

(l) Contractors shall identify in their proposals the names and citizenship of all non-U.S. citizens proposed to work under the contract. Any additions or deletions of non-U.S. citizens after contract award shall also be reported to the Contracting Officer.

(End of Clause)

3052.212-70 Contract Terms And Conditions Applicable to DHS Acquisition of Commercial Items (SEP 2012)

The Contractor agrees to comply with any provision or clause that is incorporated herein by reference to implement agency policy applicable to acquisition of commercial items or components. The provision or clause in effect based on the applicable regulation cited on the date the solicitation is issued applies unless otherwise stated herein. The following provisions and clauses are incorporated by reference:

(a) *Provisions*.
____ 3052.209-72 Organizational Conflicts of Interest.
____3052.216-70 Evaluation of Offers Subject to An Economic Price Adjustment Clause.
__X__3052.219-72 Evaluation of Prime Contractor Participation in the DHS Mentor Protégé Program.

(b) Clauses

__X__3052.204-71 Contractor Employee Access.
__X__Alternate I
__X__3052.205-70 Advertisement, Publicizing Awards, and Releases.
__X__Alternate I
____3052.209-73 Limitation on Future Contracting.
__X__3052.215-70 Key Personnel or Facilities.
____3052.216-71 Determination of Award Fee.
____3052.216-72 Performance Evaluation Plan.
____3052.216-73 Distribution of Award Fee.
____3052.217-91 Performance. (USCG)
____3052.217-92 Inspection and Manner of Doing Work. (USCG)
____3052.217-93 Subcontracts. (USCG)
____3052.217-94 Lay Days. (USCG)
____3052.217-95 Liability and Insurance. (USCG)
____3052.217-96 Title. (USCG)
____3052.217-97 Discharge of Liens. (USCG)
____3052.217-98 Delays. (USCG)
____3052.217-99 Department of Labor Safety and Health Regulations for Ship Repair (USCG)
____3052.217-100 Guarantee. (USCG)
__X__3052.219-71 DHS Mentor Protégé Program.
__X__3052.219-72 Evaluation of Prime Contractor Participation in the DHS Mentor-Protégé Program
__X__3052.222-70 Strikes or Picketing Affecting Timely Completion of the Contract Work
__X__3052.222-71 Strikes or Picketing Affecting Access to a DHS Facility
____3052.228-70 Insurance.
____3052.228-90 Notification of Miller Act Payment Bond Protection. (USCG)
____3052.228-91 Loss of or Damage to Leased Aircraft. (USCG)
____3052.228-92 Fair Market Value of Aircraft. (USCG)
____3052.228-93 Risk and Indemnities. (USCG)
____3052.236-70 Special Provisions for Work at Operating Airports.
__X__3052.242-72 Contracting Officer's Technical Representative.
____3052.247-70 F.o.B. Origin Information.
____Alternate I
____Alternate II
____3052.247-71 F.o.B. Origin Only.
____3052.247-72 F.o.B. Destination Only.

(End of Clause)

3052.215-70 Key Personnel or Facilities (Dec 2003)

(a) The personnel or facilities specified below are considered essential to the work being performed under this contract and may, with the consent of the

contracting parties, be changed from time to time during the course of the contract by adding or deleting personnel or facilities, as appropriate.

(b) Before removing or replacing any of the specified individuals or facilities, the Contractor shall notify the Contracting Officer, in writing, before the change becomes effective. The Contractor shall submit sufficient information to support the proposed action and to enable the Contracting Officer to evaluate the potential impact of the change on this contract. The Contractor shall not remove or replace personnel or facilities until the Contracting Officer approves the change.

The Key Personnel or Facilities under this Contract: see Section L (Staffing Plan and Key Personnel) and Section C (Performance Work Statement).

(End of Clause)

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[END OF SECTION I]

SECTION J:
LIST OF ATTACHMENTS

PWS Attachments	
Attachment 1:	Applicable Current Wage Determinations: WD 2015-5215 Rev.-15
Attachment 2:	Prison Rape Elimination Act Regulations
Attachment 3:	Performance-Based National Detention Standards (PBNDS) 2011 with 2016 Revisions
Attachment 4:	Quality Assurance Surveillance Plan
Attachment 4A:	Performance Requirements Summary
Attachment 4B:	Contract Discrepancy Report
Attachment 5:	G-391 Data Collection Categories and Descriptions
Attachment 5A:	G-391 Upload Template
Attachment 6:	Interim ICE Firearms Policy
Attachment 7:	Operations of ERO Holding Facilities
Attachment 8:	ICE Suitability Screening Requirements
Attachment 9:	Personal Property Operations Handbook
Attachment 10:	ICE Body Armor Policy
Attachment 11:	Authorized Restraint Devices Guidelines
Attachment 12:	Interim Use of Force Policy

Proposal Attachments	
Attachment 13:	Cost and Pricing Summary
Attachment 14:	Detention Services Cost Statement
Attachment 15:	Price Proposal dated 7/10/2020
Attachment 16:	Technical Proposal dated 7/10/2020
Attachment 17:	Small Business Subcontracting Plan

PWS Requirement Specific Addendum	
Addendum A:	Performance Work Statement
Addendum B:	Requirement B Addendum

Contract References

Performance-Based National Detention Standards (PBNDS) 2011 with 2016 Revisions	http://www.ice.gov/detention-standards/2011/
American Correctional Association (ACA)	http://www.aca.org/

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[END OF SECTION J]

SECTION K:
REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS OR RESPONDENTS

Incorporated by reference. See Contractor's Proposal, Volume IV.

[END OF SECTION K]

U.S. Department of Homeland Security
Immigration and Customs Enforcement

Section C
Performance Work Statement
Detention Services
(Texas-Wide RFP)
(November 2019)

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I. EXPLANATION OF TERMS/ACRONYMS

1. ADMINISTRATIVE SEGREGATION: A form of separation from the general population used when the continued presence of the detainee in the general population would pose a threat to life, property, self, staff, or other detainees or to the security or orderly running of the facility. This housing status also includes detainees who require protective custody, those who cannot be placed in the local population because they are in route to another facility (holdovers), those who are awaiting a hearing before a disciplinary panel, and those requiring separation for medical reasons.
2. ADULT LOCAL DETENTION FACILITY (ALDF): A facility which detains persons over the age of 18.
3. ALIEN: Any person who is not a citizen or national of the United States.
4. AMERICAN CORRECTIONAL ASSOCIATION (ACA): The American Correctional Association is the oldest and largest international correctional association in the world. ACA serves all disciplines within the corrections profession and is dedicated to excellence in every aspect of the field.
5. BED-DAY: The total billable cost to the Government to maintain and house one detainee for one day. Bed-day means a detainee that is referred to a contractor for detention. The bed days are calculated by subtracting the date booked into custody from the date released from custody. The contractor may charge for day of arrival, but not day of departure.
6. BED-DAY RATE: The rate charged for each individual detainee per day. Bed-day rate is an all-inclusive burdened rate including direct costs, indirect costs, overhead, and profit necessary to provide the detention, and food service requirements as described in the PWS.
7. BOOKING: A procedure for the admission of an ICE detainee, which includes searching, fingerprinting, photographing, medical screening, and collecting personal history data. Booking also includes the inventory and storage of the individual's accompanying personal property. The Contractor may be responsible for booking the detainee into ICE systems upon receiving the detainee.
8. BUREAU OF PRISONS (BOP): The U.S. Federal Bureau of Prisons protects society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens.
9. CATEGORICAL EXCLUSION (CATEX): Activities that do not need to undergo detailed environmental analysis in an Environmental Assessment (EA) or Environmental Impact Statement (EIS) because the activities have been determined to normally not have the potential, individually or cumulatively, to have a significant effect on the human environment.
10. CLASSIFICATION: A process for determining the needs and requirements of aliens for whom detention has been ordered and for assigning them to housing units and programs according to their needs, security risk level, and existing resources of the facility.
11. CONTRABAND: Items that pose a threat to the security of people or property. A contraband item fits into either the category of hard or soft contraband as defined below:

a) Hard Contraband: Any item that is inherently dangerous as a weapon or tool of violence, e.g., knife, explosives, "zipgun," brass knuckles. Because hard contraband presents an immediate physical threat in or to the facility, a detainee found in possession of hard contraband could face disciplinary action or criminal prosecution.
b) Soft Contraband: Any item that presents a nuisance, which does not pose a direct and immediate threat to an individual's safety. None-the-less, soft contraband has the potential to create dangerous or unsanitary conditions in the facility, such as excess papers that create a fire hazard, food items that are spoiled or retained beyond the point of safe consumption, etc.

12. CONTRACTING OFFICER (CO): An employee of the Government responsible for the complete conduct and integrity of the contracting process, including administration after award. The only individual authorized to issue changes to this contract.
13. CONTRACTING OFFICER'S REPRESENTATIVE (COR): Employees of the Government responsible for monitoring all technical aspects and assisting in administering the contract.
14. CONTRACTOR: The entity, which provides the services, described in this Performance Work Statement (PWS).
15. CONTRACTOR EMPLOYEE: An employee of a private Contractor hired to perform a variety of detailed services under this contract.
16. CONTROL ROOM: Integrates all internal and external security communications networks within a secure room. Activities conducted within the control room have a critical impact on the institution's orderly and secure operation.
17. CREDENTIALS: Document providing primary source verification including education, training, licensure, experience, board certification, and expertise of an employee.
18. DEPARTMENT OF HOMELAND SECURITY (DHS): A department of the United States Government, which includes U.S. Immigration and Customs Enforcement (ICE).
19. DEPARTMENT OF JUSTICE (DOJ): A department of the United States Government, which includes the Executive Office of Immigration Review (EOIR), the Federal Bureau of Investigation (FBI), the Federal Bureau of Prisons (BOP), and the U.S. Marshals Service (USMS).
20. DESIGNATED SERVICE OFFICIAL: An employee of U.S. Immigration and Customs Enforcement designated in writing by the ICE Field Office Director (FOD) to represent ICE on matters pertaining to the operation of the facility.
21. DETAINEE: Any person confined under the auspices and the authority of any Federal agency. Many of those being detained may have substantial and varied criminal histories.
22. DETAINEE RECORDS: Information concerning the individual's personal, criminal and medical history, behavior, and activities while in custody, including, but not limited to:
    a) Detainee, Personal Property
    b) Receipts, Visitors List, Photographs
    c) Fingerprints, Disciplinary Infractions
    d) Actions Taken, Grievance Reports, Medical
    e) Records, Work Assignments, Program Participation
    f) Miscellaneous Correspondence, etc.
23. DETENTION OFFICERS: Contractor's uniformed staff members responsible for the security, care, transportation, and supervision of detainees during all phases of activity in

a detention facility. The officer is also responsible for the safety and security of the facility.

24. DETENTION STANDARDS COMPLIANCE UNIT (DSCU): The purpose of the DSCU is to develop and prescribe policies, standards, and procedures for ICE detention operations and to ensure detention facilities are operated in a safe, secure, and humane condition for both detainees and staff.
25. DIRECT SUPERVISION: A method of detainee management that ensures continuing direct contact between detainees and staff by posting an officer(s) inside each housing unit. Officers in general housing units are not separated from detainees by a physical barrier. Officers provide frequent, non-scheduled observation of and personal interaction with detainees.
26. DIRECTIVE: A document issued by the U.S. Government and signed by the President, Departmental Secretary, or an Assistant Secretary that establishes policy, delegates' authority, and/or assigns responsibilities.
27. DISCIPLINARY SEGREGATION: A unit housing detainees who commit serious rule violations.
28. EMERGENCY: Any significant disruption of normal facility procedure, policy, or activity caused by riot, strike, escape, fire, medical exigency, natural disaster, or other serious incident.
29. EMERGENCY CARE: Care for an acute illness or unexpected serious health care need that cannot be deferred until the next scheduled sick call.
30. ENFORCEMENT AND REMOVAL OPERATIONS (ERO): A division within ICE, whose mission is the planning, management, and direction of broad programs relating to the supervision, detention, and removal of detainees who are in the United States illegally.
31. ENTRY ON DUTY (EOD): The first day the employee begins performance at a designated duty station on this contract.
32. ENVIRONMENTAL ASSESSMENT (EA): A concise public document for which a Federal agency is responsible that serves to: briefly provide sufficient evidence and analysis for determining whether to prepare an EIS or a Finding of No Significant Impact (FONSI), aid an agency's compliance with the National Environmental Policy Act (NEPA) when no EIS is necessary, and facilitate preparation of an EIS when one is necessary.
33. ENVIRONMENTAL IMPACT EVALUATION: The process of determining the level of significance of a potential impact on the human environment. It includes all necessary studies, consultation, and public involvement needed to analyze the potential for environmental impact of a proposed action, assign a value to the level of impact (e.g., minor, moderate, or major), consider mitigation, and determine the level of significance; whether significant or not. An environmental impact evaluation results in either the application of a CATEX, documentation in the form of an EA and FONSI or a final EIS and ROD.
34. ENVIRONMENTAL IMPACT STATEMENT (EIS): A detailed written statement as required by section 102(2)(C) of the NEPA. It is a comprehensive document that provides full and fair discussion of significant environmental impacts caused by the proposed action(s). It also states the reasonable alternatives, and which of those would

avoid or minimize the adverse impact(s) or enhance the quality of the human environment.

35. EXECUTIVE OFFICE OF IMMIGRATION REVIEW (EOIR): An agency of DOJ. The primary mission of the Executive Office for Immigration Review (EOIR) is to adjudicate immigration cases by fairly, expeditiously, and uniformly interpreting and administering the Nation's immigration laws. Under delegated authority from the Attorney General, EOIR conducts immigration court proceedings, appellate reviews, and administrative hearings.
36. FACILITY: The physical plant and grounds in which the Contractor's services are operated.
37. FACILITY ADMINISTRATOR: The official, regardless of local title (e.g., jail administrator, Warden, Facility Director, superintendent), who has the ultimate responsibility for managing and operating the contracted detention facility. The qualifications for the holder of this office shall be consistent with ACA standards.
38. FINDING OF NO SIGNIFICANT IMPACT (FONSI): A document by a Federal agency briefly presenting the reasons why an action, not otherwise excluded, will not have a significant effect on the human environment, and for which an EIS therefore will not be prepared.
39. FIRST AID: Health care for a condition that requires immediate assistance from an individual trained in first aid care and the use of the facility's first aid kits.
40. FLIGHT OPERATIONS UNIT (FOU): The FOU is the principal mass air transportation and manages government and contract flights.
41. GOVERNMENT: Refers to the United States Government.
42. GRIEVANCE: A written complaint filed by a detainee with the facility administrator concerning personal health/welfare or the operations and services of the facility.
43. HEALTH AUTHORITY: The physician, health administrator, or agency on-site that is responsible for health care services pursuant to a written agreement, contract, or job description.
44. HEALTH CARE: The action taken, preventive and therapeutic. To provide for the physical and mental well-being of the detainee population. Health care may include medical services, dental services, mental health services, nursing, personal hygiene, dietary services, and environmental conditions at the facility.
45. HEALTH CARE PERSONNEL: Duly licensed individuals whose primary duties are to provide health services to detainees in keeping with their respective levels of health care training or experience.
46. HEALTH UNIT (HU): The physical area in the facility and organizational unit set-aside for routine health care and sick call. The HU is the designated part of the facility for the delivery of care to detainees on an ambulatory or observation basis.
47. ICE HEALTH SERVICES CORP (IHSC): The ICE Health Service Corps serves as the medical authority for ICE on a wide range of medical issues, including the agency's comprehensive detainee health care program.
48. IMMEDIATE RELATIVES: Spouses, children (including stepchildren and adopted children) and their spouses, parents (including stepparents), brothers and sisters (including stepbrothers and sisters and half-brothers and sisters) and their spouses.
49. IMMIGRATION AND CUSTOMS ENFORCEMENT (ICE): A law enforcement agency within the U.S. Department of Homeland Security.

50. INCIDENT REPORT: A written document reporting an event, such as minor disturbances, officer misconduct, any detainee rule infraction, etc.
51. JUVENILE DETAINEE: Any detainee under the age of eighteen (18) years.
52. KEY PERSONNEL: Any one of the following positions employed by the Contractor; Warden or Facility Director, Assistant Warden or Assistant Facility Director, Supervisory Detention Officer, Training Officers, Quality Assurance Manager, Corporate Security Officer.
53. LIFE SAFETY CODE: A manual published by The National Fire Protection Association specifying minimum standards for fire safety necessary in the public interest.
54. LOG BOOK: The official record of post operations and inspections.
55. MAN-HOUR: Man-hour means productive hours when the required services are performed. Only productive hours can be billed and invoiced.
56. MEDICAL RECORDS: Separate records of medical examinations and diagnosis maintained by the responsible physician or nurse. The following information from these records shall be transferred to the detainee record: date and time of all medical examinations; and, copies of standing or direct medical orders from the physician to the facility staff.
57. MEDICAL SCREENING: A system of structured observation and/or initial health assessment to identify newly-arrived detainees who could pose a health or safety threat to themselves or others.
58. MILEAGE RATE: A fully burdened rate inclusive of the mileage rate in accordance with General Service Administration Federal Travel Regulation, vehicle equipment, maintenance, and fuel costs.
59. NON-CONTACT VISITATION: Visitation that restricts detainees from having physical contact with visitors using physical barriers such as screens and/or glass. Voice communications between the parties are typically accomplished with telephones or speakers.
60. NON-DEADLY FORCE: The force a person uses with the purpose of not causing or which would not create a substantial risk of causing death or serious bodily harm.
61. OFFICE OF PROFESSIONAL RESPONSIBILITY, PERSONNEL SECURITY UNIT (OPR-PSU): The ICE office which implements a component-wide personnel security program.
62. ON CALL/REMOTE CUSTODY OFFICER POST: Posts operated as requested by the COR, or other ICE officials designated by COR, and including, but not limited to, escorting and custody of detainees for hearings, ICE interviews, medical watches, and any other location requested by the COR.
63. PAT DOWN SEARCH: A quick patting of the detainee's outer clothing to determine the presence of contraband.
64. PERFORMANCE WORK STATEMENT (PWS): That portion of the contract, which describes the services to be performed under the contract.
65. PHASE I ENVIRONMENTAL SITE ASSESSMENT (PHASE I ESA): An evaluation and report prepared to identify potential or existing environmental contamination liabilities associated with real property. Phase I ESAs must be carried out in accordance with the standard promulgated in ASTM 1527-13.
66. POLICY: A definite written course or method of action, which guides and determines present and future decisions and actions.

67. POST ORDERS: Written orders that specify the duties of each position, hour-by-hour, and the procedures the post officer will follow in carrying out those duties.
68. PREVENTIVE MAINTENANCE: A system designed to enhance the longevity and/or usefulness of buildings and equipment in accordance with a planned schedule.
69. PROCEDURE: The detailed and sequential actions that must be executed to ensure that a policy is implemented. It is the method of performing an operation or a manner of proceeding on a course of action. It differs from a policy in that it directs action required to perform a specific task within the guidelines of that policy.
70. PRODUCTIVE HOURS: These are hours when the required services are performed and can be billed.
71. PROJECT MANAGER: Contractor employee responsible for on-site supervision of all Contractor employees, with the authority to act on behalf of the Contractor. The Project Manager cannot simultaneously serve in the role of manager and Detention Officer or Supervisory Detention Officer.
72. PROPERTY: Refers to personal belongings of a detainee.
73. PROPOSAL: The written plan submitted by the Contractor for consideration by ICE in response to the Request for Proposal (RFP).
74. QUALIFIED HEALTH PROFESSIONAL: Physicians, dentists, and other professional and technical workers who by state law engage in activities that support, complement, or supplement the functions of physicians and/or dentists who are licensed, registered, or certified, as appropriate to their qualifications, to practice.
75. QUALITY ASSURANCE: The actions taken by the Government to assure requirements of the PWS are met.
76. QUALITY ASSURANCE SURVEILLANCE PLAN (QASP): A Government-produced document that is based on the premise that the Contractor, and not the Government, is responsible for the day-to-day operation of the facility and all the management and quality control actions required to meet the terms of the contract. The role of the Government in quality assurance is to ensure performance standards are achieved and maintained. The QASP (Section J, Attachment 4, 4A, and 4B) validates that the Contractor is complying with ERO-mandated quality standards in operating, maintaining, and repairing detention facilities.
77. QUALITY CONTROL (QC): The Contractor's inspection system which covers all the services to be performed under the contract. The actions that a Contractor takes to control the production of services so that they meet the requirements stated in the contract.
78. QUALITY CONTROL PLAN (QCP): A Contractor-produced document that addresses critical operational performance standards for services provided.
79. RECORD OF DECISION (ROD): A document that explains an agency's decision, describes the alternative the agency considered, and discusses the agency's plans for mitigation and monitoring, if necessary.
80. RELIEF FACTOR: Indicates how many persons it takes to fill a single job position for a single shift, taking into account vacation, sick leave, training days, and other types of leave.
81. RESPONSIBLE PHYSICIAN: A person licensed to practice medicine with whom the facility enters into a contractual agreement to plan for and provide health care services to the detainee population of the facility.

82. RESTRAINT EQUIPMENT: This includes but is not limited to: handcuffs, belly chains, leg irons, strait-jackets, flexi cuffs, soft (leather) cuffs, and leg weights.
83. SAFETY EQUIPMENT: This includes but is not limited to firefighting equipment, i.e., chemical extinguisher, hoses, nozzles, water supplies, alarm systems, portable breathing devices, gas masks, fans, first aid kits, stretchers, and emergency alarms.
84. SALLYPORT: An enclosure situated either in the perimeter wall or fence to the facility or within the interior of the facility, containing gates or doors at both ends, only one of which opens at a time. This method of entry and exit helps to ensure that there shall be no breach in the perimeter or interior security of the facility.
85. SECURITY DEVICES: Locks, gates, doors, bars, fences, screens, hardened ceilings, floors, walls, and barriers used to confine and control detainees. In addition, electronic monitoring equipment, security alarm systems, security light units, auxiliary power supply, and other equipment used to maintain facility security.
86. SECURITY PERIMETER: The outer portions of a facility, which provide for secure confinement of detainees.
87. SECURITY RISK – HIGH, MEDIUM, LOW:
    High Risk Level – (Level 3) Detainees exhibit behavioral problems, or manifest a pattern of such behavior, or have a history of violent and/or criminal activity. These detainees may not be co-mingled with low custody detainees.
    Medium High Risk Level – (Level 2) Detainees exhibit minor behavioral problems or have a history of nonviolent criminal behavior. These detainees have a history of violent or assaultive charges, convictions, institutional misconduct, or those with gang affiliation.
    Medium Low Risk Level – (1.5) Detainees with no history of violent or assaultive charges or convictions, no institutional misconduct, and no gang affiliation.
    Low Risk Level – (Level 1) Detainees exhibit no behavioral problems and have no history of violent criminal behavior. This level may not include any detainee with a felony conviction that included an act of physical violence. Low risk level detainees may not be co-mingled with high custody detainees.
88. SENSITIVE INFORMATION: Any information which could affect the national interest, law enforcement activities, the conduct of federal programs, or the privacy to which individuals are entitled under Title 5, U.S. Code, Section 552a. All Detainee records are considered sensitive information.
89. SIGNIFICANT EVENT NOTIFICATION REPORT (SEN): A written document reporting a special event (e.g., the use of force, use of chemical agents, discharge of firearms).
90. SPECIAL MANAGEMENT UNIT (SMU): A housing unit for detainees in administrative or disciplinary segregation.
91. STRIP SEARCH: An examination of a detainee's naked body for weapons, contraband, and physical abnormalities. This also includes a thorough search of all of the individual's clothing while not being worn.
92. SUITABILITY CHECK: Security clearance process for Contractor and all Contractor Employees to determine favorable suitability to work on a Government contract.
93. TOUR OF DUTY: No more than 12 hours in any 24-hour period with a minimum of eight hours off between shifts, except as directed by state or local law.

94. TRAINING: An organized, planned, and evaluated activity designed to achieve specific learning objectives. Training may occur on site, at an academy of training center, at an institution of higher learning, through contract service, at professional meetings or through closely supervised on-the-job training. Meetings of professional associations are considered training when there is clear evidence of the above elements. All trainers must be certified, and certification shall be approved by the COR or ICE-designee.
95. TRANSPORTATION COSTS: The cost of all materials, equipment, and labor necessary to respond to requests by designated officials for secure movement of detainees from place to place necessary for processing, hearings, interviews, etc.
96. TRAVEL COST: Cost inclusive of lodging and meals and incidental expenses (MI&E) for Transportation Officers exceeding the standard working hours. Contractor tour of duties will comply with all current federal, state, and local laws. This includes but is not limited to the Federal Motor Carrier Safety Administration, CFR 395.5 - Maximum driving time for passenger-carrying vehicles. Cost is based on actual charges per occurrence, not to exceed the allowable Federal Travel Regulation rates/costs in effect on the dates of travel.
97. WEAPONS: This includes but is not limited to firearms, ammunition, knives, slappers, billy clubs, electronic defense modules, chemical weapons (mace), and nightsticks.

II. PERFORMANCE WORK STATEMENT

A. Objective

The objective of this contract is to obtain comprehensive detention services as detailed below for various levels as described within this document.

B. Background and Mission

The United States Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) is responsible for the detention, health, welfare, transportation, and deportation of detainees in removal proceedings, and those subject to a final order of removal from the United States.

The mission of ICE Enforcement and Removal Operations (ERO) is to identify, arrest, and remove aliens, who present a danger to national security or are a risk to public safety, as well as those who enter the United States illegally or otherwise undermine the integrity of immigration laws and border control efforts.

In implementing its mission, ERO is responsible for carrying out all orders for the securing and departure activities of detainees who are designated in removal proceedings and for arranging for the detention of detainees when such becomes necessary and prescribed by law.

C. Scope of Work

A Contractor-owned/Contractor-operated detention facility to house detainees on a 24 hour per-day, seven day per week, 365 day per-year basis.

The detention center shall provide safe and secure conditions of confinement based on the individual characteristics of a diverse population, including: threat to the community, risk of flight, type and status of immigration proceeding, community ties, medical and mental health issues. The detention center shall provide easy access to legal services; abundant natural light throughout the facility; ample indoor and outdoor recreation that allows for vigorous aerobic exercise with extended hours of availability - a minimum of four hours per day of outdoor recreation; private showers and restrooms (where practicable); cafeteria style meal service or satellite feeding; non-institutional detainee clothing; contact visitation (if applicable), including special arrangements for visiting families, with extended hours including nights and weekends; private areas for attorney-client visits, with video teleconferencing capabilities; noise control; enhanced, but controlled freedom of movement (although the manner and degree of implementation may vary based on security levels); enhanced law library and legal resources; and enhanced programming, including religious services and social programs and dedicated space for religious services.

Detention services shall be preformed in accordance with optimal level of the most current version of the ICE Performance-Based National Detention Standards (PBNDS) 2011 with 2016 revisions. The current version is PBNDS 2011 revised in 2016 available at

www.ice.gov/detention-standards/2011. NOTE: Where ICE PBNDS 2011 is referenced through this solicitation and its attachments, it shall be interpreted to designate ICE PBNDS 2011 with 2016 revisions. The contractor shall also abide by the March 7, 2014, DHS regulation under the Prison Rape Elimination Act of 2003 (PREA; P.L. 108-79), *Standards to Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities* (DHS PREA Standards) available at https://www.gpo.gov/fdsys/pkg/FR-2014-03-07/pdf/2014-04675.pdf.

The Contractor shall be responsible for obtaining and maintaining American Correctional Association (ACA) accreditation under the most current version of the Adult Local Detention Facilities (ALDF) Standards to include any supplement. Conformance with the ACA ALDF Standards is required on the first day of contract performance and accreditation shall be obtained within 18 months from contract award. If the facility is already accredited, reaccreditation shall occur as required by the ACA.

In cases where there is a conflict in standards, the most stringent shall apply. If the Contractor is unable to determine which standard is more stringent, the COR shall determine the appropriate standard.

The COR does not have the authority to modify the stated terms of the contract or approve any action that would result in additional charges to the Government beyond what is stated in the CLIN schedule. The CO shall make all modifications in writing.

The Contractor shall furnish all personnel, management, equipment, supplies, training, certification, accreditation, and services necessary for performance of all aspects of the contract. Unless explicitly stated otherwise, the Contractor is responsible for all costs associated with and incurred as part of providing the services outlined in this contract.

DHS, ICE, federal entities, and third-party inspectors will conduct periodic and unscheduled audits and inspections of contract performance and the facility to ensure contract compliance. All inspectors shall have full access to the facility at all times and in all areas of performance. The Contractor shall provide full and complete cooperation for any request or investigation conducted by the Government.

Detainees are classified as High (Level 3), Medium High (Level 2), Medium Low (Level 1.5) or Low Risk (Level 1). Upon discovery that a detainee may be a juvenile, the Contractor shall immediately notify the COR or ICE-designee and follow the instructions of the COR or ICE-designee.

The Contractor shall not add any non-ICE detainee population to the facility from any other entity without the expressed prior written approval of the CO and/or ICE-designee.

The Contractor agrees to accept and provide for the secure custody, care, and safekeeping of detainees in accordance with the State and local laws, standards, policies, procedures for firearms requirements, or court orders applicable to the operations of the facility.